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Complications After Surgery for Anorectal Malformations: An ARM-Net consortium Registry Study

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ABSTRACT

Objective: Establishing the incidence and types of complications following surgical intervention for ARM, primarily after reconstruction. Patient- and treatment-related risk factors were also determined.
Background: Postoperative complications of ARM surgery vary widely, with data predominantly derived from single-center retrospective studies with limited number of patients. Whether factors such as ARM type, associated congenital anomalies, prior enterostomy, or type of reconstructive surgery affect complication incidence remains unclear.
Methods: This multicenter cohort study was performed using the ARM-Net registry with prospectively collected data. Enterostomy-related and post-reconstructive complications in patients who underwent reconstructive surgery before the age of five years were recorded. Patients with more than 25 % missing data, unknown sex, ARM type, or reconstruction date, or without (information on) reconstruction or complications, were excluded. Multivariable analyses identified independent risk factors for the development of complications.
Results: A total of 2,043 patients were eligible for analysis. Complications after enterostomy formation and closure occurred in 25 % and 12 % of patients, respectively. Post-reconstructive complications occurred in 25 % of patients, with wound complications comprising half of the complications. In a multivariable analysis, recto-bladder neck fistula, any associated anomaly, and the LAARP procedure were identified as independent risk factors for post-reconstructive complications. In contrast, anoplasty and mini-PSARP reduce the risk of complications.
Conclusions: Post-reconstructive complications in ARM patients are common, and certain patient- and treatment-related characteristics affect postoperative outcomes. These results aid counselling and

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clinical decision-making, and may guide the operative planning of ARM types that are amenable to several different surgical approaches.

1. Introduction

Anorectal malformations (ARM) are rare congenital malformations of the gastrointestinal tract with an incidence ranging from 2 to 6 per 10,000 births worldwide [1], requiring highly specialized reconstructive surgery. ARM complexity varies widely, with additional associated birth defects present up to 60 % of patients [2]. Although reconstructive surgical techniques have improved in recent decades, with the posterior sagittal approach presently being the preferred technique [3], the functionality of the affected structures is often impaired, causing constipation, fecal incontinence, sexual, reproductive and urinary tract dysfunction, which may reduce the quality of life [4]. Similarly, post-surgical complications also contribute to impaired functionality. Colostomy-related complications occur up to 70 % after formation, and up to 29 % after closure [5,6]. Post-reconstructive complications develop in 5–40 %, including wound infection (7–24 %), wound dehiscence (2–43 %), anal stenosis (5–38 %), rectal mucosal prolapse (3–27 %), and recurrent fistula (1–16 %) [7–14]. However, these widely varying numbers are predominantly based on single-center, retrospective studies on a small number of patients over a wide range of time. Whether other factors, such as ARM type, associated congenital anomalies, prior enterostomy, and type of reconstructive surgery, affect the incidence of complications remains unclear. Therefore, the aim of this study was to investigate the incidence and types of post-surgical complications within one year of follow-up and to determine patient- and treatment-related risk factors using the largest European ARM registry currently available.

2. Methods

2.1. Study design and population

This multicenter cohort study of 34 participating centers in 13 European countries used data from the ARM-Net Consortium patient registry. This registry prospectively collects pseudonymized data of all consecutive patients with ARMs treated at the involved pediatric surgical centers.

All registered patients who underwent reconstructive surgery at one of the participating centers before the age of five years were included. Exclusion criteria were as follows (I) patients with more than 25 % missing data for mandatory, closed-ended items (II) patients with unknown sex or ARM type, or contradictory combinations; and (III) patients with missing data for age at the time of reconstruction.

The primary objective of this study was to describe the incidence and types of post-reconstructive complications and determine independent risk factors for complication development. The secondary objective was to describe the incidence and types of complications after enterostomy formation and closure, and determine independent risk factors for complication occurrence. The Human Research Ethics Committee of the Radboud University Medical Center reviewed our study proposal and waived the study (study ID: 2022–13705). Conduction and reporting of this study followed the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines [15].

2.2. Data collection

Available data include demographic data, ARM type, associated congenital anomalies, surgical procedures, and postoperative complications. The registry particularly contains closed-ended single- or multiple-choice questions, with free text possibilities for elaboration or clarification.

