ADDIS ABABA UNIVERSITY COLLEGE OF HEALTH SCIENCE SCHOOL OF MEDICINE, DEPARMENT OF SUGERY

FUNCTIONAL OUTCOMES OF ANORECTAL MALFORMATIONS: A 5 YEARS RETROSPECTIVE STUDY AT SINGLE INSTITUTION, ETHIOPIA.

A Thesis Submitted to Department of Surgery, Pediatric Surgery Division, College of Health Science, Addis Ababa University; in Partial fulfillment for the requirement of Specialty Certificate for Pediatric Surgery.

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COLLEGE OF HEALTH SCIENCE SCHOOL OF MEDICINE

DEPARMENT OF SUGERY

(Approval Sheet)

Functional Outcomes of Anorectal malformation: A 5 years Retrospective Study at single institution, Ethiopia

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Declaration

I, Gobena Mormata, declare that this thesis is my original work and has not been presented for a certificate in any other university. All sources of materials used for this thesis have been duly acknowledged.

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The undersigned have examined the thesis report entitled ‘‘**Functional Outcomes of Anorectal malformation: A 5 years Retrospective Study at single institution, Ethiopia’’** presented by Dr Gobena Mormata with registration number GSR/3245/13, a candidate for speciality certificate in pediatric surgery and hereby certify that it is worthy of acceptance.

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Abstract

Background: Anorectal malformation (ARM) is a wide spectrum of congenital malformation seen in pediatric patients. While the surgical techniques have advanced long term functional outcomes like voluntary bowel movement, soiling and constipations remain significant challenge for clinicians and patients especially in low income countries like Ethiopia.

Objectives: To assess the functional outcomes of surgically reconstructed anorectal malformations and identifying factors affecting the outcomes at single tertiary institution in Ethiopia.

Methodology: This is a retrospective cohort study which was conducted on 119 children treated for ARM over a 5-year period from September 2018 to September 2022. Functional outcomes was assessed using the Krickenbeck classification systems. Bivariate analysis was performed by using Chi-square, Fisher's exact tests and Mann-Whitney U tests where they were appropriate according to the types of variables, then followed by multivariable logistic regression to identify independent affecting factors with Adjusted Odds Ratios [AOR] and 95% Confidence Intervals [CI].

Results: 84.9% of patients achieved VBM, while soiling and constipation were 47.1% and 24.4%, respectively. High ARM types were associated with higher soiling rates (77.8%; AOR 0.133, 95% CI: 0.031- 0.564, p=0.006). Conversely, low ARM type was associated with constipation (43.5%; AOR 8.4, 95% CI: 1.48-47.66, p=0.016). Redo anoplasty was associated with poor VBM (AOR 0.1, 95% CI: 0.02-0.49, p=0.005) and increased soiling (AOR 0.128, 95% CI: 0.028-0.582, p=0.008). While three-stage repairs showed higher soiling in bivariate analysis, multivariable analysis showed no independent effect. Early age at definitive surgery was associated with better voluntary bowel movement (AOR 0.97, 95% CI: 0.93-0.99, p=0.024).

Conclusion and Recommendation: A functional outcome of ARM patients after surgical reconstruction at TASH is comparable to international studies. Types of ARM, redo anoplasty and age at definitive surgery were indentified as independent affecting factors of the functional outcomes. However; neither stages of the surgery nor birth weight was independent affecting factor. So, the high rate of soiling need structured postoperative bowel management and follow-up. Early definitive surgery and decreasing of technical failures requiring reoperation are required for improving functional outcomes.

Keywords: Anorectal Malformations, Voluntary bowel movement, Soiling, Constipation, Redo Anoplasty, Functional Outcomes, Ethiopia, Pediatric surgery.

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Table of Contents

List of Table

List of Abbreviations

ARM- Anorectal malformation

ASARP- Anterior sagittal anorectoplasty

PSARP- Posterior sagittal anorectoplasty

PSARVUP-Posterior sagittal anorectovaginourethroplasty

TASH- Tikur anbessa specialized hospita

TUM- total urogenital mobilization

VBM- Voluntary bowel movement

CHAPTER 1: INTRODUCTION

1.1 Background

Anorectal malformation (ARM) encompasses spectrum of anomaly which affects anorectum, genitourinary, sacral spine and perineal musculature which is caused by embryological maldevelopment of cloaca and urorectum. It occurs about 1 in 4,000 to 5,000 live births with male predominance.[1,2,8,9]

Most of the cases are diagnosed after birth and have associated anomalies. These associated anomalies form a VACTERL association (VACTERL- Vertebral, Anorectal, Cardiac, Tracheo esophageal, Renal,Limb)[8,9].

