Addis Ababa University College of Health Science School of Medicine Department of Surgery Pediatrics Surgery Unit

Patterns of Associated Cardiac and Renal anomalies in Anorectal Malformation/ARM/ Patients seen at Black Line Hospital, Addis Ababa Ethiopia, November 2024 - October 2025.

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Patterns of Associated Cardiac and Renal Anomalies in Anorectal Malformation (ARM) Patients at Black Line Hospital, Addis Ababa, Ethiopia (November 2024 – October 2025)

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Submitted to Addis Ababa University (AAU), College of Health Sciences (CHS), School of Medicine, Department of Surgery, Pediatric Surgery Unit, In Partial Fulfillment of the Requirements for Specialization in Pediatric Surgery

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ASSURANCE OF INVESTIGATOR

The undersigned agrees to accept responsibility or the scientific, ethical and technical conduct of the research Project and for provision of required progress reports as per terms and conditions of the Research and Publication Directorate or /and Department of Pediatric surgery, at department of Medicine, college of health science, Addis Ababa University.

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Declaration

I hereby 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 and properly cited.

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The undersigned have examined the thesis report entitled ‘‘**Patterns of associated cardiac and renal anomalies in Anorectal malformation patients seen at Black lion specialized hospital, Addis ababa Ethiopia, November 2024- October 2025’’** presented by Dr Yidnekachew Getachew with registration number GSR/4386/12, a candidate for speciality certificate in pediatric surgery and hereby certify that it is worthy of acceptance.

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External Evaluator: Dr Tihitena Negussie Signature:---------- Date:----------

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Acronyms

AAU	Addis Ababa university
ARM	Anorectal malformation
ASARP	Anterior sagittal Anorectoplasty
CHD	Congenital heart disease
PAPVR	Partial anomalus pulmonary venous return
PFO	Patent foramen ovale
PSARP	Posterior sagittal Anorectoplasty
PUJO	Pelviureteric junction obstruction
RPF	Recto perineal fistula
RUF	Recto ureteral fistula
RVF	Recto vestibular fistula
VACTERL	Vertebral, Anal, Cardiac, Tracheo-esophageal, Renal and Limb
VUR	Vesico-ureteral reflux

Abstract

Background:
Anorectal malformations (ARM) encompass a broad spectrum of congenital anomalies affecting the distal gastrointestinal tracts like anus and rectum as well as urinary tract, and genital tract in both boys and girls. These anomalies range from minor, easily managed cases with excellent functional outcomes to complex cases that are challenging to treat, often associated with other anomalies, and have poor functional prognoses. Approximately 50% of ARM cases present with additional defects or are part of a syndrome.

Methods:
This study was employed as an institution-based prospective cohort design. It involves direct physical examination and by reviewing medical records of cases seen or managed at Black Lion Specialized Hospital between November 2024 and October 2025. The source population was included all children admitted during this period. The study population consist of children diagnosed with ARM.

Result

A total of 59 children diagnosed with anorectal malformation (ARM) were admitted to Black Lion Specialized Hospital during the study period. Of these, 35 (59.3%) were male and 24 (40.7%) were female. The age at presentation varied: 21 children (35.6%) presented within the first 24 hours of life, while the oldest patient was a 10-year-old boy with ARM and rectoperineal fistula. Regarding the types of ARM, the most common in males were rectoperineal fistula (n=12, 34.3%) and ARM without fistula (n=11, 31.4%). In females, rectovaginal fistula was the most frequent (n=13, 54.2%), followed by persistent cloaca (n=5, 20.8%). Associated congenital anomalies were common. Cardiac anomalies were present in 29 patients (49.2%), with atrial septal defect (ASD) and patent ductus arteriosus (PDA) being the most common

structural heart defects. Renal anomalies were detected in 12 patients (20.3%), predominantly hydronephrosis and renal ectopia.