2.3. Complications

Complications were recorded after enterostomy formation, anorectal reconstruction, and enterostomy closure. Data regarding the moment of occurrence of complications were not available, so all registered complications were eligible for analysis. Based on predefined answer options and additional free-text responses, we defined four complication groups: wound complications (infection and dehiscence), anal stenosis, other complications (i.e. prolapse, UTI), and requirement for redo surgery. Redo surgery is a predefined answer option, which in itself does not comprise a complication, but is a surgical approach to a complication. Its indication reflects a complicated recovery and was, therefore, selected as the answer option when developing the registry. Each complication was recorded as an individual event. Distinguishing between minor and major complications was based on the Clavien-Madadi classification specific to pediatric surgery (Grade I-II considered minor, III-V considered major) [16]. If no additional information regarding treatment or consequences of selected complication(s) was provided, and therefore no judgement could be made on the potential need for general anaesthesia (Grade III-IV by definition), the classification for minor and major complications was deemed ‘unknown’.

2.4. Potential risk factors

Patient-related characteristics included sex, ARM type, associated congenital anomalies, and approximate age at the time of reconstruction (<3 and $\geq$ 3 months). Associated congenital anomalies included at least one of any skeletal, renal, genital, spinal, cardiac, and tracheoesophageal anomalies. Patent ductus arteriosus and patent foramen ovale were excluded from cardiac anomalies, as these are usually physiological and depend on the timing of diagnostic procedures.

Treatment-related characteristics included type of reconstruction and enterostomy formation. Details regarding the type, location, and complications of enterostomy formation and closure are available. Reconstructive surgery was performed by standard or ‘mini’ posterior sagittal anorectoplasty (PSARP), anterior sagittal anorectoplasty (ASARP), cutback and anoplasty, laparoscopic assisted anorectoplasty (LAARP), posterior sagittal anorectovagino (urethro)plasty (PSARV(U)P), and ‘other type of surgery’. The definition of standard versus mini-PSARP was up to the discretion of the surgeon.

2.5. Statistical analyses

Patient characteristics, sex, ARM type, age at reconstruction, associated congenital anomalies, and surgical details, including enterostomy formation, type of reconstruction, and complications,

were analyzed using descriptive statistics. The frequencies are presented as percentages.

The associations between patient- and treatment related characteristics and post-reconstructive complications were estimated as odds ratios (OR) and 95 % confidence intervals (CI) using univariable and multivariable regression modelling to identify independent risk factors. The factors considered in the multivariable model were patient sex, ARM type (rectoperineal fistula as reference), one or more associated congenital anomalies (yes/no), enterostomy formation (yes/no), age at the time of reconstructive surgery (<3 and ≥ 3 months), and type of reconstructive surgery (PSARP as reference), based on existing literature and expert knowledge.

Subanalyses were also performed to estimate the associations between the potential risk factors and (I) any major post-reconstructive complications, (II) wound complications, and (III) stenosis.

Surgical approaches for rectoperineal and rectovestibular fistulas, such as ASARP or PSARP, are based on surgeon preference. To aid surgeons in their future decision-making, additional analyses were performed to investigate the associations between the reconstructive surgical approach and complications separately for different ARM types. Multivariable logistic regression models were used, including sex, enterostomy, associated congenital anomalies, and age at surgery. The same was done for enterostomy formation in ARM types, where enterostomy formation was at the surgeon's discretion and not as a standard procedure (e.g., rectoperineal fistula, rectovestibular fistula, and rectal stenosis).

Finally, the potential risk factors for enterostomy-related complications after formation and/or closure (if applicable) were investigated. Associations were estimated using univariable and multivariable logistic regression modelling, including ARM type (rectoperineal fistula as reference), patient sex, associated congenital anomalies, bowel section (descending/sigmoid junction as reference), and enterostomy type (divided type as reference). Separate analyses were also performed for patients with a rectoperineal or rectovestibular fistula with an enterostomy.

All statistical analyses were conducted using SPSS Statistics (v.29.0.0.0; 241, IBM Corporation, Armonk, United States) and were considered significant at a p-value <0·05.

3. Results

The registry contained 2,627 patients on March 1st, 2023. After excluding patients with unknown data for complications (n = 130), more than 25 % missing data (n = 8), without a specified ARM type (n = 102), an ARM type - sex mismatch (n = 7), unknown sex (n = 6), unknown or no reconstruction (n = 271), reconstruction at a different center (n = 28), missing data for date of birth or date of reconstruction (n = 20), and patients who were five years or older at the time of reconstruction (n = 12), a total of 2,043 patients were eligible for analysis.

3.1. Clinical and surgical characteristics

Most patients had a rectoperineal fistula (43 %), followed by a rectobulbar fistula in males (10 %) and a rectovestibular fistula in females (17 %) (Table 1). Associated congenital anomalies were frequent (65 %), with skeletal anomalies being the most common (47 %). Of all patients, 8 % had a tethered cord, which accounted for 38 % of patients with spinal cord anomalies. Less than half of the patients (44 %) underwent an enterostomy, mostly a divided type (76 %) in the descending colon/sigmoid junction (88 %). Standard or mini-PSARP was most frequently performed (75 %), and 54 % of patients underwent surgery at or beyond 3 months of age.

