Evaluation of Risk Factors for Development of Stoma Related Complications in Patient with Anorectal Malformation

Humam Isam Abdulrahman , Ali Egab Joda ***

ABSTRACT:

BACKGROUND:

Colostomy in patient with ARM has complications. There are some risk factors have impact on complications development.

OBJECTIVE:

Predict risk factors for development of stoma complications in ARM patients.

METHODS:

A prospective study conducted on neonates and infants with ARM who underwent colostomy at the department of pediatric surgery - central Child Teaching Hospital/Baghdad-Iraq from January/2019 till January/2021, searching for stoma complications and evaluating the effect of several variables on stoma morbidity.

RESULTS:

A total (64) patients, the most common associated anomaly was cardiac one. The mean operative time was 69.8 minutes. The mean stoma duration was (9.7) months. The postoperative stoma care was good in (59.4%) and poor in (40.6%) cases.

54.7% of patients had complications. The most common were skin excoriation. Mortality was reported in two cases (3.1%).

CONCLUSION:

Colostomy Creation carries a lot of complications. Variables of sex, associated anomaly, operative time, stoma care, and stoma duration were determinant of morbidity while age, weight, type and level of stoma have no significant associations. Loop type has shorter operative time but higher incidence of UTI than divided one. Prolapse of stoma was not related to stoma type.

KEY WORDS: anorectal malformations, stomas, complication, risk factor.

INTRODUCTION:

Diversion of fecal stream by colostomy is commonly used before definitive surgical repair of anorectal malformation[1]. In children with a high anorectal malformation, a colostomy is created in the neonatal period when direct reconstruction in the first few days of life is not possible. However, In the last two decades several pediatric surgeons have advocated primary repair of anorectal malformations because of the problems formation and closure without need of full laparotomy and shorter operative time(5).The separated descending stoma has been reported as an ideal ostomy for ARM patients(5) as there is a relatively short segment of defunctionalized distal colon, therefore megarectosigmoid isn't expected to developed. the other advantages are that distal colostogram and mechanical cleansing of the distal colon prior to surgery[6].

*Pediatric Surgery, Al-Turath University College, Baghdad, Iraq

** Pediatric Surgery, College of Medicine, Al-Mustansiriyah University, Baghdad, Iraq

associated with colostomy creation, and its significant morbidity[2].

The traditional approach prefers divided colostomy[3]. Some recent publications seem to suggest comparable results using a loop type [4]. The advantages of loop colostomy include ease of Divided stoma is supposed to help complete diversion of fecal materials and hence potentially reduce the risk of UTIs. However, it has the disadvantage of being more invasive at both the initial procedure and stoma closure with the potential for intra-abdominal adhesion formation[7].

Several complications have been reported after colostomy formation in neonates and infants like skin excoriation, wound infection, sepsis, prolapse, UTI, bleeding, disruption, intestinal obstruction, stenosis, retraction, megarectum, stoma necrosis, mislocation, parastomal hernia. Prolapse is a common complication with some potential consequences that are mostly preventable.

It is more common in patients who underwent transverse loop colostomy than in those who underwent sigmoid and diverting type colostomy, possibly due to relative mobility of the transverse colon[8].Wound infection was defined as any signs of surgical site infection starting from cellulitis that treated with antibiotics or a superficial surgical site infection to severe wound infection with disruption of stoma skin bridge requiring opening of the wound or need for -revision of stoma-[9]. Skin excoriation in colostomies could occur when stoma nursing care is insufficient or when frequent loose stools come into contact with the skin. The risk is greater in the case of a transverse colostomy compared with a sigmoid colostomy because in the former less colonic length is available for absorption of salts and bile acids [10]. Skin excoriation, despite of being not a life threatening complication, it may significantly affect the quality of life when it occurs in these patients [11].

With regard to urinary tract infections, it has been suggested that a split colostomy may prevent it because there is no fecal contamination of the mucous fistula and thus no contamination of the urinary tract via the recto-urinary fistula[10].

In the presence of a large recto-urinary fistula, the patients frequently voids into the colon and a more distal stoma will permit the urine to get away through the distal stoma with minimal absorption while with the proximal stoma the urine is absorbed in the colon rising the incidence of metabolic acidosis[12].