Conclusion and recommendation

A substantial proportion of children with anorectal malformation (ARM) presented to the hospital beyond 72 hours of life, underscoring the persistent need for enhanced awareness, clear communication, training, and logistical support to primary healthcare facilities and community health workers to promote early detection, prompt referral, and timely definitive management. Additionally, this study revealed that a significant number of patients, particularly males, had ARM without an overt fistula to the urinary tract (no visible fistulous communication). Consequently, a distal colostogram should be routinely performed in all cases as a fundamental diagnostic tool to precisely define the distal rectal anatomy, confirm the level of rectal atresia, identify possible occult fistulas, and guide the optimal surgical approach during definitive corrective surgery. Also MRI can be used in selected cases to see the exact location of the rectum, identify fistulas, visualize pelvic muscles and sacral bone structures, and find associated anomalies guiding precise surgical repair for better functional outcomes.

Key words: Anorectal malformation, Cardiac anomalies, renal anomalies.

1. Introduction

1.1 Background

Anorectal malformations (ARM) encompass a wide spectrum of congenital anomalies affecting the distal anus, rectum, urinary tract, and genital tract in both males and females. These defects range from minor anomalies with excellent functional outcomes to complex cases that are challenging to manage and often associated with poor prognoses. ARM is characterized by the absence of a normal anal opening (except in cases like rectal atresia where the anus may appear normal). Instead, patients often have fistulous tracts that open onto the perineum, anterior to the anal muscle complex, or into adjacent anatomical structures. In males, these fistulas may connect to the urinary system, while in females, they may involve gynecological structures (1).

The exact etiology of ARM is unknown, but genetic factors are thought to play a significant role. The recurrence risk for a second child with ARM in the same family is approximately 1% (2). Risk factors include a family history of ARM or certain genetic syndromes, such as Down syndrome and Hirschsprung disease (3). Approximately 50% of ARM cases are associated with other congenital anomalies or syndromes, including the VACTERL association (vertebral, anorectal, cardiac, tracheoesophageal fistula, renal, and limb anomalies).

While ARM can occur as an isolated condition, additional workup is often required due to the high prevalence (60%) of associated anomalies (4). If not diagnosed at birth, affected infants may present with symptoms such as:

- Inability to pass stool (constipation),
- Stool leakage from the vagina or visible in urine, and
- Urine discharge from the anus.

1.2 Statement of the Problem

Anorectal malformation (ARM) is a leading cause of intestinal obstruction in neonates, surpassed only by intestinal atresia and Hirschsprung disease in frequency (5). It occurs in approximately 1 in 5,000 live births worldwide. According to projections from the 2024 Ethiopian Demographic and Health Survey and Central Statistical Agency, Ethiopia's crude birth rate is 29.76 births per 1,000 population, with a total projected population of 132.06 million. This translates to approximately 3,928,320 annual births, suggesting at least 786 expected ARM cases per year nationwide—though underreporting is likely in resource-limited settings.

ARMs exhibit a slight male predominance (1.2:1 ratio). In males, approximately 70% of cases involve a recto-urethral fistula (most commonly bulbar or prostatic types), while in females, the recto-vestibular fistula is the predominant anomaly. The frequency of associated congenital heart diseases (CHD) in ARM patients varies widely in the literature. For example, Schierz IAM et al. reported a CHD frequency of 15.5% in ARM patients, while Gokhroo RK et al. documented a frequency as high as 74.4%(8). Even local Ethiopian studies show significant variability, with frequencies ranging from 8% to 38% (6).

Congenital malformations represent a significant portion of the surgical workload in African pediatric referral hospitals, accounting for one-third to two-fifths of cases (7). ARM is the most common structural congenital malformation managed by pediatric surgeons on the continent and is the leading congenital cause of intestinal obstruction. Colostomy creation and definitive anorectoplasty or anoplasty are among the most frequently performed colorectal procedures for ARM patients (9).

Associated anomalies significantly contribute to morbidity and mortality. Children with VACTERL association, for instance, have poorer quality of life compared to those without associated anomalies. These anomalies can also negatively affect sexual function and fertility, further influencing long-term outcomes (9, 10).

1.3 **Justification of the Study**

Between 5% and 31% of patients with anorectal malformations (ARM) exhibit associations with vertebral, anorectal, cardiac, tracheoesophageal fistula, renal, and limb anomalies, collectively referred to as VACTERL (≥3 anomalies) (11). Early detection and management of ARM are critical for achieving optimal outcomes. Prompt intervention leverages the pliability of sphincter muscles and helps preserve somatosensory integration, ensuring better functional results.