Table 1
Demographic, clinical, and surgical characteristics of 2043 ARM patients included in the ARM-Net registry who underwent reconstructive surgery.

	N (%[a])
Male sex	1,063 (52.0)
ARM type	
Rectoperineal fistula (M/F)	876 (436/440) (42.9)
Rectovestibular fistula	348 (17.0)
Rectourethral fistula	412 (20.2)
Bulbar type	*202 (9.9)*
Prostatic type	*170 (8.3)*
Unspecified	*40 (2.0)*
Recto-bladder neck fistula	53 (2.6)
Anal atresia without fistula	136 (6.7)
Anal stenosis	34 (1.7)
Cloacal malformation	88 (4.3)
<3 cm common channel	*56 (2.7)*
>3 cm common channel	*23 (1.1)*
Unspecified length	*9 (0.4)*
Rare and other types	96 (4.7)
At least one associated congenital anomaly[b]	1,324 (65.0)
Vertebral anomaly	300 (16.5)
Sacral anomaly	380 (21.0)
Absent coccyx	322 (21.6)
Spinal cord anomaly	375 (22.3)
Cardiac anomaly	502 (28.8)
Tracheoesophageal anomaly	136 (7.1)
Renal anomaly	630 (34.1)
Genital anomaly	395 (20.4)
Limb anomaly	204 (10.5)
Enterostomy	897 (43.9)
Enterostomy closed	839 (93.5)
Age at reconstructive surgery	
<3 months	945 (46.3)
≥3 months	1,098 (53.7)
Type of reconstructive surgery	
PSARP	1,110 (54.5)
Mini-PSARP	409 (20.1)
ASARP	181 (8.9)
Anoplasty	100 (4.9)
Cutback	45 (2.2)
LAARP	71 (3.5)
PSARV(U)P	51 (2.5)
PSARVUP with TUM	38 (1.9)
Other	33 (1.6)

Abbreviations: ARM, anorectal malformation; PSARP, posterior sagittal anorectoplasty; ASARP, anterior sagittal anorectoplasty; LAARP, laparoscopic assisted anorectoplasty; PSARV(U)P posterior sagittal anorectovagino(urethro)plasty; TUM, total urogenital mobilization.

[a] Of total known data, excluding missing data per variable.

[b] Vertebral, sacral, coccygeal, spinal, cardiac, tracheoesophageal, renal, genital, or limb anomalies.

3.2. Post-reconstructive and enterostomy-related complications

Post-reconstructive complications were registered in 503 patients (25 %) (Table 2), of which half were wound complications. Redo reconstruction was performed in 75 patients, accounting for 15 % of patients with complications and an overall redo-rate of 4 %. Patients with less complex ARM-types - including rectoperineal fistula, rectovestibular fistula, anal stenosis - had the least complications, most commonly wound complications, whereas in complex ARM-types - including recto-bladder neck, cloacal malformation - most complications, primarily stenosis, were recorded (Table 3). Regarding the surgical approach, cutback, anoplasty, and mini-PSARP resulted in the least number of complications, whereas PSARV(U)P and LAARP had most (Table 3). LAARP had the highest stenosis rate, but LAARP complications were also dominated by the "other" group, which, although not a formal outcome in the registry, frequently described rectal/mucosal prolapse in free text. The complication rate after enterostomy formation was higher (25 %) than that after closure (12 %).

Table 2
Post-reconstructive and enterostomy-related complications in 2043 ARM patients included in the ARM-Net registry.

	N (%)
At least one complication after reconstructive surgery	503 (24.6)[a]
Wound complications	257 (12.6)[a]
Stenosis	96 (4.7)[a]
Others	191 (9.3)[a]
Urethral lesion	17 (0.8)[a]
Recurrent fistula	15 (0.7)[a]
Mucosal prolapse [b]	57 (2.8)[a]
Bladder/urinary tract issues [b]	28 (1.4)[a]
Vaginal lesions [b]	17 (0.8)[a]
Small bowel obstruction [b]	9 (0.4)[a]
Megarectum [b]	6 (0.3)[a]
Redo reconstruction	75 (3.7)[a]
At least one complication after enterostomy formation	202 (25.3)[c]
Wound infection	52 (6.5)[c]
Stenosis	38 (4.8)[c]
Prolapse	32 (4.0)[c]
Other	123 (15.4)[c]
Misplaced/inverted loops [b]	29 (3.6)[c]
Dehiscence [b]	24 (3.0)[c]
Retraction [b]	10 (1.3)[c]
Dermatitis [b]	8 (1.0)[c]
Adhesions [b]	5 (0.6)[c]
At least one complication after enterostomy closure	92 (12.0)[d]
Wound infection	28 (3.7)[d]
Leakage	15 (2.0)[d]
Other	61 (8.0)[d]
Adhesions/obstruction [b]	13 (1.7)[d]
Excoriation [b]	6 (0.8)[d]
Other infection [b]	6 (0.8)[d]
Parastomal hernia [b]	5 (0.6)[d]