Although making the abdominal wall incision small may increase stomal stenosis, it mostly occurs because of bowel ischemia regarding an inadequate bowel's blood supply, or due to surgical site infection and scarring of skin[11]. The fecal impaction in the distal colon lead to megarectum, particularly when a patient spends a longer duration between the opening of the colostomy and the main repair of the malformation[15]. The presence of a megarectum correlates with the severity of constipation that these patients suffer after the repair of their malformation [3].

AIM OF STUDY:

To predict the risk factors for development of stoma complications in anorectal malformation's patients.

PATIENTS AND METHODS:

This is a prospective study conducted on neonates and infants born alive with the diagnosis of anorectal malformation and who underwent colostomy, as part of their surgical management at the department of pediatric surgery - Central Child Teaching Hospital in Baghdad where the study is implemented during 25 months period from January 2019 till the end of January 2021.

Inclusion criteria

The study includes all eligible patients of both genders that born with anorectal malformation and have colostomy (divided or loop) at any age during their surgical management and followed up for development of complications from time of stoma creation to the time of stoma closure.

Exclusion criteria

We excluded the following groups of patients:

1. Those patients who have stoma done previously outside our pediatric surgery center.
2. Those patients with lost follow up.

Variables and outcomes

Study data were collected according to special data form and then recorded on Excel sheet. The variables were chosen based on published researches that emphasized their correlation with outcomes. these data were Demographic variables including gender, age at creation of stoma (in days). The Clinical variables include weight of patient, type of anorectal malformation, clinical condition of patients on arrival to hospital (sepsis, hypothermia, hypovolemia), stoma type, the level at which stoma is created, operative time, stoma duration, post-operative stoma care, type of reconstructive surgery, surgeon experience level, and associated anomaly.

The outcomes were any reported mortality or any encountered stoma related complications, and all cases were followed up till the time of stoma closure. Clear validated definitions are provided for all variables and complications where possible.

The type of anorectal malformation was identified clinically by inspection in some types like rectovestibular type or radiologically by distal colostogram in majority of cases. Some of ARM was identified during the reconstructive surgery.

Stoma type in this study includes loop and divided. Double barrel and separated included in divided one. None of the patients is managed with Hartman's procedure or ileostomy. The selection between loop and divided stoma was random according to surgeon preference and clinical situation of the patient. Some surgeons prefer loop stoma, others prefer divided one, and usually most of surgeon prefer use loop stoma for female with

rectovestibular fistula and divided stoma for other types of anorectal malformation. If the patient is vitally unstable despite resuscitation, then we do loop colostomy because it takes relatively shorter time to construct.

Stoma level is the level of colon at which the stoma is created including sigmoid, descending, transverse, and the end of colonic pouch. Operative time (in minutes) was measured from time of skin incision to time of applying dressing. Operative room preparation time and anesthetic times were not included in this definition. Mean operative time MOT of all patients was the chosen cut-off value for establishing the two groups regarding operative time: group -1: Operative time equal to or less than MOT and group -2 Operative time greater than MOT. Stoma duration (in months) was measured from age of stoma creation to the age of stoma closure.

Post-operative stoma care is the care afforded by the nurse at hospital or the caregiver at home and this is usually assessed during the follow up visit of patients. We categorized it into two groups: good care and poor care. Caregivers and parents need special education about proper stoma care in order to provide safe and appropriate care, minimizing risks of complications resulting from damage to immature skin and organ systems. They need to be informed about Types of topical medications used, diet, activity, bathing, clothing…etc. The good care group includes the families who follow the instructions of their doctor correctly, frequently cleaning the stoma, committed to doctor visit dates, and immediately return to the hospital if anything wrong with stoma. The poor care group includes the families who don't follow the instruction of their doctor correctly, bad in stoma cleaning, don't have commitment regarding doctor visit dates, and delay in returning to the hospital when something wrong with the stoma.

Types of reconstructive surgery include posterior sagittal anorectoplasty (PSARP) alone and posterior sagittal anorectoplasty with laparotomy (abdomino-perineal approach). Surgeon experience level generally was categorized in two groups: specialist surgeon group and surgeon assistant group. Surgeon assistant is surgeons under training (5th or 4th stage candidate pediatric surgeon).