While screening for associated anomalies in ARM patients is widely recommended, there remains considerable debate regarding the scope and extent of screening necessary (12). Additionally, obtaining accurate birth incidence data for ARM is challenging in many African countries due to the lack of formal birth registries (13). Within the first 24 hours of life, newborns should be systematically evaluated for ARM and associated anomalies, such as esophageal atresia, cardiac defects, and renal anomalies.

Currently, there is limited knowledge about the specific patterns and prevalence of cardiac and renal anomalies in ARM patients. Aside from a single study conducted five years ago at Tikur Anbessa Specialized Hospital (TASH) that assessed the frequency of congenital anomalies in ARM patients, there is a significant gap in local data on this subject.

Given this context, further research is urgently needed to better understand the frequency of congenital heart disease (CHD) and renal anomalies in ARM patients. Comprehensive studies incorporating clinical, operative, and imaging findings are essential to enhance diagnostic accuracy, guide treatment protocols, and ultimately improve patient outcomes.

2Literature Review

2.1 Anorectal Malformation

Anorectal malformations (ARM) represent a unique category of anomalies involving the anus and rectum, characterized by a high association with other congenital defects. The reported prevalence of associated anomalies ranges from 20% to 80%. The most commonly associated anomalies globally are of urogenital origin, with cardiovascular, gastrointestinal tract (GIT), renal, vertebral, and nervous systems also frequently affected (14).

The Krinkenbeck Conference on ARM provided a systematic review and classified ARM into two categories: less complex and complex types.

- **Less complex ARM** includes perineal (cutaneous) fistula, anal stenosis, anterior ectopia syndrome, rectal stenosis/atresia, and vestibular fistula.
- **Complex ARM** encompasses cloacal malformation, recto-bladder neck fistula, recto-urethral fistula (bulbar, prostatic, or unspecified), no fistula, and other rare types (15).

2.2 Incidence of Cardiac Anomalies in ARM

Studies on the prevalence of cardiac anomalies in ARM show significant variability: In India, a retrospective study by Schierz IAM et al reported congenital heart disease in 15.5% of newborns with isolated gastrointestinal malformations (17). A study by Gokhroo RK et al in Milan, Italy, found that 74.41% of gastrointestinal tract anomalies were associated with ARM, with 50% of these cases presenting with congenital heart disease (18). Kamal JS et al conducted a study at Khyber Teaching Hospital, Peshawar, where 24.6% of imperforate anus cases exhibited congenital cardiac abnormalities (17). In South Africa, a study on ARM prevalence in Western Cape Province reported 17.78% of patients with ARM also had congenital cardiac

anomalies (18). A case series in Karachi by Qazi SH et al documented a 38% prevalence of cardiac abnormalities in ARM patients, whereas a prospective observational study in Lahore reported an 8% prevalence (19). A one-year prospective study at Black Lion Comprehensive Hospital in Ethiopia (2019–2020) reported a 20.4% incidence of cardiac anomalies among ARM patients, typically as isolated associations (20).

2.3 Incidence of Renal Anomalies in ARM

Renal anomalies in ARM refer to structural abnormalities of the kidney but can also encompass broader urological anomalies, such as ureterocele, megaureter, neurogenic bladder, and vesicoureteral reflux (VUR). Common renal anomalies associated with ARM include duplicated collecting systems, ectopic kidney, ureteropelvic junction obstruction, and renal agenesis or dysplasia (23). Urinary tract anomalies are the most common associated anomalies in ARM, present in 26%–52% of several large case series (24). Among these, unilateral renal agenesis and vesicoureteral reflux are predominant in cases of high anorectal malformation.

A study conducted in Ethiopia reported that the most common associated anomalies in ARM patients were genitourinary anomalies (49.3%). Of these, 26.5% were urological, and 22.8% were genital anomalies (20).

3. Objective

3.1 General Objective

- To determine the pattern of associated cardiac and renal anomalies in children with anorectal malformations (ARM) at Black Line Specialized Hospital, Addis Ababa, Ethiopia.

3.2 Specific Objectives

- To identify the incidence and types of cardiac anomalies in children with ARM at Black Line Specialized Hospital, Addis Ababa, Ethiopia.
- To identify the incidence and types of renal anomalies in children with ARM at Black Line Specialized Hospital, Addis Ababa, Ethiopia.

