

The European Anorectal Malformation Network (ARM-Net) patient registry: 10-year review of clinical and surgical characteristics

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Background

Anorectal malformations (ARM) are a group of rectal and anal birth defects with a European prevalence of about 1 in 2500–5000 live births^{1–4}. These rare and complex conditions require highly specialized reconstructive surgery in early life, often with a temporary defunctioning stoma^{5–7}. ARM are associated with other organ anomalies in 58–78% of patients; therefore, all ARM newborns should be screened for associated anomalies^{2,5,8–11}. The introduction of posterior sagittal anorectoplasty has improved the management of ARM in recent decades¹². Nevertheless, problems with bowel function can remain throughout adulthood and compromise quality of life^{13–20}.

With the rarity of ARM, specialized centres see 5–20 new patients each year²¹ and knowledge on epidemiology, demographics, treatment strategies and outcomes is scattered. In 2010, the Anorectal Malformation Network (ARM-Net) Consortium, a group of European paediatric surgeons, patient

advocacy groups, geneticists, epidemiologists and psychologists, established a patient registry²². The ARM-Net registry represents the collaboration among multiple paediatric surgical centres with a wide geographical coverage^{22–36}. Since its inception, more than 2600 patients have been registered. The aim of this study is to describe the clinical and surgical characteristics of ARM patients in the registry.

Methods

Objectives

The primary objective of this retrospective cohort study was to describe patients treated within the ARM-Net Consortium in terms of demographics, diagnostics, clinical characteristics including associated anomalies, surgical details including type of reconstruction, stoma placement, complications, and functional outcomes one year after reconstructive surgery. Secondary

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objectives were to investigate the relations between associated anomalies and ARM types, and timing of reconstructive surgery.

Subjects and data collection

ARM patients under 18 years of age treated in one of the ARM-Net Consortium and registered in the ARM-Net registry until 1 March 2023 were included. Each centre has a lead paediatric surgeon who is responsible for patient registration and data collection at their respective centre. Patient data are de-identified and pseudonymized before collection. Surgeons can only re-identify their own patients with personal code-breaking documentation. Data on demographics, ARM type according to Krickbeck classification^{33,37}, diagnostic screening and associated anomalies, surgical details and complications, and one-year follow-up functional outcomes are collected.

Renal, bladder, cardiac, tracheoesophageal, genital, skeletal, vertebral, sacral, spinal cord, and brain-associated anomalies, but also other (minor) anomalies, could be registered. Data on genetic studies were collected, including the presence of a syndrome or association. Surgical information included dates and types of stoma and anorectal reconstruction, and postoperative complications (for example infection, wound dehiscence, urethral injury, stenosis, recurrent fistula, or insufficient reconstruction requiring redo surgery). Data on short-term colorectal outcome one year after reconstruction were collected, including constipation and treatment, faecal consistency and frequency, anal dilatations, and late complications including perianal dermatitis and rectal mucosal prolapse, assessed at the surgeons' discretion. Surgeons were at liberty to provide additional information in the free-text sections.

Records with more than 25% missing data for closed-ended items were excluded from our analyses.

Statistical analyses

Descriptive statistics were performed for patient demographics, ARM phenotype, clinical characteristics including associated anomalies, surgical details including complications, and functional outcomes one year after reconstruction. Patients with reconstruction within one year of 1 March 2023 were excluded from the follow-up analyses. To calculate patients' age at time of surgery, date of birth and surgery used the 15th of the month, due to availability of month and year only. Mother's approximate age at time of patient's birth was calculated using birth year of mother and patient.

Logistic regression modelling estimated ORs and 95% c.i. for associations between accompanying anomalies and ARM phenotypes, using perineal fistula as the reference. Associations between anomalies and median age at time of reconstruction were examined using Mann-Whitney U-tests, and using chi-squared tests when age was categorized into older or younger than 3 months. All statistical tests were considered significant at $P < 0.05$.

