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Assessment of the perioperative Global Quality of Life of the surgical management pattern of small bowel vascular gangrene; A prospective research study

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ABSTRACT

In patients with Critical conditions of intestinal gangrene, an exploratory laparotomy should be performed immediately. After removing the affected segment, the remaining portion would either be anastomosed or diverted as a stoma. few studies have investigated the psychosocial effects and the Global Quality of Life after the surgical treatment for intestinal vascular gangrene (anastomosis versus stoma) and the subsequent events. In this study, perioperative outcomes of psychosocial issues were evaluated in relation to the surgical treatment of mesenteric vascular gangrene patients. Two hundred patients subjected to emergency surgical laparotomy due to mesenteric vascular gangrene were randomly divided into two groups with one hundred patients of anastomosis group and the other group of one hundred patients who had a diverting stoma. A comparative evaluation was established between the two groups using the global quality of life as a primary endpoint of the study. There was a significant difference in the quality of life between the anastomotic group and the stoma group. The global quality of life of stoma patients significantly improved after closure, ($p < 0.001$). The ileostomy appeared to be a safer procedure to perform in mesenteric vascular occlusion as regard morbidity and mortality rates but need strict nutritional, psychological and special home care to enhance the quality of life. On other hand, there is a higher mortality risk for the anastomosis group, particularly after a leak, but experienced a better global quality of life with uncomplicated anastomosis. The critical decision for the surgeon after resection of infarcted bowel either to do stoma or anastomosis should consider the long- term impact on patient life quality and psychological status.

1. INTRODUCTION

Acutely ischemic bowel or peritonitis should be treated as an emergency, regardless of the underlying cause, with exploratory laparotomy. When intestinal gangrene is evident, this is followed by trimming off as much as possible of the affected segment, leaving a safety margin of 5-10 cm, and then either anastomosing or diverting the remainder onto the anterior abdominal wall as a stoma. This is performed simultaneously with resuscitation with IV fluids and antibiotics. Early diagnosis and treatment remain the keystone for improving the outcome of intestinal gangrene [1- 3]. Anastomosis of the bowel should not be performed in the case of severe sepsis or septic shock, or if adequate resuscitation is not possible. In the case of limited necrosis, with no doubt about the viability of the remaining bowel, in the event, the patient is properly resuscitated and there is no evidence of shock, some authors advocate for anastomosis with a planned second look. In this case, laparoscopy may be useful. Anastomotic failure can be avoided with stomas, and endoscopy and inspection can be done easily with them. Patients with very proximal jejunostomies may be re-fed through a mucous fistula of the distal bowel. It is possible to restore continuity later if appropriate [4- 6].

However, few studies have investigated the effects of psychosocial and the Global Quality of Life (GQOL) because of surgical management of intestinal vascular gangrene (anastomosis versus stoma) and their subsequent events. The purpose of this study was to evaluate the perioperative outcomes of psychosocial issues of patients with mesenteric vascular gangrene in relation to the method of surgical intervention with either primary anastomosis or diverting ileostomy, also to determine the patient's safety with each technique and the impact on the GQOL in a consecutive series of patients with intestinal gangrene.

2. Materials and Methods

2.1 Study design, setting, and patients' recruitment

The study was a prospective, randomized comparative study involving 200 patients who will be subjected to emergency surgical laparotomy due to mesenteric vascular gangrene at Mansoura emergency hospital/Egypt in the period from May 2017 to November 2020. it involved all eligible patients of intestinal vascular gangrene fulfilling the inclusion criteria of the study. Patients were randomly allocated by computer into two groups with 100 patients undergoing primary anastomosis after resection of gangrenous part and the other 100 patients undergoing diverting ileostomy after resection of the gangrenous part.

2.2 Sample size and group allocation

A Wilcoxon Mann–Whitney (two groups) test was used to analyze the sample size using the GQOL as a primary endpoint based on a prior pilot study. For a power of 80 % (using G power v3.1.3), we needed a minimum sample size of 40 patients in each group. (7) 200 patients were recruited to allow for dropout. After resection of gangrenous parts, study participants were divided into two groups: the stoma group and the anastomosis group. The stoma group included patients with uneven numbers, while the anastomosis group included patients with even numbers.