There have been several classification systems developed to categorize the ARMs. The first classification was in 1970s which uses the position of the terminal rectum relative to the levator ani. And the next classification is the Wingspread Classification of 1984 which modified the first system by distinguishing between male and female anomalies. In 1995 Alberto Pena classified based on the presence and position of fistulas. This has improved surgical guidance and prognosis prediction for bowel outcomes. He also introduced posterior sagittal anorectoplasty (PSARP). In spite of these classifications there were no uniform follow up and it hass been difficult to compare the functional outcomes of surgical repair of ARM patients[9].

So Krickenbeck group developed a comprehensive classification system in 2005 that has diagnostic, surgical procedure, and functional outcome catagories. All defect types and surgical procedure options were included [9,10].

The diagnostic category is classified as major clinical groups (perineal fistula, rectourethral fistula (bulbar or prostatic), recto vesical fistula, vestibular fistula, cloaca, no fistula, anal stenosis) and rare or regional variants (pouch colon, rectal atresia or stenosis, recto vaginal fistula, H-type fistula and others).

The operative procedures category are definitive surgery which are listed as perineal operation, anterior sagittal approach, sacroperineal procedure, Posterior sagittal anorectoplasty, abdominosacroperineal pull through, abdominoperineal pull through and laparoscopic assisted pull through[9].

Third category is the functional outcomes following definitive surgery and colostomy closure after age greater than three years. It evaluates three key parameters: VBM, soiling and constipation. Each of these parameters is graded to reflect the severity and the grade is discussed under operational definition. The aim of krickenbeck classification is to assess and compare functional outcome among these different clinical and surgical groups to allow better meaningful comparisons[10].

Prevention and treatment of the functional outcome of surgical repair of ARM patients is more challenging, demanding and expensive than the anatomical reconstruction upon which more emphasis has been given previously. So long-term follow up of children after the ARM repair should be a fundamental part of ARM management [16].

1.2 Statement of the problem

Management of Anorectal malformation patient is a significant challenge for pediatric surgeons due to the complexity of th conditions and associated long term functional outcomes. Eventhough surgical techniques have evolved, the long term outcomes in ARM patients, especially regarding bowel function, remain a major area of concern. Publications on the long-term outcomes of ARM patients are relatively scarce which has made it difficult to assess the impact of surgical interventions on quality of life of these patients.

In recent decades advancements in neonatal care and surgical techniques have improved the survival rates of ARM patients. As survival rates have increased the focus of ARM treatment has shifted towards ensuring that patients achieve good bowel function and enjoy an improved quality of life.

Krickenbeck international classification system standardizes the assessment of functional outcomes following ARM surgery. It allows for a more consistent evaluation of patients and their long term outcomes but there is still a lack of extensive studies using this system, particularly in Africa.

To best of the investigator's and advisor's knowledge, no comprehensive study on the functional outcome of ARM patients using krickenbeck classification at Tikur Anbessa Specialized Hospital (TASH), Addis Ababa, Ethiopia has been done. This research aims to assess the diagnosis, functional outcomes and factors affecting the functional out comes of ARM patients, specifically on voluntary bowel movement, constipation and fecal soiling according to krickenbeck classification system.

1.3 Significance of the study

The study will find out the functional outcomes of anorectal malformations at TASH Addis Ababa, Ethiopia. It also helps to identify factors influencing these outcomes and will help to develop a holistic approach of the treatment and follow up; then it will improve quality of life of ARM patients.

CHAPTER 2: LITERATURE REVIEW

Anorectal malformation is spectrum of congenital defects which has a range of from simple to treat to more complex and have associated anomalies[1,2,8,9]. The current management of ARM patients is focusing on the functional outcomes after the definitive surgery [1, 9]. There are different scoring systems to assess the functional outcomes which have showed various outcomes [3, 9,11].

One of these scoring systems is the Krickenbeck scoring system. It has three components or variables: voluntary bowel movement (VBM), soiling and constipation[9].

The krickenbeck classification has clear description of functional outcome criteria which are based on a simple grading system and well defined variables[4,9]. This enables it to be used easily in a number of different settings and by different health professionals. The questions are simple and the classification is relevant to both younger child when parents are responsible for toileting and older children who are usually able to answer the questions [7].