Data were exported from the ARM-Net registry online database, cleaned with OpenRefine (v.3.4.1; 437dc4d, Google Inc. and contributors) and further cleaned and analysed in SPSS Statistics (version 29.0.0.0; 241, IBM Corporation, Armonk, USA).

Results

There were 2627 patients included in the ARM-Net registry. Eight records with more than 25% missing data were excluded, resulting in a total of 2619 patients included for analysis. Patients were registered through 34 different European centres (Fig. 1). Patient sex distribution was equal, and the most

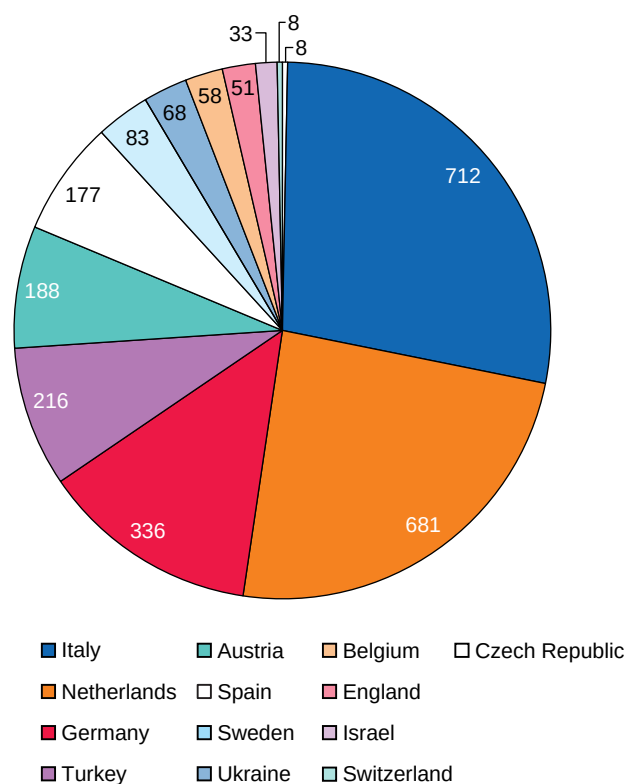


Fig. 1 ARM patients in the ARM-Net registry per country (N)

common ARM phenotype was perineal fistula for both sexes (41.5%), followed by vestibular fistula (31.8%) and cloaca (8.8%) in females, and rectobulbar (16.8%) and rectoprostatic fistula (15.0%) in males (Table 1). Patients were born to mothers with a median age of 32 years (i.q.r. 28–36).

Associated congenital anomalies

A minority of patients (11.4%) had a confirmed genetic diagnosis at time of analysis, and 31.7% of ARMs were isolated, without any associated anomalies. Frequency of associated anomalies is presented in Table S1.

Significant associations between ARM phenotypes and other anomalies were found (Table 2). Patients with vestibular fistula, rectourethral fistula (any type), recto-bladder neck fistula, cloaca, no fistula, or the group rare and other types were each more likely to have any associated anomalies compared to patients with perineal fistula. The same was true for skeletal, renal, bladder and genital anomalies separately. Patients with vestibular, rectourethral or recto-bladder neck fistula were more likely to have cardiac, spinal or tracheoesophageal anomalies than perineal fistula patients. There was no increased risk for cardiac anomalies in patients with cloaca or the group rare and other types, or for spinal anomalies in patients with no fistula, compared to perineal fistula patients. Patients with anal stenosis were not more likely to have any associated anomalies than patients with perineal fistula. Patients with no fistula had a two-fold increased risk for brain anomalies compared to perineal fistula patients, but this was not associated with Down syndrome ($P=0.469$). Furthermore, there was no association between complex ARM types and any genetic abnormality ($P=0.123$).