2.3 Inclusion criteria

The study recruited hemodynamically stable patients with acute abdominal pain, testing for mesenteric vascular gangrene in the laboratory and radiological reports. The study excluded cases of large bowel gangrene and mesenteric occlusion affecting the entire small intestine.

2.4 Perioperative work-up

Full preoperative evaluation and investigations (laboratory and radiological) were done for all patients of the study population. The patients were shifted to OR for exploratory laparotomy. UGA, Patients had midline exploratory laparotomy incision. The gangrenous part was resected. after resection, re-anastomosis was done by hand sewing technique, or diverting stoma was matured on the abdomen. Oral intake was initiated upon stoma was functioning or after good bowel motion in case of anastomosis group. All the patients were monitored properly till discharge. The patients were followed up at the OPD at 1 week, 2 weeks, 1 month, 3 months, and 6 months intervals, and the stoma was closed after 2 months. Afterward, a close follow-up with Dietitian was arranged for the stoma patient.

Prior to conducting the study, the Mansoura faculty of medicine ethical committee approved it. All patients participating in the study provided informed consent after being informed of the benefits and potential risks.

2.5 Outcomes

a-Primary outcomes include HRQL with stoma versus Anastomosis and immediate post-operative complication of stoma or Anastomosis b-Secondary outcomes include Hospital stay for each group and the complications related to the index operation or closure of an ileostomy.