Functional outcomes of ARM patients show a range variability. A retrospective review done by Alberto Peña and colleagues in 2000 reported that about 75% of patients were able to achieve voluntary bowel movements. However, about half of these patients still experienced occasional soiling on their underwear, which means that only around 37.5% could be considered as completely continent. Constipation is the most common reported long-term complication [15,17]. Urinary incontinence was also relatively common, specifically in patients who had cloacal malformation reconstruction. Additionally about a quarter of patients experienced fecal incontinence. Despite this challenge, many patients achieved improved quality of life with structured bowel management programs[11].

Several other studies showed the functional outcomes for ARM vary as follows: voluntary bowel movement 53-90% , constipation 9.3- 23% and soiling 4-35% depending on types of ARM and associated factors[5,6,7,14, 16,19].

An unpublished cross-sectional study which assesses the functional outcomes of ASARP was conducted by Zinedine et.al in 2020 at Tikur Anbessa Specialized Hospital and Menelik II Hospital. 74 patients were included in the study, 43 patients were older than three years. Among these, 26 patients were successfully contacted by telephone and assessed for bowel function using the Krickenbeck classification system. The results showed that 25 of the 26 patients (96.5%) had VBM, one patient (3.8%) had no VBM, Grade 1 soiling was 2 patients (7%) and constipation was present in 1 patient (3.8%) which was managed with dietary modification. Overall, good bowel function outcomes was 96.2% of the evaluated patients[25].

Studies demonstrate several factors contribute to the variability in functional outcomes. One of the these factor is the type of ARMs . These studies found out that patients with low type ARMs such as recto-perineal fistula, have better outcomes compared to these high type anomalies[1,3,4,7, 15,17]. However, a study done in Indonesia said no association between VBM and types of ARM[12].

It has been published that the choice of surgical technique has a role in the functional outcomes. However, it is difficult to prove since there are no randomized controlled studies. During the last 40 years there has been advances in the management of anorectal malformations due to the introduction and standardaization of PSARP by Pena and Devries in the 1982. It is said to be the gold standard of ARM repair. Despite this, there are still many patients who experience complications that are avoidable[6,9,15,24].

Sacral abnormalities one the factors that has long-term functional outcomes. Patients with sacral defect like absence of more than two sacral vertebrae, hemivertebrae or vertebral fusion has the tendency to experience worse functional outcomes compared to with those relatively normal sacrum. The poor outcomes observed in patients with severe sacral malformations are often related to inadequate sphincter function. Additionally, sacral dysplasia can contribute to constipation due the interference with normal rectal sensation[9,15].

Spinal cord abnormalities are also observed in patients with ARMs. Imaging techniques like ultrasound and magnetic resonance imaging (MRI) allow the assessment of the spinal cord in these patients. Occult forms of myelodysplasia have been reported in about 20-50% of cases. These spinal cord lesions occur more often in patients with high types of ARMs and are usually associated with sacral abnormalities. However, the exact impact of these spinal lesions on long-term bowel function remains uncertain as existing studies have shown inconsistent findings[8,15].

The other factor reported is the age of the patient at the time of definitive surgery for ARM patients. It has been suggested it influences the long-term functional outcome. However, at present there is no evidence that early repair would provide better functional outcome than a repair at the age of 6-12 months, although some reports suggest early repair has better functional outcome [9,19].

A five year retrospective study conducted in Tanzania showed sex has no significant effect on functional outcomes of ARM patients. However, the study found that type of surgical procedure, the patient's body weight and the type of ARM have significant role in achieving optimal voluntary bowel movement [26].

CHAPTER 3: OBJECTIVES

3.1 General objective

To evaluate the functional outcome of anorectal malformation and factors affecting it.

3.2 Specific Objective

To evaluate the magnitude of operated anorectal malformations during study period.

To investigate functional outcome of operated anorectal malformations.

To find out factors affecting the functional outcome.

CHAPTER 4: METHODS

4.1 Study design

A 5 years retrospective cross sectional study

4.2 Study area

Tikur Anbessa Specialized Hospital, Addis Ababa, Ethiopia

4.3 Study period

This study will be conducted on ARM patients who underwent repair from September 2018 to September 2022 GC.

4.4 Study population

4.4.1 Target population

ARM patients in Ethiopia

4.4.2 Study population

ARM patients operated at TASH

4.5 Inclusion criteria and Exclusion criteria

Inclusion criteria

All patients who have undergone surgical correction of ARM and now age > 3 Years and after 6 months of colostomy reversal.

Exclusion criteria

Incomplete data
These guardians or parents that don't give consent.

