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Evaluation of the Factors Associated with Post-Operative Outcome in Patients of Ulcerative Colitis Undergoing Ileal Pouchanal Anastomosis with Comparison of Functional Outcome between Stapler and Hand-Sewn Anastomosis

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Introduction

Ulcerative colitis defined as a non-granulomatous idiopathic inflammatory disease which mainly affects the colon and rectum. The disease may arise at any age but most commonly affects the adults between the age group of 30–40 years.[1,2.] The etiology of the disease is multifactorial, involving genetic predisposition, dysregulated immune responses, epithelial barrier defects and environmental factors. No sex predilection is seen in ulcerative colitis.[3,5] The peak age of onset of disease is between 30 to 40 years.[4,6] The environmental factors has also been found to play an important role in the etiopathogenesis of ulcerative colitis. Cigarette smoking is one of the major factor associated with ulcerative colitis, non-smokers have a milder disease course and active smokers are less likely to develop ulcerative colitis[7] Appendectomy also confers a protective effect against ulcerative colitis, especially in young patients operated for acute appendicitis.[8.] Classic findings in endoscopy in patients with ulcerative colitis include loss of normal vascular pattern, erythema, erosions, granularity, friability, ulcerations and bleeding[9].

The primary aim of medical management is to induce and maintain remission with the long-term goals of improving quality of life and prevent disability. Absolute indications for surgery include uncontrolled hemorrhage, perforation, and colorectal carcinoma or dysplastic lesions not amenable to endoscopic removal.[10] Surgery is also indicated in refractory acute severe ulcerative colitis or medically refractory disease. The most commonly performed surgery for ulcerative colitis is restorative proctocolectomy with ileal pouch-anal anastomosis (IPAA). An important aspect of the surgery is the use of either sutures or staplers for anastomosis. Two types of ileal pouch-anal anastomosis (IPAA) have been described: a mucosectomy of the rectal stump followed by a hand-sewn ileal pouch-anal anastomosis.[11] The alternative technique is to retain the mucosa of the rectal stump and perform a stapled pouch-anal anastomosis.

Material and Methods

It is a Hospital based Descriptive Study(both retrospective and prospective) ,in which 41 patients of ulcerative colitis operated for

Restorative proctocolectomy with ileal pouch anal anastomosis ,were followed for a period of 3 years to evaluate early as well as late complications ,risk factors influencing the post-operative outcome, including comparison of the functional outcome in terms of day time and night time bowel frequency and seepage in patients undergoing stapler and hand sewn anastomosis. 24 (58.5%) were male and the rest (17;41.6%) were female. Mean age was 32.61 +-6.39 SD. Out of total 41 cases, 5 (12.19%) surgeries were done for emergency indication (acute severe ulcerative colitis, perforation and toxic megacolon) and remaining 36 (87.8%) were done in elective setting. Most common indication of surgery was persistent disease despite medications in 26 patients(63.41%) followed by non affordability (9.75%), non compliance (14.63%).Hand-sewn anastomosis was done in 34(82.9%) while stapler in 7(17%). Mean haemoglobin of patients in the preoperative period was 10.67 +- 1.12.Patients were then followed for a period of three years and post-operative outcome in terms of major and minor (according to Clavien Dindo classification) complications including correction of anemia and improvement in functional outcome in terms of average bowel frequency, day time and night time frequency and seepage were recorded. Hand sewn and stapler anastomosis were compared in terms of complications and functional outcome.

Results

Table 1 Distribution of Study Subjects on the Basis of Gender (as shown in Figure 1)

Gender	N	%
Female	17	41.46%
Male	24	58.5%
Total	**41**	**100.0%**

Among total 41 patients 17 (41.46%) were female and rest were male 24 (58.5%).

Table 2 Distribution of Study Subjects Mean Baseline Variables

Variables (n = 41)	Mean	SD
Age (years)	32.61	6.39
Duration of Disease (months)	27.12	11.93
No. of Acute Episode	4.34	1.71

Majority of the patients in our study belonged to younger age group. Average age of patients at the operation was 32.61 years while the average duration of disease was 27.12 months. Numbers of acute episodes before operations were 4.34

Table 3 Distribution of Study Subjects Based on type of Surgery

Surgery Done	N	%
Emergency	5	12.19%
Elective	36	87.8%
Total	41	100.0%

Out of total 41 cases, 5 (12.19%) surgeries were done for emergency indication (acute severe ulcerative colitis, perforation and toxic megacolon) and remaining 36 (87.8%) were done in the elective setting.