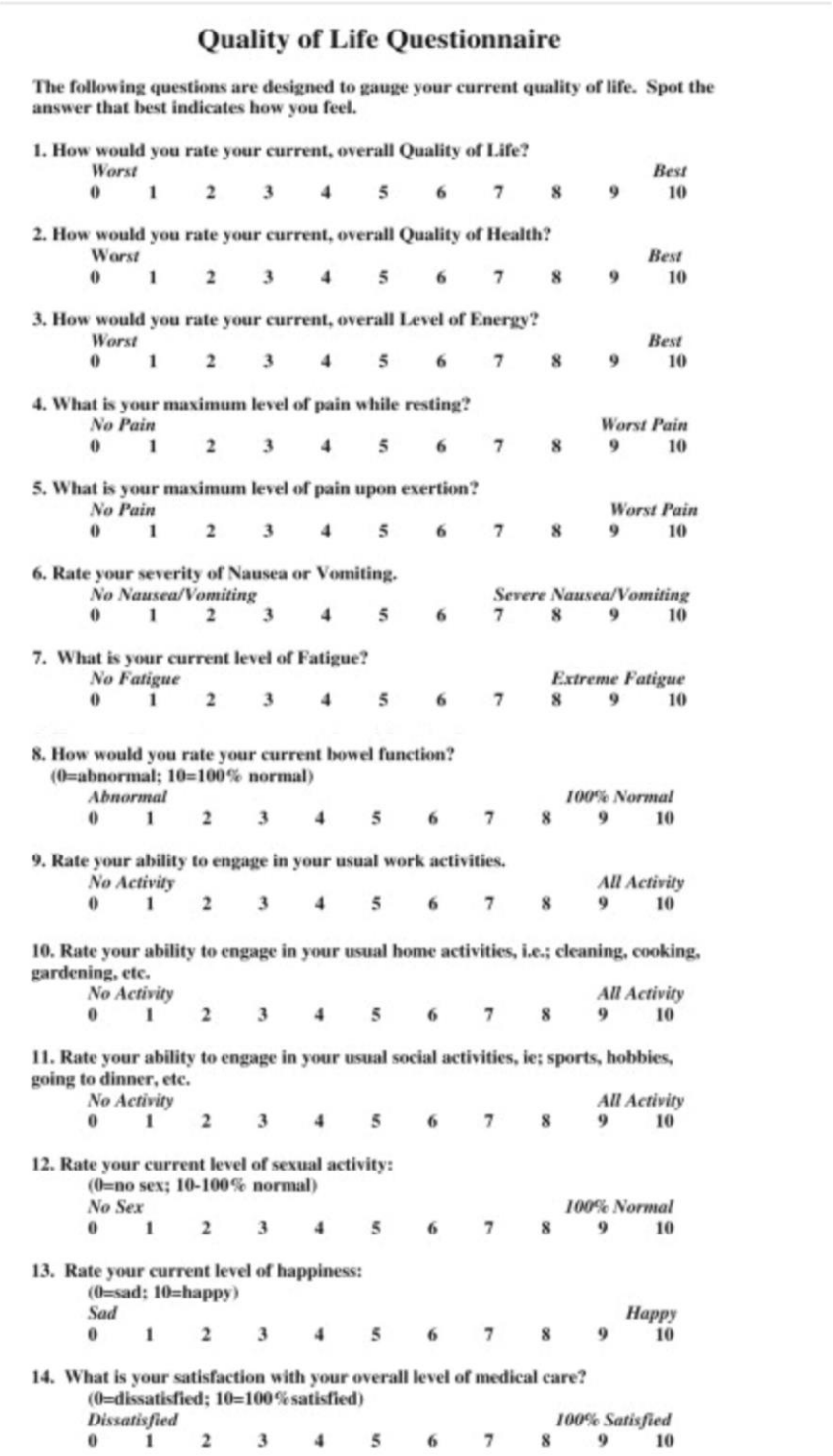
2.6 Perioperative variables

1. Demographic data and comorbidity Including the presentation time and risk factors
2. Intra-operative data (Anastomosis or stoma)
3. Post-operative variables

- The time of starting oral feeding and the length of stay
- Ileostomy and Anastomosis related complications
- After one month of re-anastomosis, ileostomy, and ileostomy closure, the Cleveland GQOL score was assessed (Fig 1).8 This health questionnaire was used as an instrument to assess GQOL. The survey was carried out either at the hospital or by phone. it was implemented prospectively.
- In the OPD, the patient's physician illustrated a questionnaire with all questions, the best score is 10 except for the questions about pain and vomiting. Statistical analysis was based on a median score of 60, and the total score was 120.

2.7 Interpretation of Statistical Data

Statistical analysis was performed using SPSS v-26 (IBM, Armonk, NY). The continuous variables are expressed as the mean + standard deviation, while categorical variables are expressed as %. Numbers and percentages were used to describe qualitative data. After testing normality with the Kolmogorov-Smirnov test, median (minimum and maximum) and interquartile range were used for non-parametric data and mean, standard deviation, for parametric data. Data were expressed as absolute values and percentages or as median values and ranges. The Chi2 test was used to compare categorical variables. For the evaluation of the survey form, the student t-test was used. A univariate analysis was performed to associate variables by using the Mann-Whitney U test and Kruskal-Wallis with Calculated 95% confidence intervals. A p-value was deemed significant at< 0.05.



Quality of Life Questionnaire

The following questions are designed to gauge your current quality of life. Spot the answer that best indicates how you feel.