Reconstructive surgery and stoma

Of all patients, 44.5% had a stoma. The majority of patients with no fistula, rectourethral fistula (bulbar, prostatic, or unspecified

Table 1 ARM patient characteristics of the ARM-Net registry

	N (%)
Sex	
Male	1314 (50.4)
Female	1292 (49.6)
Twins	101 (3.9)
Mother's age at childbirth in years (median, IQR)	32 (28-36)
Krickbeck classification	
Perineal fistula	1086 (41.5)
Vestibular fistula (only female)	415 (15.8)
Rectobulbar fistula (only male)	222 (8.5)
Rectoprostatic fistula (only male)	198 (7.6)
Recto-bladder neck fistula (only male)	66 (2.5)
Rectourethral fistula unspecified (only male)	51 (1.9)
Anal atresia without fistula	162 (6.2)
Anal stenosis	53 (2.0)
Cloaca (only female)	113 (4.3)
<3cm common channel	65 (2.5)
>3cm common channel	29 (1.1)
unspecified common channel	19 (0.7)
Rare types:	
Ventrally dystopic anus	13 (0.5)
Rectal stenosis	17 (0.6)
Rectal atresia	16 (0.6)
Cloacal exstrophy	18 (0.7)
Rectovaginal fistula (only female)	18 (0.7)
H-type fistula	12 (0.5)
Pouch colon	7 (0.3)
Other	50 (1.9)
Unknown	102 (3.9)
Genetic diagnosis confirmed†	298 (11.4)
Down Syndrome	65 (2.5)
Cat Eye Syndrome	21 (0.8)
Townes-Brocks Syndrome	15 (0.6)
Currarino Syndrome or HLXB9 mutation	14 (0.5)
VACTERL Association‡	11 (0.4)
Pallister-Hall Syndrome	4 (0.2)
Other (including chromosomal aberrations)	168 (6.4)

*Of total known data, excluding unknown or missing data. †All other patients have no confirmed genetic diagnosis or results are pending at time of analysis.

‡This diagnosis was provided by the pediatric surgeon, not by checking the combination of anomalies for the VACTERL association entered (11). IQR, interquartile range.

type), cloaca or recto-bladder neck fistula received a stoma (78.8%, 96.6%, 97.3% and 98.5%, respectively), while 9.5%, 12.0% and 34.0% of perineal fistula, anal stenosis or vestibular fistula patients, respectively, did. Of patients that underwent reconstruction, 45.0% received a stoma, and of those without a reconstruction or with unknown data, 29.9% did. Most were divided stomas (73.3%) and placed at the descending/sigmoid colon junction (80.3%). Stoma formation complication rate was 25.0%, including stenosis, wound infection or dehiscence, stomal prolapse or retraction. Stomas were closed in 83.7% of patients, with complications after closure in 12.3%, including wound infection, anastomotic leakage, adhesions or incisional hernia. Of the patients whose stoma was not closed ($n = 183$), 21 patients died, 10 had an end stoma, 8 were lost to follow-up, 3 were awaiting reconstruction, and 1 patient had closure delayed due to prioritization of other issues. The reasons for not closing the stoma could not be deduced from free-text entries for the remaining patients.

Of all 2619 patients, 2278 had undergone reconstructive surgery. Information on whether a reconstruction had been performed was unknown for 5.2% of all patients (due to secondary referrals or missing data), and the remaining 7.8% of patients did not undergo reconstructive surgery. Of the patients that did not undergo reconstruction, 30 (14.8%) patients had died before surgery. Of the remaining 173 patients, most had a

perineal fistula (64.7%), followed by anal stenosis (8.7%) and ventrally displaced anus (5.2%). Only 16.8% of them had a stoma. Deduction of free text of these 173 patients showed that for 62 patients a reconstruction was not indicated, due to anal dilatation management only or a perineal fistula sufficiently surrounded by sphincter musculature²⁴. Ten patients were awaiting surgery, four had a definitive colostomy, three were treated for other issues with priority and three patients refused surgery. For the remainder of patients (91; 52.6%), the reason to refrain from reconstruction remains elusive.