4. Methods and Materials

4.1 Study Area

The study was conducted at Black Lion Specialized Hospital; the tertiary children care center in Ethiopia. Located in Addis Ababa, Black Lion is a tertiary university hospital serving as the referral center for children with a complicated congenital anomalies across the country.

4.2 Study Design and Period

It was an institution-based prospective cohort study conducted from November 2024 to October 2025.

4.3 Source Population

All children admitted and treated at Black Lion Specialized Hospital from November 2024 to October 2025.

4.4 Study Population

Children diagnosed and admitted with anorectal malformations (ARM) at Black Lion Specialized Hospital during the study period.

4.5 Study Subjects

Children diagnosed and admitted with ARM at Black Lion Specialized Hospital during the specified timeframe and screened with echocardiography and abdominal ultrasound.

4.6 Inclusion and Exclusion Criteria

Inclusion Criteria: Children diagnosed with ARM and admitted for the first time during the study period and screened by echocardiography and abdominal ultrasound.

Exclusion Criteria: Patients without a diagnosis of ARM, those admitted outside the study period and ARM patients admitted in the study period but don't have proper echocardiography and abdominal ultrasound study.

4.7 Study Variables

Presence of anorectal malformation.

Presence of cardiac and renal anomalies.

4.8 Sample Size and Sampling Technique

The sample size was adjusted and determined using the number of neonatal admissions in the previous year (Yamane's formula or Cochran's formula)

The formula is as follows:

$$n= N/1+ N (e^2)$$

$$n= 43/1+ 43(0.05^2)$$

$$n=39$$

Where-

n- is the required sample size.

N-is the population size (total number of admissions from the previous year).

e-is the margin of error or desired precision level (e.g., 0.05 for a 5% margin of error).

Given the limited number of cases, the study was included all children presented for the first time with the diagnosis of anorectal malformations (ARM) during the study period using consecutive sampling.

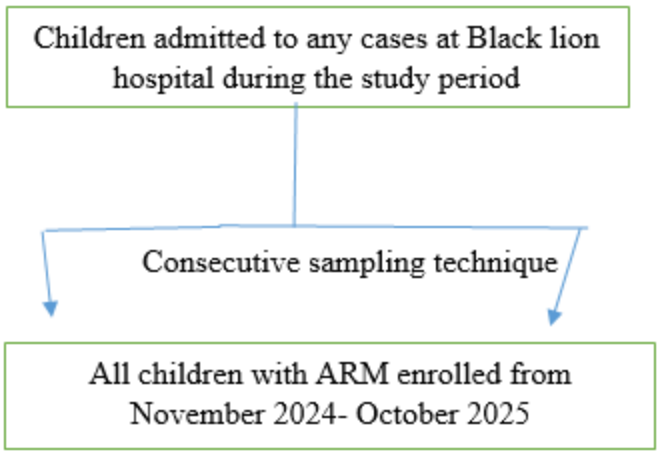

Figure 1. Sampling procedure in selection of the study participants

4.9 Data Collection Instrument and Technique

Data were gathered from operation theatre logbooks and individual patient records using a structured questionnaire adapted from existing literature. ARM types were classified according to the Krickenbeck classification.

4.10 Data Quality Assurance

All data were collected by trained data collectors who was trained by the principal investigator. There was on-site supervision and regular feedback for the data collectors to ensure completeness and clearance of the data.

4.11 Data Analysis Procedure and Interpretation

Data was collected via structured questionnaires that was exported to SPSS (version 25) for analysis. Descriptive statistics, including frequency distributions and percentages, were used to analyze the data, and results were cross tabulated in tables, charts, and graphs.

5. Result

There was a total of 59 children diagnosed with ARM were admitted at black lion specialized hospital in the study period, of which 35 children were male and 24 were female. Regarding to the age of presentation 21 (35.6 %) children presents with in the first 24 hours of life with the oldest age at presentation was 10 years male for ARM with RPF. Related to the types of ARM, male children has ARM with rectoperineal fistula and ARM without fistula were 12 (34%) and 11(31%) respectively. And from Types of ARM in female children ARM with RVF 13 (54%) and Persistent cloaca 5(21%) were the major.