Table 4. Distribution of Study Subjects Based on Indication of Surgery (as shown in Figure 3)

Indications of Surgery	N	%
Acute severe ulcerative colitis	5	12.19%
Non responsive to medications	26	63.41%
Non affordability to long term medications	4	9.75%
Non compliance to medications	6	14.63%
Total	41	100.0%

Table 5. Distribution of Study Subjects Based on type of Anastomosis

Anastomosis	N	%
Stapler	7	17.07%
Hand sewn	34	82.9%
Total	41	100.0%

Out of total 41 subjects undergoing RPC with IPAA, Hand sewn anastomosis was done in 34 (82.9%) patients while stapler anastomosis was done in 7 (17.07%) patients.

Table 6: Classification of Complications according to Clavien Dindo Classification

	No . of Patients
Grade 1 **SSI**	**13**
Grade 2 **Pulomnary (Minor)** **Deep Vein Thrombosis** **SAIO**	**5** **3** **3**
Grade 3 **Pouchitis** **Incisional Hernia** **Wound Dehiscence** **Pouch Leak** **Stricture At IPAA**	**9** **3** **4** **1** **3**
Grade 4 **Pulomoary Complications(Requiring ICU, High Flow Oxygen Support/NIV)**	**4**
Grade 5 **Death**	**Nil**

Majority of the complications were grade 1 and 2.four patients required ICU management due to post-operative pulomary complication.no mortality was recorded.

Early complications(within 1 month) were Surgical site infection(31.70%), wound dehiscence (9.75%) pulmonary complications (21.9%), DVT(7.3%) and pouch leakage 1 (2.43%).with incidence of pouchitis as 9 (21.9%). Other reported late complications were incisional hernia 4 (9.75%), bowel obstruction 3 (7.3%) and stricture at IPAA site 3 (7.31%).

Table 7. Distribution of Study Subjects based on Functional Outcome

Functional Outcome	1st year	2nd year	3rd year
24 hour stool frequency	6.08	5.05	3.05
Day time stool frequency	4.32	3.59	2.60
Night time stool frequency	1.76	1.46	0.45
Seepage frequency per week	2.40	1.10	0.46

Above table shows the mean of various parameters of functional outcomes of ileal pouch anal anastomosis at 1st, 2nd and 3rd years. Average 24-hour frequency was reduced from 6.08 to 3.05 bowel movements/day after procedure while night time stool frequency reduced from 1.76 to 0.45.

Table 8. Mean Haemoglobin Levels Before Operation and in the Follow Up Period

	Pre-op hemoglobin		6 month post IPAA		1 year post IPAA		3 year post IPAA		
	MEAN	SD	MEAN	SD	MEAN	SD	MEAN	SD	P Value
Male	11.09	1.72	11.7	0.919	11.7	0.919	11.5	0.65	0.28
Female	10.08	1.23	11.1	0.66	11.1	0.66	11.2	0.44	0.0013*
Pancolitis	9.2	1.15	10.8	0.73	10.8	0.73	11.3	0.45	0.001*
Prolonged Duration of Illness (>36 Months)	10.5	1.9	11.08	0.84	11.08	0.84	11.5	0.59	0.08

According to the results shown above, post IPAA haemoglobin measured 6 months and 1 year and 3 years post IPAA showed statistically significant improvement in haemoglobin levels in females and patients with pancolitis with low pre-op haemoglobin levels.

Table 9: Table Showing Change in the Functional Outcome Post-Surgery over a follow-up period of 3 years

Variables	1 st year		3RD YEAR		p- value
24 hour stool frequency	Mean	6.05	Mean	3.05	**0.001***
	SD	1.04	SD	0.65	
Day time frequency	Mean	4.32	Mean	2.60	**0.003***
	SD	0.93	SD	0.59	
Night time frequency	Mean	1.76	Mean	0.45	**0.001***
	SD	0.58	SD	0.50	
Seepage	Mean	2.40	Mean	0.46	**0.02***
	SD	0.51	SD	0.48	

As shown in the table above there is significant improvement in the functional outcome after RPC-IPAA irrespective of the anastomositc technique used

Table 10. Table Depicting the factors Affecting the incidence of Pouchitis in Study Subjects