Stoma related complications Include prolapse, Parastomal hernia, urinary tract infection, intestinal obstruction, disruption with evisceration that need revision, retraction, skin excoriation, stoma necrosis, wound infection, stenosis, megarectum, bleeding, Mislocation and sepsis.

Ethical considerations:

The ethical approval was taken for the proposal of this study from The Iraqi Board for medical Specialization and Hospital authorities in addition to the informed verbal consent taken from all patients' parents and caregivers for enrollment in the study.

Statistical analysis

Analysis of data was performed using the available statistical package of SPSS-27. Data were presented in simple means of frequency, percentage, mean, standard deviation, and range (minimum-maximum values). The significance of difference of different means (quantitative data) were tested using Students-t-test for difference between two independent means. The significance of difference of different percentages (qualitative data) were tested using Pearson Chi-square test (□2-test) with using of Yate's correction or Fisher Exact test whenever applicable. Statistical significance was considered when the P value was equal or less than 0.05.

Limitations of study

1. Lost follow up of patients
2. Effect of COVID 19 lockdown
3. Long waiting operation list
4. Limited resources in our setting
5. Multivariant variables and confounding factors affecting outcomes.

RESULTS:

A total number of patients were (64). Age at stoma creation was divided into two groups: neonatal group (30 days or less) which was (44) patients and post neonatal group (more than 30 days) and those were (20) patients. Male to female ratio was (1:1). Associated anomaly was identified in (25) cases, that is (39.1%) of total cases; the most common was cardiac anomaly (22 cases, 34.4%) and renal anomaly (11 cases, 17.2 %), table.1.

The types of anorectal malformation that require fecal diversion were seven types: perineal fistula were (2 cases, 3.1%), recto-vestibular fistula were (29 cases, 45.3%), recto-urethral fistula were (20 cases, 31.3%), recto-bladder neck fistula were (4 cases, 6.3%), recto-vaginal fistula was (one case, 1.6%), imperforate anus without fistula were (7 cases, 10.9%), and congenital pouch colon was (one case, 1.6%). The two most common types of anorectal malformations here were recto-vestibular fistula (45.3%) and recto-urethral fistula (31.1%). The level of colon at which stoma created

were four levels: sigmoid colon (51 cases, 79.7%), descending colon (11 cases, 17.2%), transverse (one case, 1.6%), and end of colonic pouch (one case, 1.6%). The stoma was of the divided type in (38) cases and loop type in [26] cases, which correspond to (59.4%) and (40.6%) respectively, table.1.

Reconstructive surgery was done via posterior sagittal approach in (60 cases, 93.8%) while abdomino-sagittal approach was required in (4 cases, 6.3%). Most of the cases (48 cases, 75%) were done by surgeon assistants (5th or 4th stage training surgeon). The mean operative time (MOT) was 69.8 minutes with range of (40-120 minutes), 27 cases (42.18%) were having equal or less than MOT while 37 cases (57.81%) were having more than MOT. The duration of stoma was divided into 3 groups; those of less than six months (12 patients, 18.8%), from 6-11 months (36 patients, 56.3%), and those of twelve months or more (16 patients, 25%). The mean stoma duration was (9.7) months, table.1.

The postoperative stoma care was good in 38 patients (59.4%) and poor in 26 patients (40.6%). We noticed that 35 patients (54.7%) had complications, the most common complications encountered were skin excoriation [31] cases and wound infection [22] cases, with a percentage of(48.4%) and (34.4%) respectively, as shown in table.2. Mortality was reported in two cases (3.1%); one had cardiac anomaly and the other had septicemia.

Male gender was associated with higher rate of complications, as its p-value was (0.024). GU anomaly increases risk of complications, with p-value (0.047), Prolong operative time more than mean time was associated with increased morbidity, with p-value (0.031), Stoma duration and poor postoperative Stoma care increase the risk of complications with p-value (0.0001) for each one of them, table.3.

DISCUSSION:

The incidence of stoma related complications ranges from 28% to 74% according to several researches. In this study, the incidence of complications was 54.7 % (35 patients), which is although higher than in Pena et al. (33%)[5] and Demirogullari et al. (31%)(6), but still comparable with many other studies[8,13,14,15].