As for patients who met criteria for VACTERL syndrome, we found four (6.7%) patients of which 2 patients with cloacae, 1 patient with fistula to the bladder neck, and 1 patient with rectobulbar fistula. There were 4 patients with Down syndrome (6.7%), of which 3 patients were male with ARM without fistula and 1 female patient with RVF. Edward syndrome were found in one anal stenosis patient.

Table 1- Age distribution of ARM patients at presentation

		Frequency	Percent
	1 to 28 days	45	76.3
	29days to 1 years	10	16.9
	1 year to 3 years	2	3.4
	above 5 years	2	3.4
	Total	59	100.0

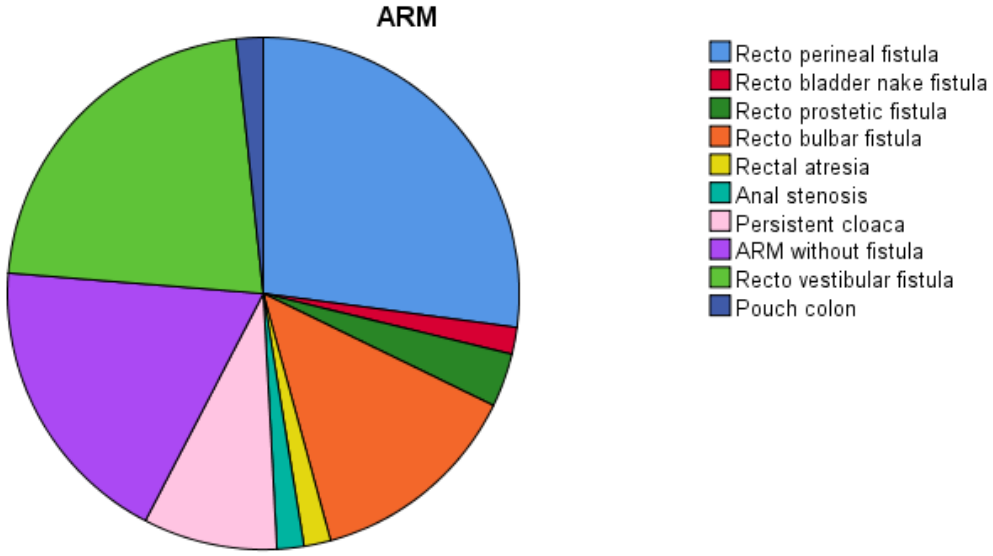

Fig. 2- Patterns of types of ARM

Table 2- Frequency of types of ARM

Types of ARM by kreckenbeck classification	Frequency	Percent
Recto perineal fistula	16	27.1
Recto bladder neck fistula	1	1.7
Recto prostatic fistula	2	3.4
Recto bulbar fistula	8	13.6
Rectal atresia	1	1.7
Anal stenosis	1	1.7
Persistent cloaca	5	8.5
ARM without fistula	11	18.6
Recto vestibular fistula	13	22.0
Pouch colon	1	1.7
Total	59	100.0

Table 3- Frequency of ARM by gender

Types of ARM		Recto perineal fistula	Recto bladder nake fistula	Recto prostetic fistula	Recto bulbar fistula	Rectal atresia	Anal stenosis	Persistent cloaca	ARM without fistula	Recto Vestibular fistula	Pouch colon	Total
sex	male	12	1	2	8	0	1	0	11	0	0	35
	Female	4	0	0	0	1	0	5	0	13	1	24
Total		16	1	2	8	1	1	5	11	13	1	59

Screening echocardiography and andominopelvic ultrasound was done for all 59 patient with ARM , from which we found 29 (49.2 %) has associated cardiac anomalies with ASD and PDA were the major structural heart defect. Multiple(more than one) cardiac lesion were found in 14 (48%) patients with associated cardiac anomallies. Of all 12 patients with ASD 10 (83%) were secundem type with defect size ranges from 3 to 8mm. Perimembranous type of VSD was the major defect found in 8 of 10 patients who has VSD as isolated or togather with other cardiac anomalies and defect size were between 3 up to 8 mm in 6 (60%) patients. From all 16 patients with PDA 50% of them has less tha 3mm in size and the other half has 3 up to 8 mm defect.