Variable		Pouchitis (n=9)		p value
		No. of patients	Percentage	
Males (n = 24)		4	16.67	0.3462
Females (n = 17)		5	29.41	0.5562
Extra intestinal manifestations (n = 5)		1	20.00	0.642
Duration of disease (> 36 months) (n = 13)		6	46.15	0.008*
Smoking (n = 5)		2	40.00	0.298
DIET	Vegetarian diet (n = 32)	7	21.88	0.6547
	Non vegetarian diet (n = 9)	2	22.22	.0956
Medical morbidities (n = 4)		0	0.00	0.455
BMI< 20 kg/m^2 (n = 13)		1	7.69	0.272
Albumin < 3mg/dL (n = 19)		6	31.58	0.166
ESR > 30 mm/hour (n = 11)		8	61.54	0.001*
Pancolitis (n = 14)		8	61.54	0.004*
Hand sewn anastomosis (n = 34)		7	20.59	0.6421
Stapler anastomosis (n = 7)		2	28.57	0.2568

As shown in the table above pancolitis, high ESR and prolonged duration of disease had a statistically significant relation to the development of pouchitis ($p<0.05$)

Table 11: Correlation between Pre-Operative Factors and Presence of Post-Operative Complications (Including Pouchitis)

Variable	Complications	No complications	p value
Males	15	9	**0.095**
	62.5	37.5	
Females	5	12	
	29.41	70.59	
Extra intestinal manifestations	1	4	**0.496**
	20.00	80.00	
Duration of disease (> 36 months)	6	7	**0.367**
	46.15	53.84	
Smoking	4	1	**0.80**
	80.00	20.00	
Vegetarian diet	13	19	**0.515**
	40.63	59.38	
Non vegetarian diet	4	5	
	44.44	55.56	
P/h of Ulcerative colitis	1	4	**0.132**
	20.00	80.00	
Medical morbidities	1	3	**0.335**
	25.00	75.00	
BMI < 20 kg/m^2	4	9	**0.1655**
	30.77	69.23	
Albumin < 3mg/dl	13	6	**0.00313***
	68.42	31.58	
ESR > 30 mm/hour	8	3	**0.0632**
	72.7	27.2	
Pancolitis	9	4	**0.0914**
	69.23	30.77	
	66.67	33.33	
Stapler anastomosis	3	4	**0.604**
	42.86	57.14	
* Significant variables			

As shown in the table above S. Albumin < 3 mg% is significantly associated with development of complications after RPC with IPAA.

Table 13: Mean Comparison between Hand Sewn and Stapler Anastomosis Group

Variables	Group	N	Mean	SD	p- value
Age (years)	**Hand sewn**	34	32.03	5.997	**0.2041**
	Stapler	7	35.43	7.997	
Operative Time (mins.)	**Hand sewn**	34	342.5	38.53	**0.001***
	Stapler	7	238.57	39.33	
Average 24 hour stool frequency	**Hand sewn**	34	4.20	0.84	**0.819**
	Stapler	7	4.12	0.83	
Day time stool frequency	**Hand sewn**	34	2.58	0.56	**0.6005**
	Stapler	7	2.71	0.75	
Seepage	**Hand sewn**	34	0.5	0.74	0.457
	Stapler	7	0.28	0.48	
Night time stool frequency	**Hand sewn**	34	0.58	0.65	**0.0928**
	Stapler	7	0.14	0.37	

No difference was observed between Hand sewn and stapler anastomosis group except that the operative time was more in the hand sewn compared to stapler group.

Discussion

Ulcerative colitis is a chronic disease with remitting and relapsing course affecting mainly the colonic mucosa .Severity of the presentation varies with up to 15% patients initially presenting with severe disease[12]. In the current scenario, majority of the patients of Ulcerative Colitis are managed medically but surgery may be required in patients who become refractory to medical therapy or develop severe complications. In a study by Nick Dai et al[13], 31 studies with 294,359 patients with UC were included for review and meta-analysis. The prevalence of colectomy at 1-, 5- and 10-years post-diagnosis were 3% (95% CI 2%-6%), 5% (95% CI 2%-9%), 10% (95% CI 6%-16%) respectively. In a 17 years long study in Western Hungarian Population of 1370 UC patients, extensive colitis and continuous active disease activity were independent predictors for colectomy.[14] In our study 13(31.70%) patients had prolonged duration of disease (>36 months) before undergoing surgery.