Of patients with available data ($n = 2481$), 91.8% underwent reconstructive surgery (Table 3). Perineal fistulas were mostly corrected by mini-posterior sagittal anorectoplasty (PSARP) (40.3%), PSARP (33.5%), or anterior sagittal anorectoplasty (ASARP; 11.4%), and vestibular fistulas mostly through PSARP (71.9%) or ASARP (19.2%). Anal stenosis was mostly corrected by anoplasty (37.8%), PSARP (21.6%) or mini-PSARP (21.6%), and rectourethral fistulas (any type), no fistula and recto-bladder neck fistulas through PSARP (88.1%, 80.7%, and 63.5%, respectively). Cloacas were most often reconstructed by posterior sagittal anorectovagino(urethro)plasty (PSARV(U)P) (42.9%) or total urogenital mobilization (39.8%). Complications after reconstruction occurred in 25.5% of patients, including wound infections, dehiscence, stenosis, urethral injury and recurrent fistula. Late complications of frequent or severe perianal dermatitis or rectal mucosal prolapse occurred in 13.8% and 12.3%, respectively. Redo surgery was required in 4.4% of patients.

Median age at time of reconstructive surgery was 4 months (i.q.r. 2–7). Patients with skeletal, spinal, cardiac, renal, bladder, genital or tracheoesophageal anomalies were older at time of surgery than patients without (4 (i.q.r. 2–7) versus 3 (i.q.r. 1–5) months, $P < 0.001$). When categorizing age into younger or older than 3 months, the patients with anomalies (43.5%) more often had undergone reconstruction later than 3 months of age than patients without anomalies (57.9%; $P < 0.001$). While skeletal, spinal, renal, bladder and genital anomalies separately were associated with older age at the time of surgery, cardiac anomalies were not. However, when excluding patent ductus arteriosus (PDA) and patent foramen ovale (PFO; mentioned in free text) from cardiac anomalies, the same relation was found ($P = 0.023$).

Functional outcomes one year after anorectal reconstruction

Functional outcomes data at one-year follow-up were available in 60–70% varying per outcome measure (Table 4). Of these patients, 55.4% suffered from constipation. Treatment for constipation included stool softeners (54.8%), diet (32.4%), laxatives (23.9%) or enemas (23.4%). Faecal consistency was soft for most patients (67.8%), and median frequency was twice per 24 h (i.q.r. 1–2). Most patients (88.3%) underwent anal dilatations and 41.9% experienced pain during dilatations.

Discussion

This study describes the clinical and surgical characteristics of patients in the ARM-Net over a 10-year period. In accordance with existing literature, most patients had a perineal fistula, followed by vestibular fistula in females and rectobulbar and rectoprostatic fistula in males⁵. The majority of patients underwent reconstructive surgery and subsequent anal dilatations. Just over half of the patients suffered from constipation one year after