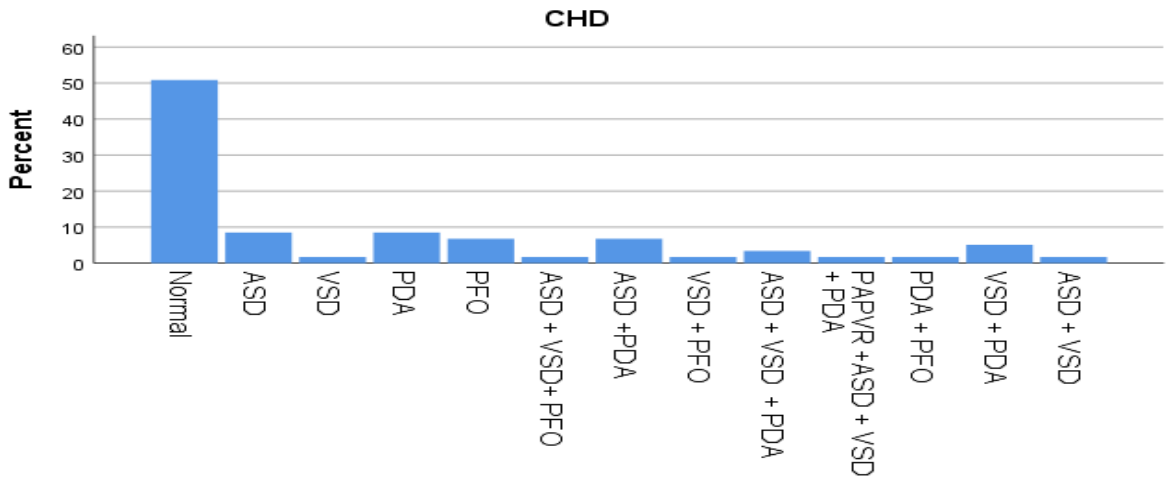

Fig. 3- Patterns of associated cardiac anomalie

Renal anomalies were detected in 12 (19.6%) patients, with hydronephrosis and renal ectopia were a major finding. From all 4 patients with ectopic kidneys, crossed fussed ectopia found in 3 (60%) and all the 3 were left to right crossed fused ectopia, the remained one patient with ectopic kidney were located in the pelvic. Hydronephrosis were found in 9(Eight of them secondary to PUJO and one patient as hydrouretronephrosis secondary to VUR) patients as solitary anomalies and associated with with renal ectopia in 4 patients. Bilateral hydronephrosis(involving both kidneys) detected in 55% of hydronephrotic patients and from unilateral hydronephrosis 75% was detected on the left side. Two (3.4%) patients has renal atresia , one on the right and the other on the left side.

Table 4- Patterns of Renal Anomalies in ARM patients

Types of ARM	Normal	Renal Atresia	Hydrone phrosis	VUR	Ectopopic kidney + Hydronephrosis	Total
Recto perineal fistula	14	0	0	0	2	16
Recto bladder nake fistula	1	0	0	0	0	1
Recto prostetic fistula	2	0	0	0	0	2
Recto bulbar fistula	5	1	2	0	0	8
Rectal atresia	1	0	0	0	0	1
Anal stenosis	1	0	0	0	0	1
Persistent cloaca	3	0	1	0	1	5
ARM without fistula	11	0	0	0	0	11
Recto vestibular fistula	10	1	0	1	1	13
Pouch colon	0	0	1	0	0	1
Total	48	2	4	1	4	59

6. Discussion

In this study, 35 patients (59.3%) were male and 24 (40.7%) were female, yielding a male-to-female ratio of 1.45:1. This distribution is comparable to a 2023 study from Alexandria University Hospital, Egypt, which reported 63.6% males and 36.4% females (23).

All patients underwent a standardized diagnostic protocol on initial presentation at our center, consisting of detailed clinical examination (including perineal inspection and digital rectal examination when appropriate), screening echocardiography, and abdominopelvic ultrasound. A minority of patients were referred after undergoing temporizing diverting colostomy at peripheral facilities. Intraoperative findings for those who underwent definitive surgery were retrieved from the electronic medical record system.

Associated congenital anomalies were frequent. Cardiac anomalies were identified in 60% of males and 33.3% of females with ARM (overall 49.2%). Renal anomalies were detected in 12 patients (20.3% of the cohort), with a higher prevalence in females: 7/24 females (29.2%) versus 5/35 males (14.3%), giving a male-to-female ratio of approximately 1:2 for renal anomalies.