[a] Out of 2,043 patients.
[b] Complications mentioned in accompanying free text at least 5 times.
[c] Out of 797 patients with an enterostomy and without missing data on complications.
[d] Out of 764 patients whose enterostomy was closed and without missing data on complications.

3.3. Clinical and surgical factors associated with post-reconstructive complications

Patients with rectourethral fistula, recto-bladder neck fistula, cloacal malformation, and rare and other ARM types showed an increased risk of post-reconstructive complications compared to patients with rectoperineal fistula in univariable analyses (Table 4). The same was true for patients with associated congenital anomalies, ≥3 months of age at the time of surgery, enterostomy, and a LAARP procedure compared to PSARP. By contrast, a cutback, anoplasty, or mini-PSARP demonstrated a reduced risk. However, in a multivariable analysis, only a recto-bladder neck fistula, any associated congenital anomalies, and the LAARP procedure remained as independent risk factors for post-reconstructive complications. Anoplasty and mini-PSARP remained associated with reduced risk. Sex, age at surgery, and enterostomy were not significantly associated with complications.

Analyses of the effect of a defunctioning enterostomy prior to reconstruction on the development of post-reconstructive complications were performed for the subgroup of ARM types that were amenable to either primary or staged repair depending on the surgeon's preference. Post-reconstructive complication rates for patients with and without enterostomy did not differ between those with rectoperineal and rectovestibular fistulas. However, patients with anal atresia without fistula showed a significantly lower post-reconstructive complication rate when a defunctioning enterostomy was present (18 %) compared to patients treated with a primary repair (39 %), even after adjustment for sex, associated congenital anomalies, and reconstruction type ($OR_{adjusted}$ 0.2, CI 0.1–0.7). The most prevalent complications after primary repair were wound complications.

Focusing on the reconstructive surgical approach for each ARM type, we observed a reduced post-reconstructive risk for complications after anoplasty (9 %) and mini-PSARP (16 %) in patients with

Table 3
Types of post-reconstructive complications by clinical and surgical characteristics in 2,043 ARM patients included in the ARM-Net registry.

	TotalN	At least one complicationN (%)	WoundN (%[a])	StenosisN (%[a])	OtherN (%[a])	RedoN (%[a])
ARM type						
Rectoperineal fistula	876	173 (19.7)	122 (13.9)	26 (3 0)	40 (4.6)	19 (2.2)
Rectovestibular fistula	348	83 (23.9)	52 (14.9)	12 (3.4)	24 (6.9)	9 (2.6)
Rectourethral fistula	412	119 (28.3)	40 (9.7)	25 (6.1)	61 (14.8)	22 (5.3)
Recto-bladder neck fistula	53	27 (50.9)	5 (9.4)	12 (22.6)	14 (26.4)	8 (15.1)
Cloacal malformation	88	33 (37.5)	10 (11.4)	5 (5.7)	18 (20.5)	8 (9.1)
Anal stenosis	34	4 (11.8)	1 (2.9)	1 (2.9)	3 (8.8)	1 (2.9)
Anal atresia without fistula	136	31 (22.8)	13 (9.6)	8 (5.9)	16 (11.8)	5 (3.7)
Rare and other types	96	33 (34.4)	14 (14.6)	7 (7.3)	15 (15.6)	3 (3.1)
Male sex	1,063	267 (25.1)	113 (10.6)	60 (5.6)	118 (11.1)	46 (4.3)
Female sex	980	236 (24.1)	144 (14.7)	36 (3.7)	73 (7.4)	29 (3.0)
No associated anomalies†	714	135 (18.9)	80 (11.2)	25 (3.5)	30 (4.2)	22 (3.1)
At least one associated anomaly†	1,324	368 (27.8)	177 (13.4)	71 (5.4)	161 (12.2)	53 (4.0)
Age at surgery						
<3 months	945	202 (21.4)	123 (13.0)	30 (3.2)	63 (6.7)	23 (2.4)
≥3 months	1,098	301 (27.4)	134 (12.2)	66 (6.0)	128 (11.7)	52 (4.7)
No enterostomy	1,132	233 (20.6)	157 (13.9)	32 (2.8)	60 (5.3)	23 (2.0)
Enterostomy	897	269 (30.0)	100 (11.1)	63 (7.0)	131 (14.6)	52 (5.8)
Reconstructive surgery type						
PSARP	1,110	290 (26.1)	144 (13.0)	57 (5.1)	110 (9.9)	42 (3.8)
Cutback	45	5 (11.1)	1 (2.2)	1 (2.2)	1 (2.2)	2 (4.4)
Anoplasty	100	11 (11.0)	7 (7.0)	2 (2.0)	3 (3.0)	3 (3.0)
mini-PSARP	409	64 (15.6)	42 (10.3)	7 (1.7)	17 (4.2)	2 (0.5)
ASARP	181	55 (30.5)	43 (23.8)	10 (5.5)	10 (5.5)	13 (7.2)
LAARP	71	35 (49.3)	7 (9.9)	11 (15.5)	24 (33.8)	7 (9.9)
PSARV(U)P	51	19 (37.3)	4 (7.8)	2 (3.9)	14 (27.5)	2 (3.9)
PSARVUP/TUM	38	11 (28.9)	4 (10.5)	4 (10.5)	3 (7.9)	2 (5.3)
Other	33	12 (36.4)	4 (12.1)	2 (6.1)	9 (27.3)	2 (6.1)
Total	2,043	503 (24.6)	257 (12.6)	96 (4.7)	191 (9.3)	75 (3.7)