4.6 Sampling size and Sampling Technique

A sample size of 423 was initially calculated using single population proportion formula, assuming the proportion of good functional outcome 50% (to achieve maximal sample size), 5% marginal error and 95% confidence interval; and adding 10% for anticipated incomplete records.

$$n = \frac{(Z_{á})^2 P(1-p)}{E^2} = \frac{(1.96)^2 * 0.5(1-0.5)}{(0.05)^2} = 384 + 10\% * 384 = 422.4 = 423$$

Where:

n = required sample size

Z = Z-score corresponds to confidence interval (95% confidence interval-1.96)

P = Assumed proportion of ARM patients with good outcome- 0.64

Z = amount of precision desired around estimated proportion-0.05

However, as this was a retrospective study all available charts meeting inclusion criteria during the study period were included by conensus sampling yielding a final sample of 119 patients.

4.7 Data source

Data were collected from patient medical records at TASH, Department of Pediatric Surgery. Secondary data extracted from patients' hospital charts and incomplete charts were supplemented where possible with primary data from parents or guardian in person or by phone call.

4.8 Data collection tools and procedures

Data were collected using a structured checklist developed by the principal investigator after reviewing relevant literature and similar studies (see Appendix A). It included sections on socio-demographic variables, pre-operative clinical variables, Operative details variables, and postoperative outcome and complication variables.

Data was collected by trained data collectors (residents and staff nurses). The collected data were stored in the Google form, exported to Microsoft Excel for completeness and consistency then entered to SPSS for analysis.

4.8.1 Study variables

A) Dependent variable

Functional outcomes of repaired ARM (VBM, constipation, soiling)

B) Independent variable

Age, sex, weight, anthropometry, types of ARM, associated anomaly (Spinal, Sacral), postoperative complications, redo anoplasty, types of surgical procedures, stages of surgery

4.9 Operational definitions

Functional outcome- refers to bowel control, continence, constipation after ARM repair

Soiling- involuntary leaking of small amounts of stool, which may be present with or without voluntary bowel movements. Soiling grade 1 occurs occasionally (once or twice per week). Grade 2 refers to soiling that occurs every day, but does not cause social problems. Grade 3 represents constant soiling with social problems.

Constipation- the incapacity to empty the rectum spontaneously without help every day (grade 1: when the patient is manageable by diet; grade 2: when he requires laxatives; grade 3: when he requires enemas).

Voluntary bowel movement- feeling the urge to use the toilet to have a bowel movement, the capacity to verbalize it, and to hold the bowel movement.

ARM- general term for a variety of diagnosis often referred to as imperf-orated anus, in which the patients do not have normal anal opening, but instead, fistulas tract opens into perineum anterior to the anal muscle complex or into adjacent anatomical structures**.**

4.10 Data quality management

The checklist was pretested on small number of patient charts to ensure clarity and consistency and necessary modifications were made accordingly. Incomplete or inconsistent records were excluded. Data cleaning was conducted before analysis.

4.11 Data analysis

Data were entered, and analyzed using the SPSS 27.1. Data cleaning was performed for completeness, consistency, and missing values before analysis.

4.11.1 Descriptive Analysis

Descriptive statistics were used to summarize sociodemographic, clinical, surgical and outcome related variables.

Categorical variables such as sex, gestational ages, type of anorectal malformation according to Krickenbeck classification, presence of associated anomalies, colostomy status, type of surgery, number of surgery or stages, Complications, redo anoplasty, voluntary bowel movement, soiling and constipation were summarized using frequencies and percentages.

Continuous variables such as current age, age at definitive surgery and birth weight were summarized using median and interquartile range.

Functional outcomes were assessed using the krickenbeck classification system. For regression analysis dichotomized functional outcome's parameters were used; voluntary bowel movement (yes/no), soiling (yes/no), and constipation (yes/no). Each functional outcome was analyzed independently.

4.11.2 Inferential Analysis

Categorical variables (ARM classification, stages of surgery, redoes anoplasty) were compared using Pearson's Chi-square or Fisher's exact tests where appropriate. Continuous variables (birth weight and age at definitive surgery) were analyzed using the Mann-Whitney U test due to skewed distribution.
Initially bivariate crosstab analysis was performed for each independent variable. Variables with p-value significance in the bivariate analysis were included in the multivariable logistic regression model to adjust for potential confounders.

Associations were reported as Adjusted odd ratios (AORs) with 95% confidence intervals (CIs). A p-value of < 0.05 was considered statistically significant.