Although ARM is one of the most common congenital anomalies worldwide and its association with cardiac and renal malformations is well documented, several findings from the present study highlight two important local observations:

1. Late presentation remains a significant challenge: 78% of patients presented during the neonatal period (<28 days), yet only 21% were seen within the first 24 hours of life. This represents an improvement compared with a previous one-year prospective study conducted at our institution five years earlier, which reported only 69.8% neonatal presentation (20).

2. ARM without fistula (particularly in males) was considerably more common than previously recognized in our setting: 35% of male patients had no fistulous communication to either the urinary tract or perineum. This is markedly higher than the 9.8% reported in the earlier institutional study (20).

Unlike prior reports from our hospital that included both new and follow-up cases (resulting in larger sample sizes), the current study exclusively enrolled patients presenting for the first time, which accounts for the relatively smaller cohort.

Screening echocardiography and abdominopelvic ultrasound were performed in all 59 patients with anorectal malformation (ARM). Cardiac anomalies were detected in 29 patients (49.2%), with atrial septal defect (ASD) and patent ductus arteriosus (PDA) being the most common structural heart defects. This prevalence is notably higher than the 34% reported by Cuneus MC de Beaufort et al. at Emma Children's Hospital, Amsterdam University Medical Center (24). Multiple cardiac lesions (more than one defect) were present in 14 (48.3%) of the 29 patients with congenital heart disease (CHD).

Among the 12 patients with ASD, 10 (83.3%) had secundum-type ASD, with defect sizes ranging from 3 to 8 mm. Perimembranous ventricular septal defect (VSD) was the predominant type, observed in 8 of the 10 patients with VSD (either isolated or combined with other anomalies), with defect sizes of 3–8 mm in 6 patients (60%). Of the 16 patients with PDA, 50% had a ductus diameter <3 mm, while the other half measured 3–8 mm. Cardiac anomalies were present in all 9 syndromic patients (100%) and in 5 of 11 patients (45.5%) with ARM without recto-urinary or recto-vestibular fistula.

Compared to other studies, our 49.2% prevalence of CHD is significantly higher than reports from Schierz IAM et al. in India (15.5% in isolated gastrointestinal malformations) (16), Kamal JS et al. in Peshawar, Pakistan (24.6%) (17), a South African study in Western Cape Province (17.8%) (18), and a prospective study from Black Lion

Comprehensive Hospital, Ethiopia (11.7%) (20). However, it aligns closely with Gokhroo RK et al. in Milan, Italy, who reported CHD in 50% of gastrointestinal anomalies associated with ARM (8), and is comparable to Qazi SH et al. in Karachi, Pakistan, who documented a 38% prevalence (19).

Genitourinary anomalies remain the most frequently associated malformations in ARM, with reported prevalence ranging from 26% to 52% in large series. In our cohort, renal anomalies were identified in 12 patients (19.6%). Hydronephrosis was the most common finding, present in 9 patients (75% of renal anomalies), of whom 8 had pelvis ureric junction obstruction (PUJO) and one had hydroureteronephrosis secondary to vesicoureteral reflux (VUR). This is consistent with a previous prospective study from the same hospital (2019–2020), which reported renal anomalies in 21.8% of cases, though hydronephrosis accounted for only 44.1% in that series, possibly due to differences in sample size (20).

Renal ectopia was another significant finding: 4 patients had ectopic kidneys, of whom 3 (75%) had crossed fused ectopia (all left-to-right), and one had a pelvic kidney. Bilateral hydronephrosis was observed in 55.6% of patients with hydronephrosis, while among unilateral cases, 75% affected the left side. Renal agenesis was noted in 2 patients (3.4%), one right-sided and one left-sided, which is lower than similar institution observational study reports renal agenesis in 5.7% of ARM patients (16). A study from Ethiopia reported genitourinary anomalies in 49.3% of ARM patients, with urological anomalies in 26.5% and genital anomalies in 22.8% (20).

VACTERL association was diagnosed in 4 patients (6.8%), two of whom were females with persistent cloaca. Esophageal atresia (Gross type C) with distal tracheoesophageal fistula was present in 5 patients (8.5%), of whom 3 had isolated esophageal atresia and 2 were part of VACTERL association.