[a] Excluding missing data per variable.

Table 4
Clinical and surgical factors associated with post-reconstructive complications in 2043 ARM patients included in the ARM-Net registry.

	Crude		Adjusted	
	OR	(95 % CI)	OR	(95 % CI)
ARM type				
Rectoperineal fistula	*ref*		*ref*	
Rectovestibular fistula	1.27	(0.95–1.71)	0.88	(0.61–1.26)
Rectourethral fistula	1.73	(1.25–2.38)	0.94	(0.61–1.44)
Recto-bladder neck fistula	4.42	(2.45–7.96)	**2.03**	**(1.01–4.06)**
Cloacal malformation	2.33	(1.43–3.81)	2.27	(0.95–5.39)
Anal stenosis	0.54	(0.19–1.56)	0.71	(0.24–2.11)
Anal atresia without fistula	1.20	(0.78–1.85)	0.80	(0.48–1.33)
Rare and other types	2.13	(1.35–3.35)	1.57	(0.90–2.71)
Male sex	*ref*		*ref*	
Female sex	0.95	(0.77–1.16)	0.98	(0.72–1.33)
No associated anomalies[a]	*ref*		*ref*	
At least one associated anomaly[a]	1.65	(1.32–2.06)	**1.36**	**(1.07–1.72)**
Age at surgery				
<3 months	*ref*		*ref*	
≥3 months	1.39	(1.13–1.70)	1.07	(0.85–1.35)
No enterostomy	*ref*		*ref*	
Enterostomy	1.65	(1.35–2.02)	1.10	(0.79–1.54)
Reconstructive surgery type				
PSARP	*ref*		*ref*	
Cutback	0.35	(0.14–0.90)	0.43	(0.16–1.14)
Anoplasty	0.35	(0.18–0.66)	**0.40**	**(0.20–0.79)**
mini-PSARP	0.53	(0.39–0.71)	**0.61**	**(0.43–0.87)**
ASARP	1.23	(0.88–1.74)	1.36	(0.94–1.98)
LAARP	2.75	(1.69–4.46)	**2.05**	**(1.21–3.46)**
PSARV(U)P	1.68	(0.94–3.01)	0.75	(0.31–1.78)
PSARVUP/TUM	1.15	(0.56–2.35)	0.45	(0.16–1.29)
Other	1.62	(0.79–3.33)	1.15	(0.51–2.63)

Abbreviations: ARM, anorectal malformation; ref, reference; PSARP, posterior sagittal anorectoplasty; ASARP, anterior sagittal anorectoplasty; LAARP, laparoscopic assisted anorectoplasty; PSARV(U)P posterior sagittal anorectovagino(urethro)plasty; TUM, total urogenital mobilization.
[a] Congenital vertebral, sacral, coccygeal, spinal, cardiac, tracheoesophageal, renal, genital, or limb anomalies.

a rectoperineal fistula, but a higher risk when an ASARP (34 %) was performed compared to PSARP (23 %) (Table 5). For rectourethral fistula (bulbar/prostatic), LAARP was associated with a significantly higher risk of post-reconstructive complications than PSARP ($OR_{adjusted}$ 2.2, CI 1.2–4.2; 46 % vs. 27 %).