In our study, patient group comprised of 24(58.5%) male and 17 female (41.46%) patients with majority below 40 years of age. Mean age is 32.61 years. In a study by Shah et al[15]., in a pooled analysis of population-based it was found that age at UC onset varied with sex. Indeed, the incidence of UC is similar between males and females until age 45. After this age, females showed a 13% to 32% lower likelihood of being diagnosed with UC than males.. Another study by Sivaran Gunishetty[16] showed that the prevalence of ulcerative colitis was more in the young age (<35 years)
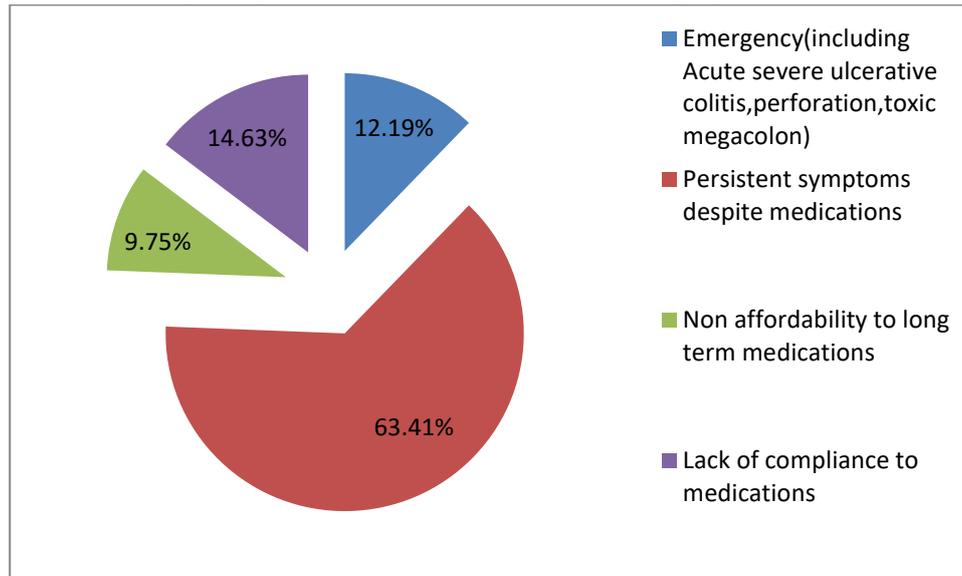
Figure 1 Distribution of Study Subjects Based on Gender
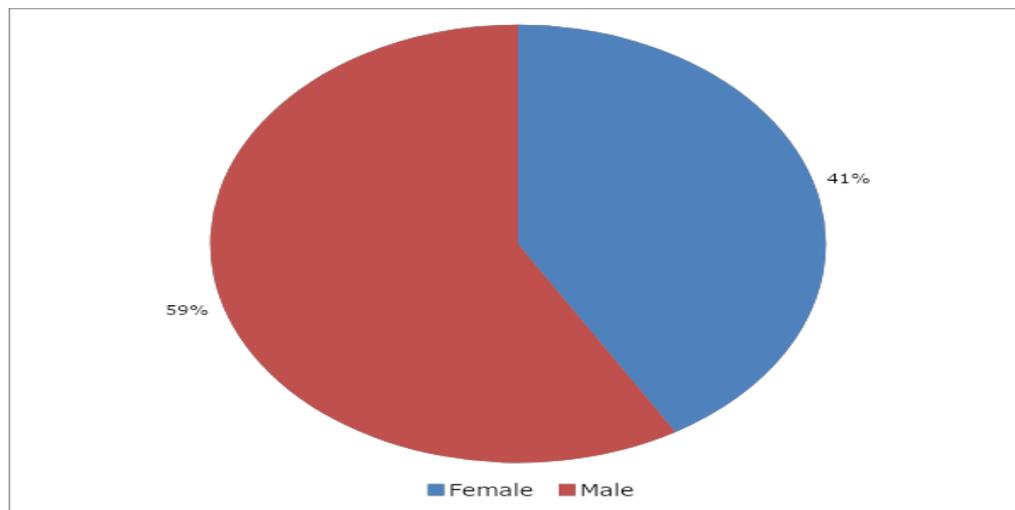
In our study refractory disease despite medications was the most common indication of surgery. Similarly in a study conducted by Giodon Almogy, refractory to medical therapy remained the main indication for elective surgery.[17]

Figure 2: Distribution of Study Subjects Based on Indication of Surgery

The present study, included 41 consecutive IPAA cases. Statistically significant improvement in functional outcome in terms of 24 hour stool frequency, day time frequency and night time frequency were seen over a follow up period of three years. In a prospective observational study Fabrizio Michelassi et al[18], 391 consecutive patients underwent an IPAA. Complete daytime and nighttime continence was achieved by 53–76% of patients. At 5 years, patients judged quality of life as much better or better in 81.4% and overall satisfaction and overall adjustment as excellent or good in 96.3% and 97.5%, respectively.(0)