4.12 Ethical clearance

Ethical approval was obtained from Tikur Anbassa Hospital College of Health sciences institution review board (IRB) before initiating the study. Patient confidentiality was kept throughout the study. All data were anonymized before analysis.

CHAPTER 5: RESULTS

5.1 Patient Demographic characteristics

During the study period a total of 215 patients with ARMs underwent definitive surgery at TASH. Of these charts of 159 patients charts were retrieved, the remaining 56 charts could not be found. 40 patients were excluded due to incomplete data (9 died upon calling, 17- were not reachable, 14- had nonfunctioning phone numbers) and the remaining 119 patients who fulfill the exclusion and inclusion criteria were included in the final analysis.

The median age at definitive surgery was 9 months (IQR 6-15) and age at follow up was 5 years (range 4- 17). There were 69 females (58 %) and 50 males (42 %) making the female-male ratio1.38:1. Out of 119 cases 46 birth weights was available and the median birth weight was 2.8kg (IQR 2.5-3.2) and Median gestational age was 38 weeks (37-39) for available 20 cases.

Table: 1 Summary of Patient Demographics (N=119)

Variable	N	Median	IQR
Age at definitive surgery (months)	119	9	6.0 – 15.0
Current age (years)	119	5.0	5.0 – 6.25
BW (kg)	46	2.8	2.5 – 3.20
Gestational Age (Weeks)	20	38.0	37.0 – 39.0

Kg- kilogram

BW- birth weight

5.2 Types of ARM and associated anomaly

The types of ARM in male are ARM with RUF 28 (56 %), ARM with RPF 11 (22 %) and in female are ARM with RVF 43 (62.3%), RPF 13 (18.8 %) and all others are listed in table 2 according to krickenbeck classification and the associated anomalies are shown in table 3.

Table: 2 ARM types based on Sex according to krickenbeck classification

Types of ARM		Male (n-50)	Female (n-69)	Total (n-119)
Major	Perineal fistula	11(22%)	13(18.8 %)	24(20.2%)
	Rectourethral fistula bulbar	18(36%)	0	18(15.1%)
	Rectourethral fistula prostatic	10(20%)	0	10(8.4%)
	Rectovesical fistula	2(4%)	1(1.4%)	3(2.5%)
	No fistula	9(18%)	5(7.2%)	14(11.8%)
	Rectovaginal fistula	0	2(2.9%)	2(1.7%)
	Recto-vestibular fistula	0	43(62.3 %)	43(36.1%)
Rare	Long cloaca (>=3cm)	0	1(1.4%)	1(0.8%)
	Short cloaca (<3cm	0	3(4.3%)	3(2.5%)
	Rectal atresia/stenosis	0	1(1.4%)	1(0.8%)

In this study of **119 patients**, associated anomalies were present in **41.2%** (n=49) of the cases and the lists are in shown in table 3.

Table: 3 Associated anomaly

Associated anomalies	Frequency	Percent	Cumulative Percent
cardiac	10	8.4	8.4
renal	11	9.2	17.6
vertebral	3	2.5	20.2
limb	1	0.8	21.0
Spinal	1	0.8	21.8
Down syndrome	7	5.9	27.7
EA/TEF	1	0.8	28.6
UDT	2	1.7	30.3
others	6	5.0	35.3
none	70	58.8	94.1
Vactrel association	7	5.9	100.0
Total	119	100.0	

5.3 Surgical details

One hundred eleven children (93.3%) had colostomy of which 23 (19.3%) were done at definitive surgery. Eight children (6.7%) underwent single stage surgery, 23 (19.3%) two stage surgeries and 88 (73.9%) three stage surgeries children (Table 4).

Table: 4 Colostomy status and stages of surgery

Colostomy	Frequency	Percent	Cumulative Percent
Yes	111	93.3	93.3
No	8	6.7	100.0
Stages of surgery			
One stage	8	6.7	6.7
Two stage	23	19.3	26.1
Three stage	88	73.9	100.0
Total	119	100.0	

Then median age at definitive surgery was 9 months (ranges 3 days to 147 months). The types of definitive surgery done was ASARP 56 (47.1%), PSARP 46 (38.7%), Cutback anoplasty 6 (5%) and others shown in Table 5.