There are several published literatures about anorectal malformations focused on the relation between type of created stoma and development of complications, but few attention was paid to other risk factors for the development of stoma related complications. So that, we here in, aim to highlight the significance of demographic or clinical variables of patients in the development of stoma related complication and their contribution to the morbidity and mortality.

In this study, the stoma was created in neonatal period in 44 patients, (68.8%), while colostomy done after neonatal period was noticed in a considerable number of patients (20 patients, 31.2%). We also noticed a wide range of weight at time of stoma creation ranging from (1.75 - 12 kg) with mean weight was (4.0 ± 2.2 kg)]. It seems that neither age nor weight at time of stoma creation had significant effect on complications, but this is not the case in Chirdan et al. were the weight ranges from (1.4 - 3.6 kg), and they found a significant effect of weight on outcomes, this is because all their cases were neonates and higher percentage of infants included in our study (31.2% vs none in Chirdan et al.)[16]

Male to female ratio in our study was 1:1, which is similar to what is reported by a large multicenter study done by Banu et al. in 2020, but differ from Demirogullari et al and Chirdan et al. were a male predominance have been reported in these studies (2.3:1 and 3:1 respectively)[6,16,17]. This difference may be due to relatively different sample sizes among different studies. We noticed in our patients that male gender was associated with increased risk of complications with a statistical significant P-value (0.024*) as shown in table.3 which is agreed with Cottam et al. (18) who reported that gender of the patient is a significant risk factor identified for development of stoma complications while there was no overall gender effect on complications shown by two other large studies (19,20), this association may be explained by the fact that the vast majority of our male patients have recto-urinary fistula and lack of real separated stomas as fecal diversion even with divided colostomy, we noticed that none of our patients use stoma bag and the caregivers cover both stoma ends by diaper or smooth clothes, allowing the fecal material to go into distal stoma end eliminating the benefit of dividing stoma with regard to fecal diversion. Also some of divided stomas were created beside each other and the stoma ends were not truly separated from each other's.

The incidence of associated anomalies reported in our setting was 39.1%, most commonly cardiac anomaly (22 patients, 34.4%) and it was ranging

from mild that didn't need intervention or just medications (21 patients) to other that need open cardiac surgery to correct it (one patient). A previous study described that the incidence of associated anomaly in anorectal malformations was as much as 75% with genitourinary anomalies were the most common one [21]. We also found that all cases with associated Down syndrome (3 patients) had imperforate anus without fistula which is consistent with the mentioned in other literatures[22]. In this study, the associated anomaly especially renal anomaly has increased rate of morbidity with a statistical significant P- value (0.047) as shown in table.3. Other researches revealed that associated anomaly mainly cardiac one increases the rate of morbidity [23], this can be explained by the fact that associated cardiac anomaly increases rate of complications in general and has no direct influence on stoma related complications and that all associated cardiac anomalies in our study except one patient were mild and have no or minimal effect on patient life.

Our finding about the most common type of ARM was comparable with other literatures, in male it was imperforate anus with recto-urethral fistula and in female it was imperforate anus with recto-vestibular fistula[3]. The type of ARM has no significant effect on complications and this is agreed with what mentioned in Almosallam et al. research[4].

Most of stoma created at proximal part of sigmoid colon (51 patients, 79.7%) to make the stoma at the fixed part of the sigmoid, to allow good length for reconstructive surgery later on and to decrease risk of prolapse so the level of stoma had no influence on outcomes, and this is the same as in reported by Pena et al. while in others like Demirogullari et al. most of stoma created were at level of transverse colon [5,6]. This explains why the latter has higher rate of complications especially prolapse as the level of transverse colon is more prone to prolapse than other levels[5]. In this study, we didn't find any significant impact of stoma type whether loop or divided on complications which is the same findings of Patwardhan et al. but differs from others who reported an increased incidence of complication with loop colostomy compared to divided stomas (8,10,24). Here, there were no statistical significance difference between loop and divided colostomy in term of complications except for UTI which is a little bit higher in loop type as there is no real total fecal diversion, this is also reported by Pena et al.(25). Some reports had increased rate of prolapse with loop stoma. It is mainly occur in mobile portion of the colon but not specific to stoma type (5) . The same thing reported by Youssef et al. and Oda O. et al. When they noticed that loop stoma increases risk of prolapse only and the development of other complications, including urinary tract infections (UTIs) and megarectum, were independent of the type of colostomy performed(14,24).

