## ORIGINAL ARTICLE

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# A study of comparison between quality of life early closure of ileostomy and late closure of ileostomy

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# ABSTRACT

Background: In the developed countries, ileostomy is mainly constructed as a protective cover for distal colorectal or ileoanal pouch anastomosis, but in developing countries, it is still often made in emergency surgical settings where infective conditions such as enteric or tubercular perforations are common and patients present late in their course of illness which precludes primary closure. Aims and Objectives: The aim of the present study is to compare health-related quality of life at 3, 6, and 12 months comparing early versus late closure of a temporary ileostomy. Materials and Methods: The study was conducted on 50 patients, 25 patients undergoing for early stoma closure and 25 patients undergoing for late closure ileostomy each in Maharani Laxmi Bai Medical College, Jhansi, between January 2020 and June 2021. Results: The mean age of patient undergoing early closure is 36.16 and mean age of patient undergoing late closure is 40.36, out of which 80% were male patient and 20% patient were female. Using SF-36 questionnaire, out of 8 domains, quality of life of early closure of ileostomy is significantly better in respect of 3 domains and that is physical functioning -P = 0.004. Mean  $\pm$  SD score for early stoma closure  $80.6 \pm 22.495$  for late closure  $73.00 \pm 25.247$ . Social functioning P=0.05. Mean  $\pm$  SD score for early stoma closure, 74.00  $\pm$  4.243 late stoma closure 71.50  $\pm$  0.707. Role emotion P=0.04, Mean  $\pm$  SD score for early stoma closure  $80.00 \pm 4.00$  late closure  $74.67 \pm 12.20$ . Conclusion: We concluded that quality of life in early closure of ileostomy is significantly better in respect of 3 domains (physical functioning, social functioning, and role emotion) out of 8 domains in SF-36 questionnaire than quality of life in late closure of ileostomy.

Key words: Early closure; Quality of life; SF-36 questionnaire; Temporary ileostomy

# **INTRODUCTION**

A loop ileostomy is one of the most common techniques used in colorectal surgery to establish a reversible fecal diversion and bypass the large bowels, in order to protect either a downstream colorectal anastomosis or a coloanal anastomosis.<sup>1</sup> However, in spite of its potential benefits, it is worth noting that the incidence of complications, in general, is very variable and some studies estimated it between 14% and 79%.<sup>2</sup> The complications that arise from stoma formation can be divided into early and late. To better understand how these complications may arise, it is essential to discuss the steps involved in the procedures of a loop ileostomy's formation. Early complications, by definition, are those occurring within 3 months of the stoma creation. These include abscess formation, wound infection, bleeding, stomal necrosis, stomal retraction, mucocutaneous separation, and peristomal skin breakdown.<sup>2</sup>

Late complications that develop after 3 months include stomal stenosis, peristomal skin breakdown, stomal prolapse, parastomal herniation, fistula formation, and negative psychological effects.<sup>2</sup> Parastomal hernia is one of the common late complications affecting about 6.2% of patients with loop ileostomies. It is a type of incisional hernia resulting in the protrusion of abdominal content

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through the created defect. It presents with an abdominal swelling around the site of the hernia with or without pain, or as an acute strangulated or incarcerated hernia.<sup>3</sup>

## Aims and objectives

#### Aims

The aim of the present study is to compare the health-related quality of life (HRQOL) at 3, 6, and 12 months comparing early versus late closure of a temporary ileostomy.

## Objectives

- To assess the HRQOL in early ileostomy closure
- To assess the HRQOL in late ileostomy
- To compare HRQOL between early and late ileostomy.

## **MATERIALS AND METHODS**

## Source of data

The study was conducted on 50 patients, 25 patients undergoing for early stoma closure, and 25 patients undergoing for late closure ileostomy each in Maharani Laxmi Bai Medical College. Jhansi between January 2020 and June 2021.

### **Inclusion criteria**

- Age >18 years and <65 years
- All patients who were underwent early and late closure ileostomy.