Table: 5 Types of definitive surgery

Types of Definitive surgery	N	%	Cumulative %
Y-V Anoplasty	2	1.7	1.7
ASARP	56	47.1	48.7
PSARP	46	38.7	87.4
Abdominal assisted PSARP	4	3.4	90.8
Cutback anoplasty	6	5.0	95.8
Minimal anoplasty	3	2.5	98.3
PSARVP,TUM	2	1.7	100.0
Total	119	100.0	

The Post post-operative complications occurred in 34(28.6%) patients. The common complications are Stricture or stenosis 12 (10.1%), mucosal prolapse 11 (9.2%), Anastomotic dehiscence 4 (3.4%) and the details is listed in table 7 below. And Redo anoplasty was required for 15(12.6%) patients.

Table: 6 Post-operative complications

Clinical Parameter	Frequency (n)	Percentage (%)
Overall Complications		
No Complications	85	71.4%
Complications Present	34	28.6%
Specific Complication Types (n=34)		
Stricture / Stenosis	12	10.1%
Mucosal Prolapse	11	9.2%
Wound / Anastomotic Dehiscence	4	3.4%
Acquired Atresia	2	1.7%
Mislocated Anus	2	1.7%
Others	3	2.5%
Surgical Interventions		
Redo Anoplasty	15	12.6%

5.5 Functional outcomes

According to krickenbeck classification system the proportion of functional outcomes of 119 children with ARM after surgical correction was voluntary bowel movement 101 (84.9%), Soiling 56(47.1%) and constipation 29 (24.4%) respectively. The type of bowel movements, grades of soiling and constipation is shown in details in table 8.

Table: 7 Functional outcomes according to krickenbeck classification and urinary incontinence

Variable	Yes/No	Frequency (n)	Percent (%)
Bowel Movement	Yes	101	84.9
	No	18	15.1
Types of BM	Hold	68	57.1
	Verbalize	25	21.0
	Feeling urge	8	6.7
Soiling	Yes	56	47.1
	No	63	52.9
Grades of Soiling	Once or twice per week	25	21.0
	Every day soiling	21	17.6
	Constant soiling and social problem	10	8.4
Constipation	Yes	29	24.4
	No	90	75.6
Grades of Constipation	Managed by diet	22	18.5
	Managed by laxative	6	5.0
	Managed by enema	1	0.8

Variable	Yes/No	Frequency (n)	Percent (%)
Urinary Incontinence	Yes	9	7.6
	No	110	92.4
Types of Incontinence	Continuous	4	3.4
	Intermittent	5	4.2

5.6 Factors associated with functional outcomes

Categorical variables (ARM classification, stages of surgery, redo anoplasty) were compared using Pearson's Chi-square or Fisher's exact tests where appropriate. Continuous variables (birth weight and age at definitive surgery) were analyzed using the Mann-Whitney U test due to skewed data distribution.

The analysis showed that factors affecting the functional outcomes in this study are ARM types, stages of surgery, redo anoplasty and age at the definitive surgery. ARM types were a strong predictor ($p < 0.05$). Patients with High ARM types had lowest voluntary bowel movement (63.0%) and high soiling rates (77.8%), while those with Low ARM types were more prone to chronic constipation (43.5%). Children requiring repeat procedures were associated with poorest voluntary bowel movement ($p = 0.011$) and were more likely to experience persistent soiling ($p = 0.010$). Additionally, Age at definitive surgery was another factor where earlier intervention favored better voluntary control ($p = 0.009$). Children who underwent one stage repair are at high risk for constipation, whereas those requiring three stage repairs are at higher risk for soiling (Table). Birth Weight (BW) was evaluated but it did not reach statistical significance ($p > 0.05$).

Table: 8 Associations of Clinical Factors with Functional Outcomes (N=119)

Variable	Level	Voluntary BM	Soiling	Constipation
ARM Classification	High	17 (63.0%)	21 (77.8%)	2 (7.4%)
	Intermediate	63 (91.3%)	30 (43.5%)	17 (24.6%)
	Low	21 (91.3%)	5 (21.7%)	10 (43.5%)
	p-value	0.0015	0.0003	0.0124
Stages of Surgery	1-stage	8 (100.0%)	1 (12.5%)	5 (62.5%)
	2-stages	22 (95.7%)	8 (34.8%)	5 (21.7%)
	3-stages	71 (80.7%)	47 (53.4%)	19 (21.6%)
	p-value	0.0948	0.036	0.0339
Redo Anoplasty	Yes	9 (60.0%)	12 (80.0%)	0 (0.0%)
	No	92 (88.5%)	44 (42.3%)	29 (27.9%)
	p-value	0.0111	0.0108	0.0206
Birth Weight (kg)	Median (IQR)	2.8 (2.5-3.2)	2.8 (2.5-3.2)	2.8 (2.5-3.2)
	p-value	0.8383	0.1347	0.1444
Age at Surgery (mo)	Median (IQR)	9.0 (6.0-14.5)	9.0 (6.0-14.5)	9.0 (6.0-14.5)
	p-value	0.0091	0.2991	0.6108

5.7 Independent Predictors of functional outcomes

Variables that had a p value of < 0.05 in bivariate analysis (ARM classification, redo anoplasty, age at surgery, and surgery stages) were entered into a multivariable binary logistic regression analysis. Adjusted Odds Ratios (AOR) with 95% Confidence Interval (CI) was calculated to identify independent predictors of functional outcomes.