7. Conclusion

Anorectal malformation is one of the most common congenital anomalies encountered in pediatric surgical practice. Associated cardiac and renal anomalies are frequent and significantly impact long-term functional and psychological outcomes. Early and thorough clinical evaluation, supported by routine screening echocardiography and abdominopelvic ultrasound, is essential for timely diagnosis and optimal management.

8. Recommendations

A considerable number of patients with ARM continue to present beyond 72 hours of life, often delaying diagnosis and intervention. Strengthening communication and referral pathways between primary health centers and tertiary facilities is crucial for early detection and timely management. Given that a significant proportion of patients with ARM lack a visible fistula, distal colostography should be considered a standard diagnostic procedure prior to definitive surgical correction to accurately delineate anatomy and guide the appropriate surgical approach. Also MRI can be used in selected cases to see the exact location of the rectum, identify fistulas, visualize pelvic muscles and sacral bone structures, and find associated anomalies guiding precise surgical repair for better functional outcomes.

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1. Annex

Annex 1 Consent Form

Black line Hospital is selected to conduct a study with the title of pattern and associated cardiac and renal anomalies in ARM patients admitted in Black line Hospitals. Prospective Cohort study will be conducted using secondary data from your hospital and it will involve records of all ARM patients who is enrolled from December 1, 2024- December 30 2025.

This study will help to determine the incidence of cardiac and renal anomalies in children with ARM and also the study will utilize a screening protocol for screening of associated anomalies. So that, the output of this study will be important to design targeted intervention mechanisms based on the identified patterns and screening protocols, which will in turn improves the management procedure in your hospital and beyond. Additionally, during reviewing patient records, it is possible to identify data recording problems. This will also help to correct recording problems if any.

All data collected from the study will be kept confidential. Presentations of the study's results at meetings/conferences or their publication in a scientific journal will not include patient's name and any other identifying factors.

However, ethics committees and research advisors will have access to the data for verification.

Name of the hospital manager _____

Signature _____

Date (DD/MM/YYYY) _____

Annex 2. Data Collection Tool

Collected by: Name _____ Signature _____ Date _____

Supervised by: Name _____ Signature _____ Date ____

Serial #	Variable	Options	Remark/Skip
	Data collection date: dd/mm/yyyy	_____/_____/_____	
	MRN #		
	Sex	1. Male 1. Female	
	Age in Day/Month/Year	_____	
	Weight in Kg	_____	
	Age at presentation		
	Clinical presentation	_____	
	Did ECHO done	1. Yes 2. No	
	Echo findings	A. Normal B. ASD C. VSD D. PDA E. TOF F. Other…….	
).	*Renal and pelvic US*	1. Yes 2. No	
.	*Finding of Renal and pelvic US*	A. Normal B. Renal atresia	

		C. Ectopic kidney D. Dysplastic kidney E. Hydronephrosis F. VUR G. Duplicate system	
.		1.	
.	Type of ARM in male	A. ARM with RPF B. ARM with rectobladde neck fistula C. ARM with recto prostetic fistula D. ARM with recto bulbar uretral fistula E. Rectal atresis F. Anal stenosis G. Persistent cloaca H. ARM without fistula I. Pouch colon	
.	Type of ARM in female	A. ARM with RPF B. ARM with RVF C. ARM with recto vaginal fistula D. Rectal atresia E. Anal stenosis F. Persistent cloaca G. ARM without fistula	

ADDIS ABABA UNIVERSITY, COLLEGE OF HEALTH SCIENCES
SCHOOL OF MEDICINE
RESEARCH ETHICS COMMITTEE (REC)

Departmental Research Ethics Committee's Decision

Meeting No: -
Protocol number: DoS/REC/179/2025/2018 Date: -

Protocol Title: Patterns of Associated Cardiac and Renal anomalies in Anorectal Malformation/ARM/ Patients seen at Black Line Hospital, Addis Ababa Ethiopia, November 2024 - October 2025.	
Principal Investigator:	Dr. Yidnekachew Getachew
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

Signature: _____

Patterns of Associated Cardiac and Renal anomalies in Anorectal Malformation/ARM/ Patients seen at Black Lion Hospital, Addis Ababa Ethiopia, November 2024 - October 2025

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