Table 2 Congenital anomalies associated with ARM Krickenbeck phenotypes

Associated anomalies	Krickenbeck type	N (%*)	OR	CI
Any anomaly	Perineal fistula	586 (54.0)	ref	ref
Sex	Vestibular fistula	314 (75.7)	2.7	2.1-3.4
Male (%): 949 (53.2)	Rectourethral fistula	398 (84.5)	4.7	3.5-6.1
Female (%)* : 835 (46.8)	Recto-bladder neck fistula	60 (90.9)	8.5	3.7-19.9
	Cloaca	111 (98.2)	47.4	11.6-192.7
	Anal stenosis	28 (52.8)	1.0	0.6-1.7
	No fistula	130 (80.2)	3.5	2.3-5.2
	Rare and other types	108 (71.5)	2.1	1.5-3.1
Skeletal anomalies	Perineal fistula	259 (32.8)	ref	ref
Sex	Vestibular fistula	161 (53.5)	2.4	1.8-3.1
Male (%): 471 (52.3)	Rectourethral fistula	222 (60.2)	3.1	2.4-4.0
Female (%)* : 430 (47.7)	Recto-bladder neck fistula	43 (81.1)	8.8	4.4-17.8
	Cloaca	64 (67.4)	4.2	2.7-6.7
	Anal stenosis	14 (37.8)	1.3	0.6-2.5
	No fistula	55 (47.8)	1.9	1.3-2.8
	Rare and other types	58 (53.7)	2.4	1.6-3.6
Spinal anomalies	Perineal fistula	91 (10.4)	ref	ref
Sex	Vestibular fistula	98 (27.8)	3.3	2.4-4.6
Male (%): 244 (52.8)	Rectourethral fistula	130 (34.4)	4.5	3.3-6.1
Female (%)* : 218 (47.2)	Recto-bladder neck fistula	26 (51.0)	8.9	5.0-16.1
	Cloaca	45 (47.4)	7.7	4.9-12.2
	Anal stenosis	7 (18.4)	1.9	0.8-4.5
	No fistula	14 (11.3)	1.1	0.6-2.0
	Rare and other types	36 (30.5)	3.8	2.4-5.9
Cardiac anomalies	Perineal fistula	265 (29.1)	ref	ref
Sex	Vestibular fistula	188 (50.9)	2.5	2.0-3.3
Male (%): 432 (50.9)	Rectourethral fistula	178 (45.1)	2.0	1.6-2.6
Female (%)* : 416 (49.1)	Recto-bladder neck fistula	23 (42.6)	1.8	1.0-3.2
	Cloaca	33 (35.1)	1.3	0.9-2.1
	Anal stenosis	10 (26.3)	0.9	0.4-1.8
	No fistula	89 (59.7)	3.6	2.5-5.2
	Rare and other types	35 (31.5)	1.1	0.7-1.7
Renal anomalies	Perineal fistula	186 (19.0)	ref	ref
Sex	Vestibular fistula	102 (27.2)	1.6	1.2-2.1
Male (%): 391 (57.5)	Rectourethral fistula	174 (40.7)	2.9	2.3-3.8
Female (%)* : 289 (42.5)	Recto-bladder neck fistula	36 (63.2)	7.3	4.2-12.8
	Cloaca	66 (61.7)	6.9	4.5-10.5
	Anal stenosis	6 (13.6)	0.7	0.3-1.6
	No fistula	40 (26.7)	1.6	1.0-2.3
	Rare and other types	42 (33.1)	2.1	1.4-3.2
Bladder anomalies	Perineal fistula	40 (4.2)	ref	ref
Sex	Vestibular fistula	32 (9.0)	2.3	1.4-3.7
Male (%): 152 (58.7)	Rectourethral fistula	67 (16.0)	4.3	2.9-6.5
Female (%)* : 107 (41.3)	Recto-bladder neck fistula	28 (50.9)	23.6	12.8-43.8
	Cloaca	35 (34.4)	11.9	7.1-20.0
	Anal stenosis	2 (5.0)	1.2	0.3-5.2
	No fistula	12 (8.8)	2.2	1.1-4.3
	Rare and other types	32 (25.4)	7.8	4.7-12.9
Genital anomalies	Perineal fistula	103 (10.4)	ref	ref
Sex	Vestibular fistula	45 (11.9)	1.2	0.8-1.7
Male (%): 323 (61.5)	Rectourethral fistula	149 (32.9)	4.3	3.2-5.6
Female (%)* : 202 (38.5)	Recto-bladder neck fistula	32 (53.3)	9.9	5.7-17.1
	Cloaca	80 (80.0)	34.6	20.4-58.9
	Anal stenosis	6 (13.0)	1.3	0.5-3.1
	No fistula	31 (20.0)	2.2	1.4-3.4
	Rare and other types	59 (41.5)	6.2	4.2-9.1
Tracheoesophageal anomalies	Perineal fistula	29 (2.9)	ref	ref
Sex	Vestibular fistula	39 (10.2)	3.7	2.3-6.1
Male (%): 99 (56.9)	Rectourethral fistula	67 (15.4)	6.0	3.8-9.5
Female (%)* : 75 (43.1)	Recto-bladder neck fistula	5 (8.3)	3.0	1.1-8.1
	Cloaca	15 (13.5)	5.2	2.7-10.0
	Anal stenosis	0 (0.0)	N/A	N/A
	No fistula	8 (5.4)	1.9	0.9-4.2
	Rare and other types	5 (3.6)	1.3	0.5-3.3
Brain anomalies	Perineal fistula	59 (9.8)	ref	ref
Sex	Vestibular fistula	37 (13.9)	1.5	1.0-2.3
Male (%): 98 (53.6)	Rectourethral fistula	39 (13.0)	1.4	0.9-2.1
Female (%)* : 85 (46.4)	Recto-bladder neck fistula	5 (14.7)	1.6	0.6-4.3
	Cloaca	8 (10.1)	1.0	0.5-2.3
	Anal stenosis	3 (10.7)	1.1	0.3-3.8
	No fistula	19 (18.4)	2.1	1.2-3.7
	Rare and other types	9 (10.8)	1.1	0.5-2.4