The results is shown in Table 9. ARM types, redo anoplasty and age at definitive surgery are the primary independent predictors of poor outcomes.

Table: 9 Independent Predictors of functional outcomes

Outcome	Variable	AOR	95% CI	p-value
VBM	ARM: High	0.22	(0.04 -1.24)	0.086
	ARM: Intermediate	2.35	(0.35 -15.68)	0.378
	Redo surgery	**0.10**	**(0.02-0.49)**	**0.005**
	Age at definitive surgery	**0.97**	**(0.93- 0.99)**	**0.024**
Soiling	**ARM: High**	**0.133**	**(0.031-0.564)**	**0.006**
	ARM: Intermediate	0.709	(0.217-2.314)	0.569
	Redo surgery	**0.128**	**(0.028-0.582)**	**0.008**
	Stages of surgery (1)	16.108	(0.962-269.8)	0.053
	Stages of surgery (2)	2.201	(0.692-7.004)	0.182
Constipation	**ARM: low**	**8.40**	**(1.48 -47.66)**	**0.016**
	ARM: Intermediate	1.49	(0.482-4.608)	0.489
	Age at definitive surgery	0.99	(0.97 - 1.02)	0.720
	Stages of surgery (1)	0.179	(0.028-1.14)	0.068
	Stages of surgery (2)	1.4	(0.436-4.49)	0.572

CHAPTER 6 : DISCUSSION

This study assessed the functional outcomes of children with ARMs after surgical correction at TASH using the Krickenbeck classification system. These functional outcomes, the third group; VBM, soiling and constipation were analyzed along with factors affecting them.

6.1 Functional Outcomes

In this study 84.9% patients achieved VBM, while 47.1 % and 24.4% were soiling ang constipation respectively. Retrospective study done in Tanzania showed VBM, constipation, and soiling with a prevalence of 63%, 22% and 15% of patients respectively[26]. Cross sectional study in Indonesia also showed VBM was achieved in 53.5% patients, soiling and constipation rates were 11.6% and 9.3% respectively[12]. In our study both VBM and soiling is higher than the the two studies.

How ever; the success rate of VBM aligns with the 75–90% reported in the French National Cohort [19] and the 81.5% reported by Qazi et al. [22]. The VBM rate also comparable with Arnoldi et al. [1] and Rintala & Pakarinen [17].

Other international studies reported comparable findings where VBM rates range from 53–90%, soiling 4–35% and constipation 9–23% [5, 7, 11, 14, 16, 19].

However, the higher soiling rate reflects limited structured bowel management and postoperative follow up like in other low resource settings [14].

6.2 Factors affecting the functional outcomes

Bivariate analysis shows 63% of high ARM patients achieved VBM compared to 91.3% of both intermediate and low type ARM patients (P=0.0015). After adjusted for other affecting factors (Table 9) High ARM types showed no significance (AOR 0.22, 95% CI: 0.04-1.24, P=0.086). Although p- value is above 0.05, the narrow CI suggest the clinically important detrimental effect of the ARM types, which may be limited by the small number of high ARM patients in the study. This anatomical factor is documented by Levitt and Peña, who emphasize that high type ARMs are associated with associated sacral dysgenesis and poorly developed levator ani muscles limiting the child's ability to achieve adequate squeeze pressure[11, 23].

Soiling more frequent in high ARM patients (77.8%) than intermediate (43.5%) or low (21.7%) ARM patients (p= 0.0003). Multivariable analysis confirmed ARM type as independent risk factor for soiling (AOR 0.133, 95% CI 0.031-0.564, p=0.006) which is supported by other studies [2,5,14,26].

Constipation pattern reverses with 43.5%, 24.6%, and 7.4% for low , intermediate and high ARM patients respectively(p=0.0124). After multivariable analysis low type ARM associated with higher constipation (AOR 8.4, 95% CI 1.48-47.66, p=0.016). This aligns with idea that low ARM patients have better voluntary bowel control but high constipation which highlight underlying milder anatomical defect[1, 21].