Most complications were graded as major according to the Clavien-Madadi classification [25] (Supplementary File, Table A). A higher risk of major complications was detected for cloacal malformation and rare and other ARM types (Supplementary File, Table B). Enterostomy formation and ASARP or LAARP procedures are also associated with an increased risk of major post-reconstructive complications. The mini-PSARP had the lowest risk of major complications (5 %).

3.4. Clinical and surgical factors associated with enterostomy-related complications

Formation of an enterostomy in a bowel section other than the descending colon/sigmoid junction was associated with a higher risk of developing complications ($OR_{adjusted}$ 2.1, CI 1.3–3.4) than formation in the descending colon/sigmoid junction. Patient sex, any associated congenital anomaly, and enterostomy type (loop vs. divided) were not associated with higher complication rates. The most prevalent type of complication differed between loop (prolapse: transverse colon, 19 %; descending/sigmoid junction, 5 %) and divided enterostomies (wound complications and stenosis). In patients with a rectoperineal or rectovestibular fistula, a divided enterostomy showed more complications (23 %) after formation than a loop enterostomy (5 %, $OR_{adjusted}$ 14.5, CI 1.7–121.3).

Complications after enterostomy closure were only borderline associated with the bowel segment, with a tendency towards a lower risk for enterostomies located in the descending colon/sigmoid junction compared to all other bowel segments described ($OR_{adjusted}$ 1.8, CI 0.9–3.6).

Table 5
Associations between post-reconstructive complications and reconstructive surgery type per ARM type, and the rates of wound complications and stenosis.

	Total N[a]	Complications N (%)	Adjusted[b]		Wound N (%)	Stenosis N (%)
			OR	(95 % CI)		
Rectoperineal fistula	871	171 (19.6)			121 (13.9)	26 (3.0)
PSARP	290	68 (23.4)	*ref*		45 (15.5)	12 (4.1)
Cutback	41	5 (12.2)	0.47	(0.17–1.25)	1 (2.4)	1 (2.4)
Anoplasty	78	7 (9.0)	**0.32**	**(0.14–0.73)**	4 (5.1)	1 (1.3)
mini-PSARP	363	57 (15.7)	**0.63**	**(0.42–0.94)**	39 (10.7)	7 (1.9)
ASARP	99	34 (34.3)	**1.73**	**(1.05–2.88)**	32 (32.3)	5 (5.1)
Rectovestibular fistula	343	82 (23.9)			52 (15.2)	12 (3.5)
PSARP	251	60 (23.9)	*ref*		40 (15.9)	7 (2.8)
mini-PSARP	21	4 (19.0)	0.87	(0.28–2.75)	2 (9.5)	0
ASARP	71	18 (25.4)	1.20	(0.64–2.27)	10 (14.1)	5 (7.0)
Rectourethral fistula	406	118 (29.1)			39 (8.4)	25 (6.2)
PSARP	362	98 (27.1)	*ref*		34 (9.4)	20 (5.5)
LAARP	**44**	**20 (45.5)**	**2.19**	**(1.15–4.18)**	5 (11.4)	5 (11.4)
Rectobulbar fistula	201	46 (22.9)			20 (10.0)	8 (4.0)
PSARP	194	44 (22.7)	*ref*		19 (9.8)	7 (3.6)
LAARP	5	2 (40.0)	2.06	(0.33–12.85)	1 (20.0)	1 (20.0)
Rectoprostatic fistula	168	62 (36.9)			16 (9.5)	10 (6.0)
PSARP	129	44 (34.1)	*ref*		12 (9.3)	6 (4.7)
LAARP	39	18 (46.2)	1.73	(0.81–3.70)	4 (10.3)	4 (10.3)
Recto-bladder neck fistula	51	26 (51.0)			5 (9.8)	12 (23.5)
PSARP	32	17 (53.1)	*ref*		4 (12.5)	8 (25.0)
LAARP	19	9 (47.4)	0.76	(0.23–2.48)	1 (5.3)	4 (21.1)

Abbreviations: ref, reference; PSARP, posterior sagittal anorectoplasty; ASARP, anterior sagittal anorectoplasty; LAARP, laparoscopic assisted anorectoplasty; PSARV(U)P posterior sagittal anorectovagino(urethro)plasty; TUM, total urogenital mobilization.
[a] Excluding missing data for type of reconstruction.
[b] Adjusted for sex, enterostomy, associated congenital anomalies, and age at surgery (<3 and ≥ 3 months).

4. Discussion

This ARM-Net registry study of 2,043 patients with ARM demonstrated that 25 % of patients developed at least one post-reconstructive complication, half of which were wound complications. Patient-related characteristics, such as certain complex ARM types, including recto-bladder neck and cloacal malformations, as well as any associated congenital anomaly, were associated with an increased risk of post-reconstructive complications. Regarding the surgical approach, cutback, anoplasty, and mini-PSARP were associated with lower complication rates than PSARP, whereas LAARP procedures had the highest complication rates. A prior enterostomy generally does not reduce the risk of post-reconstructive complications. Enterostomy-related complications are common.