## **Exclusion criteria**

- Age <18 years and >65 years
- All patients operated for other than early and late closure ileostomy.

#### Randomization

Consenting patients who fulfilled the inclusion criteria was randomized either to the intervention group with early closure of the ileostomy or to the control group with late closure. Randomization was executed in computergenerated blocks of six. The randomization was performed on the surgical ward using sequentially numbered thick, opaque and sealed envelopes. Blinding of the intervention is not possible.

The basis of this study is the quality-of-life analysis of the operated patients. Using short form questionnaire (SF-36) developed from the RAND Corporation Medical Outcomes Study (RAND Health. Santa Monica, CA, USA) which was translated to the English language without the questions' meaning changes.

The SF-36 questionnaire is a standardized procedure for the assessment of health-related quality of life which analyzes eight domains of quality of life:

- 1. Physical functioning
- 2. Satisfaction of physical role
- 3. Emotional role
- 4. Social functioning
- 5. Bodily pain
- 6. Psychological (mental) status
- 7. Vitality
- 8. General health.

The answers were categorized in the form of scores in the way recommended from RAND, transforming them into linear analog scale where the score of 100 indicated the optimal health. After that, they were grouped into the domains. The questionnaire was sent by mail to the addresses of the patients with the accompanying letter, where we explained the kind of research. SF-36® is a generic tool that evaluates patients' self-reported quality of life. It consists of 36 items that measure eight dimensions of health on a multi-item scale, including social and physical function. The scoring scale ranges from 0 to 100, with lower scores indicating worse health. The instrument has been validated, and for comparison in this study, a Swedish reference population was used.

## **Statistical analysis**

The data were collected and entered in Microsoft Excel sheet and later Excel sheet is transported to the SPSS 21.0 and appropriate statistical test Chi-square and unpaired t-test are applied.

# RESULTS

The mean age of patient undergoing early closure is 36.16 and mean age of patient undergoing late closure is 40.36, out of which 80% were male patient and 20% patient were female. Using SF-36 questionnaire, out of eight domain quality of life of early closure of ileostomy is significantly better in respect of 3 domain and that is physical functioning – P=0.004. Mean±SD score for early stoma closure  $80.6\pm22.495$  for late closure  $73.00\pm25.247$ . Social functioning P=0.05. Mean±SD score for early stoma closure  $74.00\pm4.243$  late stoma closure  $71.50\pm0.707$ . Role emotion P=0.04, Mean±SD score for early stoma closure  $80.00\pm4.00$  late closure  $74.67\pm12.20$ .

Table 1 shows a mean age of patients undergoing early closure is 36.16 and mean age of patient undergoing late closure is 40.36. The most common age group is 20–30 years old, early closure 44% and late closure 36%.

Table 2 shows that out of 50 patients, 80% are male patient and 20% patient are female.

| Table 1: Age (in years) distribution |                              |            |                                 |            |  |  |  |
|--------------------------------------|------------------------------|------------|---------------------------------|------------|--|--|--|
| Age<br>(in years)                    | Group A (Early closure n=25) |            | Group A (Later<br>closure n=25) |            |  |  |  |
|                                      | No. of patients              | Percentage | No. of patients                 | Percentage |  |  |  |
| 20–30 years                          | 11                           | 44         | 9                               | 36         |  |  |  |
| 31–40 years                          | 5                            | 20         | 3                               | 12         |  |  |  |
| 41–50 years                          | 6                            | 24         | 6                               | 24         |  |  |  |
| 51–60 years                          | 3                            | 12         | 7                               | 28         |  |  |  |
| Total                                | 25                           | 100        | 25                              | 100        |  |  |  |

| Table 2: Sex distribution |                                 |            |                                 |            |  |  |  |
|---------------------------|---------------------------------|------------|---------------------------------|------------|--|--|--|
| Sex                       | Group A<br>(Early closure n=25) |            | Group A<br>(Later closure n=25) |            |  |  |  |
|                           | No. of patients                 | Percentage | No. of patients                 | Percentage |  |  |  |
| Male                      | 22                              | 88         | 18                              | 72         |  |  |  |
| Female                    | 3                               | 12         | 7                               | 28         |  |  |  |
| Total                     | 25                              | 100        | 25                              | 100        |  |  |  |