1. How would you rate your current, overall Quality of Life?

Worst *Best*

0 1 2 3 4 5 6 7 8 9 10

2. How would you rate your current, overall Quality of Health?

Worst *Best*

0 1 2 3 4 5 6 7 8 9 10

3. How would you rate your current, overall Level of Energy?

Worst *Best*

0 1 2 3 4 5 6 7 8 9 10

4. What is your maximum level of pain while resting?

No Pain *Worst Pain*

0 1 2 3 4 5 6 7 8 9 10

5. What is your maximum level of pain upon exertion?

No Pain *Worst Pain*

0 1 2 3 4 5 6 7 8 9 10

6. Rate your severity of Nausea or Vomiting.

No Nausea/Vomiting *Severe Nausea/Vomiting*

0 1 2 3 4 5 6 7 8 9 10

7. What is your current level of Fatigue?

No Fatigue *Extreme Fatigue*

0 1 2 3 4 5 6 7 8 9 10

8. How would you rate your current bowel function?
(0=abnormal; 10=100% normal)

Abnormal *100% Normal*

0 1 2 3 4 5 6 7 8 9 10

9. Rate your ability to engage in your usual work activities.

No Activity *All Activity*

0 1 2 3 4 5 6 7 8 9 10

10. Rate your ability to engage in your usual home activities, i.e.; cleaning, cooking, gardening, etc.

No Activity *All Activity*

0 1 2 3 4 5 6 7 8 9 10

11. Rate your ability to engage in your usual social activities, ie; sports, hobbies, going to dinner, etc.

No Activity *All Activity*

0 1 2 3 4 5 6 7 8 9 10

12. Rate your current level of sexual activity:
(0=no sex; 10-100% normal)

No Sex *100% Normal*

0 1 2 3 4 5 6 7 8 9 10

13. Rate your current level of happiness:
(0=sad; 10=happy)

Sad *Happy*

0 1 2 3 4 5 6 7 8 9 10

14. What is your satisfaction with your overall level of medical care?
(0=dissatisfied; 10=100%satisfied)

Dissatisfied *100% Satisfied*

0 1 2 3 4 5 6 7 8 9 10

Figure (1): Cleveland Global Quality of Life score.

3. Results

3.1 Demographic characteristics

In terms of demographic characteristics, the average age of the included 200 cases was 52.0±6.9 years with the range of 39.0-78.0 years. 132 men (66%) and 68 women (34%) participated in the study. The following table1 illustrates these data. There were no statistically significant differences between the study groups

regarding age or gender (p > 0.05) based on demographic data.

Table (1): socio-demographic characteristics of anastomosis and stoma groups.

	Stoma		*Anastomosis*		*Test of significance*	*p value*
	n=100	*%*	*n=100*	*%*		
Age/years Mean±SD	53.82±5.85		55.36±8.85		t=1.03	0.31
Sex						
• Male	68	68.0	64	64.0	χ^2=0.18	0.67
• Female	32	32.0	36	36.0		

3.2 Comorbidities

Table3, hepatic diseases were the top medical comorbidity (40%) among the study subjects, followed by diabetes mellitus (74 cases - 37%). In 70 cases (35%), hypertension was present. The presence of cardiac comorbidities such as atrial fibrillation and myocardial infarction was detected in 46 cases.

Table (2): Co-morbidity distribution among studied cases.

Co-morbidity	*n=200*	%
Cardiac (atrial fibrillation, myocardial infarction, and valvular heart disease)	46	23.0
DM	74	37.0
Hepatic	80	40.0
Hypertension	70	35.0

3.3 Risk factors of mesenteric ischemia in the studied patients

There were 86 cases (43%) where previous splenectomy was the biggest risk factor, followed by liver cirrhosis and portal hypertension (80 cases – 40%), while prior myocardial infarction (Table3) was the lowest at 4 cases (2%)

Table (3): The distribution of risk factors among the studied cases.

Risk factor	*n=200*
History of splenectomy	*86*

History of liver cirrhosis and portal hypertension	*80*
History of hypercoagulable state	*40*
History of intestinal angina	*6*
History of atrial fibrillation	*14*
History of myocardial infarction	*4*

3.4 Comparison of study group pathologies and presentation times

On average, patients presented at the emergency department for about 3.21 days, ranging from one day to six days. Ninety percent of the cases of ischemia we studied had venous origins (180 patients - 90%), while the remaining ones had arterial origins. Stoma group presentations were on average 3.24 days while primary anastomosis presentations were on average 3.18 days (p = 0.79). A significant difference was not observed between the two groups regarding arterial and venous pathologies (Table 4).

3.5 Types of surgical intervention

The operations (Table5) that were done for the study cases were resections with primary anastomosis or resections diverting stoma, 100 cases (50%) for each.

Table (4): time of presentation and aetiology of cases of anastomosis and stoma.

	Stoma		*Anastomosis*		*Test of significance*	*p value*
	n=100	*%*	*n=100*	*%*		
Arterial	8	8.0	12	12.0	χ^2=0.44	0.51
Venous	92	92.0	88	88.0	χ^2=0. 39	0.49
Presentation Timing /day Mean±SD	3.24±0.98		3.18±1.26		t=0.23	0.68

χ^2:Chi-Square test t:Student t test

Table (5): Type of surgery among studied cases.

	n=200	*%*
Anastomosis	100	50
Stoma	100	50

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Table (6): Operative characteristics of anastomosis and stoma cases.