N/A, not applicable. *Of total known data, excluding not checked, unknown or missing data per variable.

Table 3 Surgical characteristics of the ARM patients in the ARM-Net registry

	N (%)
Sex	
Male	1314 (50.4)
Female	1292 (49.6)
Stoma placement*	1125 (44.5)
Type	
Divided	825 (73.3)
Loop	248 (22.0)
Unknown	52 (4.6)
Bowel section	
Descending/sigmoid colon junction	903 (80.3)
Transverse colon	90 (8.0)
Ileum	16 (1.4)
Sigmoid colon	12 (1.1)
Ascending colon	5 (0.4)
Descending colon	4 (0.4)
Other	16 (1.4)
Unknown	79 (7.0)
Complications stoma placement*	242 (25.0)
Stoma closed*	942 (83.7)
Complications stoma closure*	101 (12.3)
Reconstructive surgery performed*	2278 (91.8)
Age at reconstructive surgery in months (median, IQR)*	4 (2-7)
Type	
PSARP	1247 (54.7)
Mini-PSARP	435 (19.1)
ASARP	197 (8.6)
Anoplasty	114 (5.0)
Cutback	49 (2.2)
LAARP	73 (3.2)
PSARV(U)P	60 (2.6)
TUM	43 (1.9)
Other	41 (1.8)
Unknown	19 (0.8)
Complications reconstructive surgery*	542 (25.5)
Late complications*	379 (24.9)
Redo reconstructive surgery*	93 (4.4)

*Of total known data, excluding not checked, unknown or missing data per variable. PSARP, posterior sagittal anorectoplasty; ASARP, anterior sagittal anorectoplasty; LAARP, laparoscopic anterior anorectoplasty; PSARV(U)P, posterior sagittal anorectovagino(urethro)plasty; TUM, total urogenital mobilization.

reconstructive surgery. Patients frequently had associated anomalies, which were mostly skeletal, cardiac or renal.

Skeletal (including vertebral), cardiac and renal anomalies were the three most common associated anomalies in the present report, in concordance with the existing literature^{5,9,10,38}. Contrary to our findings, some studies^{9,10,38,39} found that genitourinary anomalies were the most frequent; however, this may be due to the inclusion of vesicoureteral reflux (VUR) under genitourinary anomalies, where it is a separate entity in the present study. Remarkably in this cohort, only about a third were screened for VUR, of which subsequently a third was diagnosed with VUR, emphasizing the potential importance of systematic screening⁴⁰. Incidences of skeletal and vertebral anomalies were within the ranges found in the literature^{5,9,10,38}, although some studies included spinal cord anomalies, such as tethered cord, in this category. The incidence of tethered cord in our study (8.2%) is similar to one study¹⁰ but lower than others (15–60%)^{9,38,41,42}. These discrepancies likely stem from a wide variation among centres in defining and diagnosing tethered cord²⁵. Although cardiac anomalies are among the three most common anomalies associated with ARM, the frequency in our study (39%) is higher compared to the 10–25% in the literature^{9,10,38}. However, when