Patient-related factors that have been determined to affect post-reconstructive complications are complex ARM types regardless of the surgical approach. An impressive 51 % of patients with a recto-bladder neck fistula experience at least one post-reconstructive complication, mostly stenosis. While the literature on recto-bladder neck fistulas primarily focuses on poor functional outcome [17], there is a paucity of evidence concerning post-reconstructive complications. One report documented no post-reconstructive stenosis [7] in a small study population, while in another series the post-reconstruction stenosis rate was 15 %, primarily after laparoscopic dissection [10]. The latter report concluded that the 50 % anal stricture rate after LAARP was caused by advancement of the rectum through an insufficiently wide pull-through tunnel and perineal incision, resulting not only in an anocutaneous anastomotic stricture, but also stenosis along the anal canal itself as well [10]. Furthermore, we speculate that mobilization of the high rectal pouch from the bladder neck level to the skin will leave an anocutaneous anastomosis solely reliant on intramural blood supply over a significant distance, adding to an increased stenosis risk.

The laparoscopic dissection as an adjunct to a posterior approach (LAARP) has been introduced by Georgeson [18] at the turn of the century, and has gained increasing advocation since [19,20]. The functional and cosmetic outcomes appear to be excellent, yet at the consistently reported expense of a considerable rate of rectal prolapse [8,20,21], and the aforementioned higher stenosis rate [10]. Our study also showed an increased risk of stenosis associated with a LAARP procedure, which was mainly executed in patients with a recto-prostatic fistula. Although not a formal datapoint in the ARM-Net registry, rectal/mucosal prolapse was also a frequently described complication in free text. A separate ARM-Net working group has studied this complication in further detail [22]. The higher complication rate in our study may reflect a learning curve or experience accumulation process, as number of LAARP procedures was limited (n = 71). Furthermore, the experience with PSARP, being the reference operation (n = 1,110), likely contributes to a lower rate of complications by itself.

Wound complications occurred most commonly, followed by stenosis, the latter accounting for around 5 % of all patients, which seems to be at the lower limit of the reported stenosis rate of 2.2–38 % in recent reports [8,9,11,23]. In addition, although wound complications comprised half of the reported complications, the numbers ranged from 2.9 to 14.9 % among the various ARM types, well within the range of the reported 7–24 % of wound infections and 2–43 % of wound dehiscences in other studies [9,12–14]. Interestingly, wound complications specifically developed more often in the less complex ARM types, while stenosis was observed more commonly in more complex types. Many studies have reported wound complications ranging from 3 to 43 % [9,12,14,24], but the distribution between the various ARM types is variable and not necessarily the highest in complex types [14]. Our results support this, showing the lowest risk of wound complications in the rectourethral and recto-bladder neck fistula groups. Potentially the development of wound complications may be more related to perioperative management, including bowel preparation, antibiotic regimens, wound care, and time of feeding [25].

Most patients with complex ARM receive an enterostomy prior to reconstruction. The protective effect of an enterostomy has been asserted in selected studies [14,24], while other studies have failed to endorse that statement [25] or have reported contrary results [26]. More importantly, whether an enterostomy protects against post-reconstructive complications can only be ascertained in ARM types that can be treated with or without an enterostomy, such as rectoperineal and rectovestibular fistulas. In these malformations, reports on the different approaches show variable results [27,28]. Our study showed no difference in post-reconstructive complications in these ARM types, regardless of a defunctioning enterostomy. Thus, when opting for an enterostomy in these less complex ARM types, the additional enterostomy-related complications [29,30] need to be considered. The only ARM type that benefitted from a defunctioning enterostomy was anal atresia without fistula. As this reconstruction is performed shortly after birth because of a missing fistulous opening to pass stool, different factors not accounted for regarding neonatal surgery and anesthesia, in addition to the larger resulting wound size that is protected by the enterostomy compared to the relatively small sagittal wounds in rectoperineal and rectovestibular fistulas, may explain this outcome.