Figure 3: Distribution of Study Subjects Based on Functional Outcome
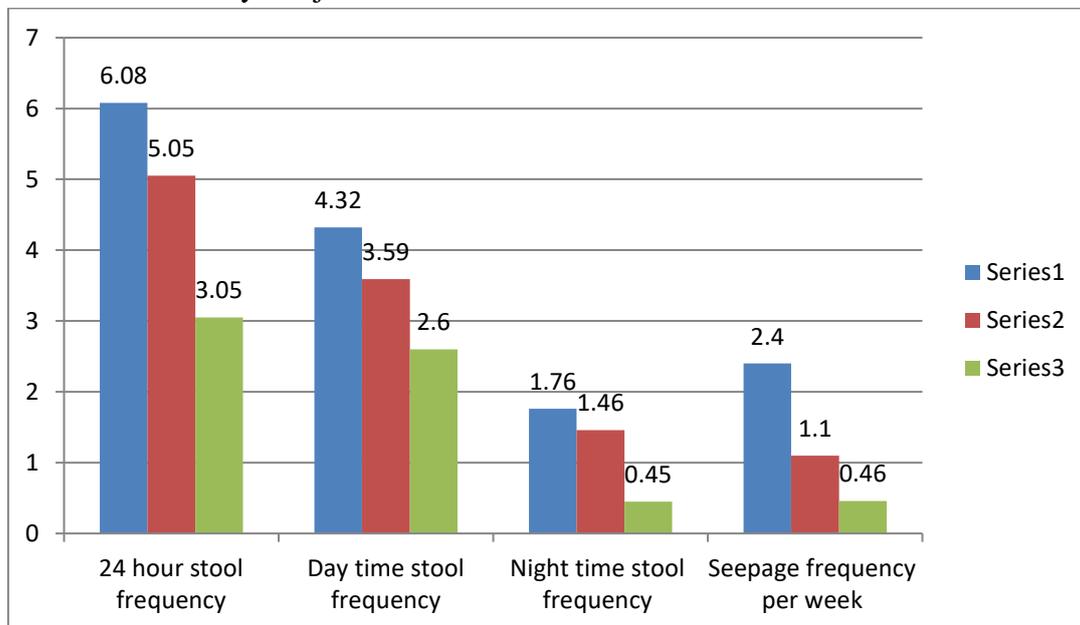
Two techniques of anastomosis described in literature are hand-sewn anastomosis and stapler ileo pouch anal anastomsis. In our study 34(82.9%) patients underwent hand sewn anastomosis and the remaining 7(17.07%) patients underwent stapler ileal-pouch anal anastomosis Functional outcome in both the groups were comparable but the operative time was found to be

higher in the hand sewn group. (p=0.001).No significant difference in the complication rates were found between the two groups. In a similar study by P. Bernard McIntyre et al[19], functional results after double-stapled and hand sewn IPAA were compared. It was concluded that stapled IPAA appears to convey no early functional advantage over handsewn IPAA for chronic ulcerative colitis. The meta-analysis by Lovegrove et al[20] showed that the two techniques were similar with regard to 24 hour an night stool frequency.

Perioperative complications in the present study were graded according to the classification proposed by Dindo et al. Prolonged duration, pancolitis and raised ESR was significantly associated with pouchitis and overall complications were more in patients with low pre-operative albumin(<3mg/dl).

In a study by Hoda et al[21], preoperative serum albumin (P = 0.07) and fulminant ulcerative colitis (P = 0.051) were statistically significant factors associated with pouchitis. Achkar J Pand his colleagues 22, found that patients with fulminant colitis with raised ESR as an indication for surgery had a increased risk for developing pouchitis. In the study by Gidon Almogy17 an albumin level of 2.8 g/dL or less, and urgent surgery were found to be independent predictors of poor outcome. In our study, stastically significant co-relation was seen between pre-operative albumin level <3mg/dl and post-operative complications.

Conclusion

In the present study ,we have analyzed various indications of the surgical management of ulcerative colitis(including both emergency and elective cases). Majority of the cases in our study were operated in elective setting with non-responsiveness to medications as the most common indication of operative intervention. Ileal pouch-anal anastomosis results in significant improvement in functional outcome. Pancolitis,

prolonged duration of disease and raised ESR were significantly associated with increased incidence of pouchitis. Overall post-operative complications were more commonly seen in patients with low pre-operative albumin level. No difference was observed between hand sewn and stapler anastomosis in terms of functional outcome as well as development of major/minor complications.

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