	Stoma *n=100*	*Anastomosis* *n=100*	*Test of significance*	*p value*
Operative time /minutes Mean±SD	59.97±7.96	89.98±9.66	t=18.50	<0.001*
Length of part resected /cm Mean±SD	71.44±9.13	72.06±16.54	t=0.23	0.82
Length from DJ/cm Mean±SD	242.52±9.04	244.68±14.33	t=0.90	0.37
Fasting time /days Mean±SD	1.72±0.97	3.78±0.82	t=10.98	<0.002*
Length of stay /days Mean±SD	9.20±2.29	15.7±5.14	t=7.78	<0.003*

3.6 The differences in the study groups' operational variables

There was a longer operating time for the anastomosis group (Table6) (89.98 minutes vs. 59.97±7.96 minutes for the stoma group) ($p < 0.001$). Furthermore, compared with the other group, it showed a significant delay in the onset of oral feeding ($p < 0.002$). The difference in intestinal length determined by DJ flexure between the two groups was not significant for either of the resected sections or the intestinal length calculated from DF. Significantly shorter hospital stays were observed in the stoma group ($p < 0.003$).

3.7 Study group postoperative complications

Compared to the anastomotic group, leakage was experienced in 36 cases (36%) while only four cases (4%) took place in the other group ($p < 0.001$). Therefore, postoperative mortality was higher in the same group (18 cases - 18%) ($p = 0.025$). According to Table 7, incisional hernia, and postoperative wound infection in the two groups did not differ significantly & Fig. 2.

Table (7): complications of anastomosis and stoma operations of the study.

Complications	*Stoma*		*Anastomosis*		*Test of*	*p value*
	n=100	*%*	*n=100*	*%*	*significance* (χ^2)	

Leakage	4	4.0	36	36.0	16.0	<0.001*
Wound infection	24	24.0	40	40.0	2.94	0.08
Post-operative morbidity	24	24.0	120	20.4	0.19	0.67
Mortality	4	4.0	18	18.0	5.01	0.025*
Incisional hernia	12	12.0	20	20.0	1.19	0.28

χ^2:Chi-Square test *statistically significant ($p<0.05$)

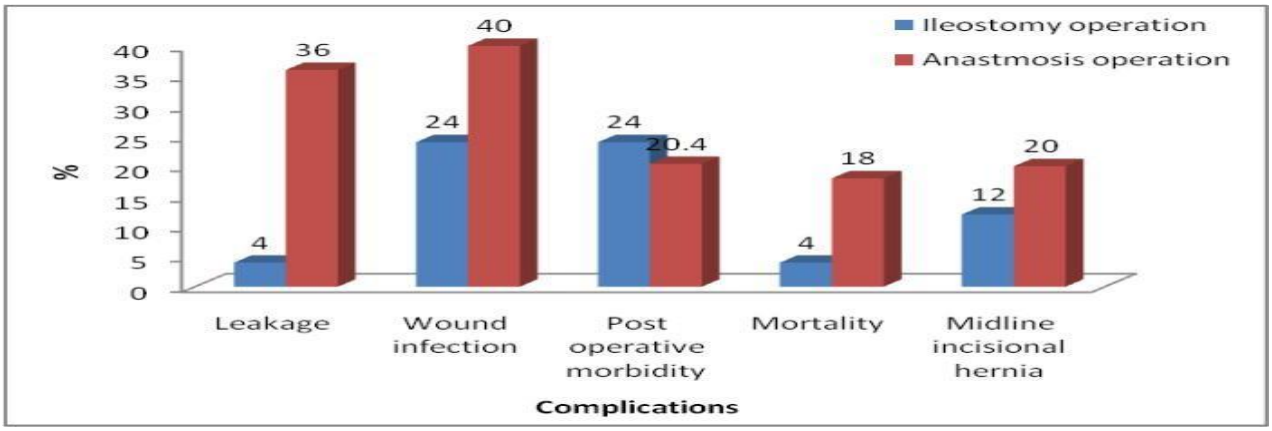

Figure (2): post-operative complications.