Redo anoplasty had worse odds of achieving VBM and higher odds of soiling, even after controlling all other factors; VBM (AOR 0.1, 95%CI 0.02-0.49, P=0.005) and soiling (AOR 0.128, 95% CI 0.028-0.582, p=0.008). This supports the results of Peña et al. whose study on reoperations showed that technical failure causes irreversible perianal fibrosis and also noted in *Holcomb and Ashcraft's Pediatric Surgery* [8,24].

Regarding the Stages of Surgery the bivariate analysis showed that soiling was higher in three stage repairs (53.4%) compared to one stage repairs (12.5%) or two stage (34.8%) (p= 0.036). However, when adjusted for ARM type, the significance was lost. This indicates that the number of stages is a proxy for the initial types of ARM rather than an independent cause of poor outcome a conclusion shared by Rocourt et al. [18]. Our study identified an early age at definitive surgery is associated with better achieving voluntary control (AOR 0.97, 95%CI 0.93-0.99, p=0.024). This is supports the study done by Kisaka et al. who reported that delayed reconstruction in Eastern Africa is a major barrier to optimal outcomes [26]. Early repair is vital to utilize neonatal neuro-plasticity and ensure cortical integration [14, 26].

CHAPTER 7: CONCLUSIONS AND RECOMMENDATIONS

7.1 Conclusions

Good bowel control was attained in most patients VBM (84.9%), while soiling (47.1%) and constipation (24.4%) remain frequent. Redo anoplasty is the strongest predictor of poor functional outcome. Multi stage repairs are associated with higher soiling. High-type ARMs tend to soil more but are less prone to constipation. Limited structured follow-up contributes to suboptimal long-term control. Overall, surgical outcomes are encouraging but emphasize the need for improved technical precision and organized long term management systems.

7.2 Recommendations

Clinical Practice

- Prioritize success of the primary definitive repair through proper diagnosis, planning, and surgical precision to reduce redos.
- Implement standardized follow up using the Krickenbeck system for all ARM patients.
- Establish multidisciplinary bowel management clinics at tertiary hospitals.
- Provide early dietary counseling and bowel training for caregivers.
- Maintain comprehensive patient records and digital outcome tracking.

Policy and Institutional Level

- Use functional outcomes as performance indicators in pediatric surgery units.
- Encourage national and regional research collaborations to develop an ARM patient registry.

Future Research

- Conduct prospective long-term studies to assess bowel, urinary, and psychosocial outcomes.
- Evaluate the effectiveness of structured bowel programs in improving continence.

Dissemination plan

The result of this research will be disseminated to the Surgical Department, Pediatric Surgery Division, Addis Ababa University. It will be sent for publication on scientific journals in related fields and it will be disseminated through presentations at scientific conferences.

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Annex

ADDIS ABABA UNIVERSITY, COLLEGE OF HEALTH SCIENCES
SCHOOL OF MEDICINE
RESEARCH ETHICS COMMITTEE (REC)
Departmental Research Ethics Committee's Decision

Meeting No: - DOS/REC/177/2025/2018 Date: - Oct 15/2025
Protocol number:

Protocol Title: Functional Outcomes of Anorectal Malformations: A 5 years Retrospective Study at Two Referral Hospitals, Ethiopia	
Principal Investigator:	Dr. Gobena Mormata
Department	Department of surgery
Elements Reviewed (Protocol):	☐ Attached ☐ Not Attached
Review of Revised Application ☐ Yes ☐ No	Date of Previous review: May 14,2024
Decision of the meeting:	☐ Approved ☐ Approved with Recommendation ☐ Resubmission ☐ Disapproved

I. Elements approved-
1. Protocol Version No: **1**
2. Protocol Version Date: **March 1 ,2025**
3. Informed consent Version No: **1**
4. Informed consent Version Date: **March 1 ,2025**

II. Obligations of the PI-
1. Should comply with the standard international & national scientific and ethical guidelines
2. All amendments and changes made in protocol and consent form needs ethics committee approval
3. End of the study, including manuscripts and thesis works should be reported to the REC

III. To CHS IRB ☐

Departmental Research Ethics Committee's Approval Period from: _____ to _____

Follow up report expected in
3 Months____ 6 Months_____ 9 Months_____ one-year__√____

Chairperson, Research Ethics committee's
(Name)__Dr.Tsegazeab Laeke_____

Signature: _____

Head Department of Surgical
Name: - Dr Seyoum Kassa Merine

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