# DISCUSSION

Systematic reviews and randomized controlled trials have shown temporary loop ileostomies effectively reduce the rate of symptomatic anastomotic leaks and the need for reoperation in such cases. Restoration of gastrointestinal continuity by reversing loop ileostomies requires a second operation, the timing of which remains controversial. Because the optimal timing of ileostomy closure remains unknown, interest has been growing in the assessment of the association between timing of closure and postoperative outcomes. Prospective and retrospective reports are available in the literature comparing ileostomy closures as early as 8 days following the primary operation to the traditionally timed closures at 12 weeks.

Abdalla and Scarpinata<sup>4</sup> study concluded that although the optimal timing of closure of loop ileostomy is unknown, there is evidence to support early rather than late closure. The current study demonstrates the length of hospital stay and average number of postoperative complications were significantly lower in the early (<6 months) than in the late (>6 months) closure group.

According to Aljorfi and Alkhamis,<sup>5</sup> early closure of loop ileostomy is defined as closure <3 months and late as more than 3 months, in accordance with conventional literature.

In our study, compares the quality of life of ileostomy closures within 3 months to those after 3 months, based on SF–36 questionnaires which having 8 domains.

Similar study was also done by Park et al.,<sup>6</sup> in 2018 compare HRQOL following early *versus* late closure of a temporary ileostomy and their results as follows.

#### **Physical functioning**

In our study, out of 50 patients, 25 patients undergoing for early stoma closure, the mean SD score of physical functioning after 4 weeks is  $80.6\pm22.495$  and 25 patients undergoing for late closure, the mean SD score of physical functioning after 4 weeks is  $73.00\pm25.247$ .

Then applying student t-test for P-value, P=0.0004 which means patient who undergoing for early closure of stoma have significantly benefitting physical activities in comparison to the patient undergoing for later closure of stoma but in Park et al.,<sup>6</sup> study, P=0.646 means there is no significant differences in the physical functioning domain.

#### **Role functioning/physical**

Patients undergoing for early closure, the mean SD score of role physical domain questionnaire is  $74.00\pm28.00$  and patients undergoing for late closure, the mean SD score of role physical is  $67.00\pm26.00$ , P=0.36 which means in comparison to this domain, there is no significant difference between the groups.

In Park et al.<sup>6</sup> study, P=0.025 means, significant differences and early closure group is benefitting in the role functioning/physical domain.

## **Bodily pain**

The mean SD score of bodily pain in the group including the early closure is  $77.80\pm5.374$  and in the group including late closure patients is  $79.30\pm3.253$ . The P=0.23 which means there is no significant difference between the groups.

In Park et al.<sup>6</sup> study, P=0.828, means no significant differences in bodily pain similar results with my study.

#### Vitality

The mean SD score for vitality in the group including the early closure is  $76.2\pm4.991$  and in the group including late closure patients is  $74.00\pm4.5991$ . The P=0.11 which means there is no significant difference between the groups. In Park et al.<sup>6</sup> study, P=0.441 means no significant differences in vitality. Similar results with my study.

#### **General health**

The mean SD score for general health in the group including the early closure is  $71.4\pm8.620$  and in the group including late closure patients is  $69.4\pm10.668$ . The P=0.46 which means there is no significant difference between the groups. In Park et al.<sup>6</sup> study, P=0.139 means no significant differences in general health. Similar results with my study.