3.8 Stoma complications

Excoriation (56 cases - 56%) as well as electrolyte disturbances (42 cases- 42%) were the most common stoma complications as can be seen in Table (8), two patient has stomal gangrene, and six patients (6%) have parastomal hernia.

Table (8): Stoma complications

	n=100	*%*
Electrolyte disturbance	*42*	*42*
Excoriation	*56*	*56*
Stomal retraction	*4*	*4*
Stomal gangrene	*2*	*2*
Parastomal hernia	*6*	*6*

Stomal prolapse	*4*	*4*

3.9 GQOL variable of the study groups

Anastomosis cases had a significantly higher quality of life than stoma sufferers (Table 9).

Table (9): GQOL of stoma versus anastomosis cases.

	Stoma *n=48*	*Anastomosis* *n=41*	*Test of significance*	*p value*
GQOL Mean±SD	61.12±3.9	93.24±20.01	t=11.06	<0.001*
≤60	25(52.1)	6(14.6)		
>60	23(47.9)	35(85.4)	χ^2=12.49	0.003*

The median (60) was chosen as a cut-off point

3.10 GQOL before and after closure of the diverting stoma

The quality of life of patients with stomas significantly improved (Table 10 &fig.3) after closure ($p < 0.002$).

Table (10): GQOL before and after of the diverting stoma.

	Before closure *n=96*	*After closure* *n=96*	*Test of significance*	*p value*
GQOL(Mean±SD)	61.76±3.9	99.52±3.37	t=51.11	<0.002*
≤60	50	00		
>60	46	96	χ^2=35.22	<0.002*