Not only ARM types but also treatment-related characteristics, such as the surgical approach, were shown to affect complication development. We determined the complication rates of different techniques in those ARM types that are typically subject to different approaches. The focus has been on either sagittal approaches (e.g., ASARP vs. PSARP) or the adjunct of abdominal dissection in reconstruction (e.g., PSARP alone vs. LAARP), as detailed earlier. In patients with a rectoperineal fistula, cutback, anoplasty, and mini-PSARP showed fewer complications than PSARP. In contrast, ASARP appeared to be associated with a higher risk of complications. Although cutback and anoplasty have been performed for many decades, since the introduction of the posterior sagittal approach in the early 80's[31], the PSARP technique has been popularized for all ARM types. Nevertheless, recent data continue to support the potential advantages of limited surgical dissections, such as cutback or anoplasty [32], with favorable long-term functional outcomes [33,34]. Our data add to this support. The ASARP procedure as an alternative to the posterior approach has been adopted and advocated by some [35,36], with mixed results concerning complications, however [37]. There are no accounts in the current literature of higher complication rates in ASARP compared to PSARP in rectoperineal fistulas, but possibly a publication bias is present, stressing the advantages of the less adopted ASARP approach by those who have become enthusiasts.

The majority of documented complications in our study were classified as major [16]. This is remarkable, especially in the light of stenosis, and wound complications, such as infection and dehiscence, which are generally considered benign, comprising up to 70 % of the described complications. However, if a surgeon decides to assess a relatively minor complication, such as for wound care, under anesthesia – a common practice in pediatric patients – the complication is classified as major by definition, even if its actual impact is minor. This could explain why the majority of our complications were rated as major, in addition to the correction of small mucosal prolapses or repetitive dilatations under anesthesia.

Enterostomy-related complications were determined to be 25 % in our study, in line with what has been reported in the literature [6,30]. Although the type of enterostomy did not significantly affect overall postoperative recovery in ARM types that can be repaired

either primary or staged, such as rectoperineal or rectovestibular fistulas, a divided enterostomy seemed to have significantly more complications than a loop enterostomy in patients who underwent an enterostomy. As a divided enterostomy has been the preferred type for years [30], more favorable reports have recently been published concerning loop colostomies [38,39], and the adoption of this technique has increased. Based on our results, loop enterostomy seems to be the preferred approach when opting for enterostomy in patients with rectoperineal or rectovestibular fistulas. Different review papers, however, show that loop enterostomies primarily in the transverse colon give rise to a higher incidence of prolapse [6,40]. Therefore, the preferred location for a loop colostomy is the descending colon/sigmoid junction. This holds true for any type of enterostomy as our study demonstrated an increased risk of complications after placement at any different location.

Although this study is the largest to date addressing post-reconstructive and enterostomy-related complications in patients with ARM, its limitations need to be addressed. No definition of complication nor a specific timeframe (i.e., within 30 days of surgery) was provided in the registry. Data checking and monitoring among centers are still under development, so underreporting of complications is possible.

The registry framework does not allow us to delineate certain elements, leaving them up for interpretation. One issue is the date of enterostomy formation, which was not documented in the registry. Although enterostomies can be fashioned during or after reconstruction to prevent or treat complications, enterostomies were interpreted as being fashioned prior to reconstruction as a standard three-stage procedure based on earlier data from our own consortium [41]. In addition, the distinction between PSARP and mini-PSARP has not been defined, and determination has been left to the discretion of the individual surgeon providing surgical care. Furthermore, a 'redo' can be selected when registering post-reconstructive complications in the registry, and would refer to a formal redo reconstruction to correct an insufficient initial reconstruction. However, as reporting of details or indications is not obligatory, the actual reintervention cannot be ascertained and may be as little as mucosal trimming or partial anoplasty for stenosis. Therefore, redo as a formal reconstructive operation is probably less prevalent than the 4 % rate found in this study. Data cleaning was extensive because of the enthusiastic usage of the free text commentary option and the structure of the registry. A cautious interpretation of the contradictory predefined answers compared to free text explanations urged us not irregularly to dismiss answers provided, and change them into unknown. Therefore, the power of reliability was prioritized over the power of size.

Nevertheless, based on the analyzed number of patients, this study provides a valuable and comprehensive overview of post-reconstructive and enterostomy-related complications in a large European cohort of patients with ARM. This is of special importance because complications after ARM reconstruction have negative implications on patients' suffering, families' lives, health care burden, and not the least on economic issues for both families and healthcare systems.

In conclusion, our study illustrates that complications after reconstructive surgery in patients with ARM are common, and certain patient- and treatment-related characteristics, including complex ARM types, any associated anomaly, and various surgical reconstructive techniques, affect the postoperative outcome. These results may impact clinical decision-making and aid patient and parent counselling. Finally, by identifying risk factors, our results can guide the operative planning of ARM types that may be corrected through several different approaches.

Data availability statement

With publication, the de-identified participant data generated, used, and/or analyzed during the current study are available from the corresponding author upon request for researchers who provide a methodologically sound proposal. No additional documents are available.

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Conflict of interest

None.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jpedsurg.2025.162403.

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