The mean operative time was (69.8 minutes) with range of (40-120 minutes), divided colostomy has longer operative time than loop type; this is nearly similar to results of Almosallam et al[4]. prolong operative time mean more risk for complications like hypothermia, surgical site infection, pneumonia, UTIs, and even prolong hospital stay; our finding of significant impact of prolong operative time on complications was statically significant with p-value (0.031), this is agreed with Bhama et al. study but disagreed with Almosallam et al; this disagreement could be attributed to improved pediatric surgical facilities in Saudi Arabia in form of specialized pediatric anesthesia, availability of sophisticated cardiopulmonary support and neonatal intensive care units[4,26].

The mean stoma duration in this study was (9.7 months) which is comparable with Almosallam et al. (10 months) and Liechty et al. (12 months)[20,28] . The duration of stoma has a great impact on complications (p-value = 0.0001) which goes with the result of two other Iraqi literatures[13,23], but unlike the study of Almosallam, may be because of a better nursing care in the latter[4].

Most of colostomy procedures were done by specialty training house officer under supervision (75%) and we were unable to detect any statistical significance of surgeon experience on rate of complication as shown in table.3.

Poor stoma care by the nurse and caregiver was reported in (40.6%) of our patients which significantly affects the relatively higher complication rate with p-value (0.0001). This finding is similar to the study done in Egypt when they found that most of the nurses and care givers had poor levels of knowledge and performance related to stoma care(38), but contrary to Slater study(27) as in UK and Ireland(28), where they have established Pediatric Stoma Nurse Group (PSNG) since 2005 to increase awareness of families about the postoperative stoma care and decreases morbidity by improving standards of

nursing care for neonates, children, and their families. All aspects of stoma care should be carefully explained to the parents in order for them to understand the needs of a pediatric with a stoma and to reduce complications that may arise. It is also paramount that parents learn how to take care for the stoma. They need to be informed about types of topical medications used, diet, activity, bathing, clothing…etc. and follow the instructions of their doctor correctly, frequently cleaning the stoma, committed to doctor visit dates, and immediately return to the hospital if anything wrong with stoma.

Skin excoriation was the most common complication encountered (48.4%). In Zamil et al. the skin excoriation was second most common complication (24.3%) after prolapse as he has more transverse loop colostomy than in our study which is more prone to prolapse than other types of stoma [23]. Other reason for this difference is the lack of real definition of skin excoriation.

The second most common complication was wound infection (34.4%). In Zamil et al.(23) and Chirdan et al.(16) the wound infection was (12.2%) and (19.7%) respectively. Higher rate of wound infection is likely because poor nursing stoma care, and COVID 19 pandemic that make patients missing their visit date.

Overall mortality was two cases (3.1%) nearly similar to Demirogullari et al.(6) (1.2%) but less than Chirdan et al.(16) (11.5%) because mostly attributed to limited resources and neonatal intensive care units in Nigeria.

CONCLUSION:

Creation of colostomy during surgical management of ARM patients carries a lot of complications; fortunately, most of them are not serious and preventable.There are some determinants of morbidity in patient undergoing colostomy for ARM like sex, associated anomaly, operative time, post-operative stoma care, and stoma duration, while Variables of age, weight, surgeon experience, type and level of stoma have no significant associations with development of complications.

Table 1: Demographic and clinical variables of patients.