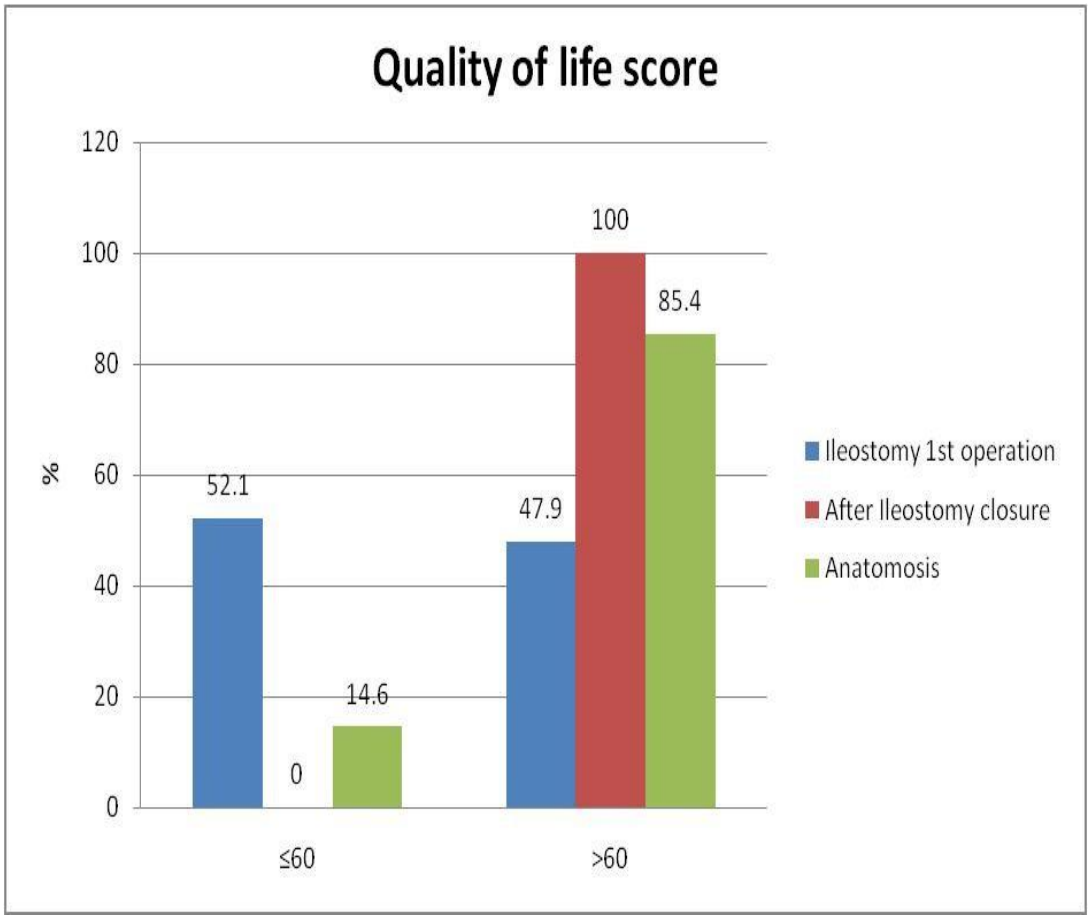

Figure (3): the GQOL of the study population.

4. Discussion

Surgery is the only option when intestinal gangrene is evident or suspected, as the affected segment must be removed, and the remaining bowel anastomosed or diverted to the anterior abdominal wall as a stoma [1].

There is a higher risk of postoperative complications following emergency operations, including wound infections, abscesses, anastomotic leaks, and wound dehiscence. Proximal diversion is highly debated in terms of its effectiveness. Anastomotic leaks and the need for urgent reoperations were prevented through proximal diversion, a systematic review found [9- 11].

In conditions such as bowel ischemic inflammatory or traumatic disorders, small bowel stomas may be needed following small bowel resection under emergent conditions. Clinically, these patients require a quick and safe procedure that preserves as much intestinal length as possible. Additionally, the restoration of continuity usually requires meticulous dissection of the afferent and efferent segments and the formation of new anastomoses, under general anesthesia [12].

An overall GQOL study was conducted on 200 patients with mesenteric vascular gangrene to compare the outcomes after resection of the gangrenous bowel portion in both primary anastomosis and diverting stoma procedures. The patients were allocated to two groups, 100 patients undergoing primary anastomosis, and 100 ones undergoing temporary diverting stomas. Atrial fibrillation and rheumatic valvular heart disease are reported to be risk factors for embolic events. Generalized atherosclerosis, hyperlipidemia, diabetes mellitus, and hypertension are more common causes of thrombotic events [13].

Compared to the previous study, in the current study, splenectomy was the predominant risk factor (44%), followed by DVT (20%), while previous ischemic attacks were present in 28 cases (14%). The Indian study included cases of acute mesenteric ischemia, there was also some evidence of comorbidity. Among the 66 patients (56%) there were 36 with hypertension (n=33; 28%), 24 with coronary artery disease (n=24; 21%) and 17 with diabetes mellitus (n=20; 17%) [14].

These comorbidities were also detected in this study, such as cardiac disease (43%), diabetes mellitus (40%), hepatic disease (40%), and hypertension (35%). These risk factors did not differ significantly between the two study groups based on the comparison of the prevalence between the two groups.

Diversion groups experienced significantly faster operative times than anastomosis groups ($p < 0.001$). A short hospital stay and early oral intake were also found in the diversion group ($p < 0.001$). The diversion of distal GI anastomoses has been shown to allow early oral feeding and shorter hospital stays than primary anastomoses, particularly in distal GI anastomoses [15].

According to the results of this study, the operative time and the beginning of oral intake were like those reported in the previous study. Operative time was longer for the anastomosis group (89.98 minutes vs 59.97±7.96minutes for the stoma group). Furthermore, compared to the other group, it displayed a significant delay in onset of oral feeding (3.78 days vs. 1.72 days). Statistically significant differences were found between the two groups for both operative time and oral diet start. Those with stomas were hospitalized for a shorter period (9.2 days vs. 15.7 days for the anastomosis group).

It's possible for skin irritation to occur at any time during the stoma, but dermatologic conditions are most common in the early postoperative period as the ostomate becomes familiar with stoma care. New ostomates are often unaware that they have peristomal dermatitis, which occurs up to 70% of the time [16].

A study among our hands found 56 cases (56%) with skin excoriation, 6 (6%) with a parastomal hernia, 4 (4%) with stomal retraction, and only two (2%) with stomal gangrene and prolapse. Infection of the postoperative wound and incisional hernia were not significantly different between the two groups.