Table 4 Functional outcomes in ARM patients one year after anorectal reconstruction

	Data available N (%)	N (%)*
Constipation	1795 (70.1)	994 (55.4)
Sex		
Male	876 (48.8)	
Female	915 (51.0)	
Constipation treatments		
Stool softener		539 (54.8)
Diet		319 (32.4)
Laxatives		235 (23.9)
Enemas		230 (23.4)
Consistency of feces	1711 (66.9)	
Soft		1160 (67.8)
Solid		483 (28.2)
Liquid		68 (4.0)
Defecation frequency per 24 hours (median, IQR)	1563 (61.1)	2 (1-2)
Dilatations	1743 (68.1)	1539 (88.3)
Sex ratio		
Male	856 (49.2)	
Female	883 (50.8)	
Pain during dilatations		645 (41.9)

*Of total known data, excluding not checked, unknown or missing data per variable.

excluding haemodynamically insignificant conditions, such as PDA, PFO or spontaneously closed ventricular septal defects, incidence decreases to 28.9%, close to the aforementioned upper limit.

Different ARM types were significantly associated with accompanying anomalies. Vestibular fistulas, rectourethral fistulas, recto-bladder neck fistulas, cloacas, no fistulas, and the group of rare and other types were more likely associated with other anomalies than perineal fistulas. Patients with cloaca were most likely to have associated anomalies, but it should be noted that confidence intervals were wide due to the low prevalence of this ARM type. These results show that for patients with common as well as rarer ARM types, thorough diagnostic screening for associated anomalies is warranted. This study showed that associated anomalies may influence timing of reconstructive surgery, as patients with associated anomalies are older at reconstruction than patients without. This probably relates to prioritization of treatment for associated anomalies.

The majority of patients underwent reconstructive surgery, where those patients that did not had either died, had an ARM type without indication for reconstruction, or were managed through dilatations only. Most reconstructed patients underwent a PSARP, which should be considered the standard operative approach^{6,12,43}. To prevent strictures, a common postoperative complication, most patients underwent subsequent anal dilatations, as described by Peña¹². Although most centres have adopted the dilatation protocol in their postoperative regimens, several studies have found that dilatations do not lower stricture rates^{44,45}. With over 40% of the patients in this study experiencing pain, protocolized anal dilatations in postoperative management should be reconsidered.

More than half of the patients experienced constipation one year after reconstruction, in accordance with the previous literature^{13,46,47}. Unfortunately, constipation continues to affect ARM patients beyond childhood into adulthood and may compromise quality of life^{17,47}.

This study has several limitations. Data quality, including completeness and comparability, poses challenges in registry

data, and should be evaluated before analysing data^{48,49}. A recent quality assessment of the ARM-Net registry found error-prone, yet with appropriate cleaning, valuable data⁵⁰. Although substantial data cleaning was required, most results in this study stem from closed-ended items, minimizing missing data and interpretation variations. The 60-day window of variability in patient's age at time of reconstruction, due to the manner that dates of birth and surgery are calculated, is another limitation. Therefore, only median age was reported, which should even out this variability. The data found that several patients did not have their stoma closed or did not undergo reconstruction, which may be explained by incomplete registration by surgeons. Therefore, one of the recommendations for an improved ARM-Net registry is to implement automatic reminders to complete or update data entry⁵⁰. Another limitation is that the current registry only collects stoma closure dates, omitting placement date or indication. Although some ARM phenotypes may require a temporary diverting stoma, management of postoperative complications might also be a stoma indication. The lack of uniform and validated scoring systems for outcome assessment at 1-year follow-up introduces heterogeneity between the participating centres and highlights the importance of standardization.

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Disclosure

None.

Supplementary material

Supplementary material is available at BJS online.

Data availability

The data generated, used and/or analysed during the current study are available from the corresponding author on request.

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