Variables		No	%
Age at stoma creation	Neonatal (= < 30 days)	44	68.8
	Post-neonatal(> 30 days)	20	31.3
Gender	Male	32	50.0
	Female	32	50.0
Weight at stoma creation (Kg)	< 3.0Kg	14	21.9
	3.0-3.9 kg	28	43.8
	4.0-4.9 kg	6	9.4
	= > 5.0 kg	16	25
Associated anomaly	Yes	25	39.1
	No	39	60.9
	Cardiac	22	34.4
	Renal	11	17.2
	Down	3	4.7
	TEF	1	1.56
Type of Ano-rectal malformation	Recto-Perineal fistula	2	3.1
	Recto-vestibular fistula	29	45.3
	Recto-urethral fistula	20	31.3
	Recto-bladder neck fistula	4	6.3
	Recto-vaginal fistula	1	1.6
	Imperforate anus without fistula	7	10.9
	Congenital Pouch colon	1	1.6
Level of stoma	Sigmoid colon	51	79.7
	Descending colon	11	17.2
	Transverse colon	1	1.6
	End of colonic pouch	1	1.6
Type of stoma	Loop	26	40.6
	Divided	38	59.4

Reconstructive surgery	PSARP	60	93.8
	PSARP & Laparotomy	4	6.3
Surgeon experience	Specialist	16	25.0
	Non-specialist	48	75.0
Operative time (minutes)	Mean ±SD (Range)	69.8± 19.0	(40-120)
	= < mean	27	42.18
	> mean	37	57.81
Stoma duration (months)	< 6 months	12	18.8
	6---11	36	56.3
	= >12 months	16	25.0
stoma care	Good	38	59.4
	Poor	26	40.6

Table 2:Stoma related complications.

		No.	%
Complications	Yes	35	54.7
	No	29	45.3
	One complication	4	6.3
	Two complications	11	17.2
	= > Three complication	20	31.3
Skin excoriation		31	48.4
Wound infection		22	34.4
Prolapse		9	14.1
UTI		8	12.5
Bleeding		7	10.9
Disruption		4	6.3
Need for revision		4	6.3
Intestinal obstruction		3	4.7
Sepsis		3	4.7
Stenosis		2	3.1
Mega rectum		2	3.1
Retraction		1	1.6
Stoma necrosis		1	1.6
Mislocation		1	1.6
Parastomal hernia		-	-

Table 3:Effect of patient's variables on complications.

variables		Complications				P value
		Yes		No		
		No	%	No	%	
Age at creation	Neonatal	27	61.4	17	38.6	0.112
	Post neonatal	8	40.0	12	60.0	
Gender	Male	22	68.8	10	31.3	0.024*
	Female	13	40.6	19	59.4	
Weight at stoma creation (Kg)	< 3.0 Kg	11	78.6	3	21.4	0.168
	3.0-3.9 kg	16	57.1	12	42.9	
	4.0-4.9 kg	2	33.3	4	66.7	
	5.0 kg and more	6	37.5	10	62.5	
Type of ano-rectal malformation	Recto-Perineal fistula	1	50.0	1	50.0	0.165
	Recto-vestibular fistula	11	37.9	18	62.1	
	Recto-urethral fistula	13	65.0	7	35.0	
	Recto-bladder neck fistula	4	100.0	-	-	
	Recto-vaginal fistula	1	100.0	-	-	
	Imperforate anus without fistula	4	57.1	3	42.9	
	Congenital Pouch colon	1	100.0	-	-	

Associated anomalies	Cardiac	11	50.0	11	50.0	0.586
	Renal	9	81.8	2	18.2	0.047*
	Down	1	33.3	2	66.7	0.447
	TEF	-	-	-	-	-
Type of stoma	Loop	12	46.2	14	53.8	0.257
	Divided	23	60.5	15	39.5	
Level of colostomy	Sigmoid	26	51.0	25	49.0	0.513
	Descending	7	63.6	4	36.4	
	Transverse	1	100.0	-	-	
	End of pouch	1	100.0	-	-	
Surgeon experience	Specialist	8	50.0	8	50.0	0.664
	Non-specialist	27	56.3	21	43.8	
Operative time (hours)	= < MOT	6	22.2	21	77.8	0.031*
	= > MOT	26	70.2	11	29.8	
Stoma duration (months)	< 6 months	2	16.7	10	83.3	0.0001*
	6---11	17	47.2	19	52.8	
	= > 12 months	16	100.0	-	-	
stoma care	Good	12	31.6	26	68.4	0.0001*
	Poor	23	88.5	3	11.5	
Reconstructive surgery	PSARP	31	51.7	29	48.3	0.060
	PSARP & Laparotomy	4	100	-	-	

*Significant difference between percentages using Pearson Chi-square test (χ^2-test) at 0.05 level.

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