#### **Social functioning**

The mean SD score for social functioning in the group including the early closure  $74.00\pm4.243$  and in the group

| Table 3: Quality of life |                              |                              |        |
|--------------------------|------------------------------|------------------------------|--------|
| Domains of QOL n=8       | Mea                          | P-value                      |        |
|                          | Group A (Early closure n=25) | Group A (Later closure n=25) |        |
| 1.Physical functioning   | 80.6±22.495                  | 73.00±25.247                 | 0.0004 |
| 2.Role physical          | 74.00±28.00                  | 67.00±26.00                  | 0.36   |
| 3.Bodily pain            | 77.80±5.374                  | 79.30±3.253                  | 0.23   |
| 4.Vitality               | 76.2±4.991                   | 74.00±4.596                  | 0.11   |
| 5.General health         | 71.4±8.620                   | 69.4±10.668                  | 0.46   |
| 6.Social functioning     | 74.00±4.243                  | 71.50±0.707                  | 0.05   |
| 7.Mental health          | 75.04±5.696                  | 73.12±2.504                  | 0.12   |
| 8.Role emotion           | 80.00±4.000                  | 74.67±12.220                 | 0.04   |

including late closure patients is  $71.50\pm0.707$ . The P=0.05, which means there is significant difference between the groups and patient undergoing early closure of stoma having better social well-being but in Park et al.<sup>6</sup> study, P=0.468 means no significant differences in social functioning.

#### Mental health

The mean SD score for mental health in the group including the early closure is  $75.04\pm5.696$  and in the group including late closure patients is  $73.12\pm2.504$ , the P=0.12, which means there is no significant difference between the groups. In Park et al.,<sup>6</sup> study, P=0.217, means no significant differences in mental health. Similar results with my study.

#### **Role emotion**

The mean SD score for role emotion in the group including the early closure is  $80.00\pm4.000$  and in the group including late closure patients is  $74.67\pm12.220$ . The P=0.04 which means there is significant difference between the groups and patient undergoing early closure of stoma having better role limitations due to emotional problems. In Park et al., study,<sup>6</sup> P=0.345, means no significant differences in role limitation due to emotional problems.

#### Quality of life assessment

Results of HRQOL at 3, 6 and 12 months after early and late closure of temporary ileostomy are compared. Out of 8 domains, physical functioning, social functioning and role emotion domains are significantly have shown that patient of early closure of stoma having better quality of life.

Rest of domains like role Physical, Bodily Pain, Vitality, General Health, Mental Health have shown that there is no significant difference in the quality of life.

In Park et al.,<sup>6</sup> study, SF-36®scores, out of 8 domains, Role Physical domain is significantly have shown that patient of early closure of stoma having better quality of life.

Rest of domains like Physical Functioning, Bodily Pain, Vitality, General Health, Social Functioning, mental Health have shown that there is no significant difference in the quality of life (Table 3). In both my study and Park et al., study, all dimensions in SF-36 improved over time.

In another similar study done in 2018 by Fayed et al.,<sup>7</sup> who concluded that Early stoma closure does not carry an increased risk of postoperative complications, reduces cost toward stoma care, and leads to better a QOL. He took 20 patients in each group.

In another similar study done in 2016 by Sarawgi et al.,<sup>8</sup> who took 47 loop ileostomies divide the 15 patient for early closure and 32 patient for late closure, then concluded that there are potential advantages of early closure of loop ileostomy and are a feasible alternative to a more conventional delayed approach.

#### Limitations of the study

This was a single-centered study.

# CONCLUSION

In our study, a comparison between quality of life early closure of ileostomy and late closure of ileostomy using SF-36 questionnaire, we concluded that quality of life in early closure of ileostomy is significantly better in respect of three domains (physical functioning, social functioning, and role emotion) out of 8 domains in SF-36 questionnaire than quality of life in late closure of ileostomy.

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Asian Journal of Medical Sciences | Aug 2023 | Vol 14 | Issue 8

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NKB, PS, MKM- Concept and design of the study, prepared first draft of manuscript; interpreted the results; reviewed the literature and manuscript preparation; concept, coordination, preparation of manuscript and revision of the manuscript.

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