Diversion to the proximal bowel reduces the rate of leaks and the need for laparotomies, as well as the clinical impact of leaks. Proximal diversion is also associated with additional morbidity. An 18% readmission rate is attributed to various problems, including dehydration, electrolyte abnormalities, and mechanical problems. Furthermore, ostomy closures cause 15–20% complications [17].

The results of the current study confirm the previous studies in that the primary anastomosis group experienced more leakage and mortality than the stoma group. (36% vs. 4%, $p < 0.001$ for leakage - 18.5 VS. 4%, $P = 0.025$ for mortality). A postoperative morbidity rate of 20% and 24% were observed in each of our study groups, respectively ($p = 0.67$). Compared to the other group, the anastomotic group experienced significantly more leakage cases (36 cases), while it only occurred in two cases (4%) ($p < 0.001$). In this group, postoperative mortality was also higher (18 cases) ($p = 0.025$).

Patients often experience stoma-related complications, but an unhappy body image and dissatisfaction with the stoma can negatively affect the quality of life. Clinical outcomes and quality of life and experience for patients with stomas are improved by patient education [17]. Choosing a suitable stoma site together with the patient before surgery confirms the site meets the patient and practitioner's needs. The surgeon can identify and rank multiple possible stoma sites based on their preference, thus providing a choice if some

intra-operative findings dictate a different location for the stoma [18], [19], [23].

GQOL scores for the ileostomy group were lower than those for the other group ($p < 0.001$). Few studies have shown a negative impact on GQOL from stoma construction. The few studies that have examined how a stoma affects a person's psychosocial well-being have found that about a third of patients suffer from depression, social problems, and/or sexual difficulties. Study results were mixed when GQOL was examined in both patients receiving a stoma and those maintaining continuity. The underlying health condition leading to the stoma could be the one that hinders the psychosocial aspects of GQOL rather than the stoma itself [20- 22].

A similar conclusion was reached in this study. When compared to the stoma group, the anastomotic group had significantly better GQOL. A significant improvement in GQOL was observed in stoma cases after closure ($p < 0.001$).

proximal diversion is not routinely recommended due to its morbidity. It is important to carefully consider the cost and the morbidity of an ostomy when deciding whether to divert proximally. Three key questions can simplify the decision-making process; (1) Based on the location of the anastomosis, what is the risk of a leak? (2) A leak is tolerable in this patient? and (3) Where do the patient's wishes lie?

Proximal diversion should be considered for patients who are elderly or have multiple medical conditions. A leak in these patients is typically not tolerated very well by their physiologic reserve [15], [24], [25].

A limitation of this study was the small sample size. Although randomization usually prevented the results from being biased, we recommend considering the psychosocial impact of surgical intervention in the decision-making process. Stomas, whether temporary or permanent, may be refused by some patients. Some people might be more concerned with the complications associated with a leak than with having an ostomy. When a patient is fully informed, they can speak up for themselves and be more satisfied with the overall outcome of their treatment. Making intraoperative decisions is easier when you know what the patient wants. As an alternative surgery that can provide a better quality of life and lower mortality rates, the focus should be directed toward new trends such as same-day ileostomy closure and damage control stomas.

5. Conclusion

Mesenteric vascular occlusion carries a challenge for physicians and surgeons for early diagnosis and proper management of these patients, especially in the postoperative period. The critical decision for the surgeon after resection of infarcted bowel either to do stoma or anastomosis should consider the long-term impact on patient life quality and psychological status. The diverting stoma group showed a significant difference in postoperative morbidity and mortality. But, on the other hand, patients faced a marked decrease in their quality of life which increased a lot after ileostomy closure. Also, the ileostomy group needed strict follow-up and nutritional support to prevent post-operative electrolyte disturbance. The ileostomy appeared to be a safer procedure to perform in mesenteric vascular occlusion as regard morbidity and mortality rates but need strict nutritional, psychological and special home care to enhance the quality of life. On another hand, the anastomosis group carried a higher risk for mortality and morbidity especially after the leak but experienced better quality of life.

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