

## Original Research Article

# Role of probiotics on surgical site infections in colorectal surgery

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### ABSTRACT

**Background:** Elective colorectal procedures are well known for their high rates of surgical site infections (SSI). Perioperative stabilization of microflora is a potential alternative. Usage of probiotics has significantly improved intestinal microflora and reduced infectious complications and improved surgical outcome.

**Methods:** Observational follow-up study on 100 patients. Probiotics were given along with standard preoperative protocol and development of SSI was inspected upto 30 days. The data thus collected was subjected to descriptive analysis.

**Results:** Colorectal malignancy was the most common indication out of which carcinoma rectum was most common comprising of 40% of the total subjects. Mean days to passage of first flatus was  $3.13 \pm 1.33$  days. Mean days to passage of first defecation was  $4.6 \pm 1.64$  days. Mean days to first solid diet was  $4.42 \pm 2.02$  days. Mean duration of total length of hospital stay was  $14.7 \pm 8.7$  days. Surgical site infections were seen in 17% of the participants of the study. Urinary tract infections were seen in 2 (2%) patients. Lower respiratory tract infections were seen in 2 (2%) patients. Anastomotic leak was present in 2 cases (2.8%) out of 70 cases. Mortality was seen in 2 (2%) cases.

**Conclusions:** Perioperative usage of probiotics can lead to decrease in incidence of infectious complications but cannot be statistically proved due to insufficient data. Also due to early bowel functioning there is decrease in the mean hospital stay which contributed to better surgical outcome and better quality of life.

**Keywords:** Elective colorectal surgery, Surgical site infections, Probiotics

### INTRODUCTION

Upto 40% mortality rates were recorded in elective colorectal resection in the early 20th century but due to improved perioperative care the mortality rates have now reduced to 1-3%. During the past 20 years there have been significant changes in the long-term survival after elective colorectal surgery both in terms of morbidity and mortality due to accelerated development of the surgical techniques and improved perioperative care.<sup>1</sup> Colorectal malignancies are the most common indication for elective colorectal surgeries.

Among all hospital acquired infections (HAI) surgical site infections are the second most common and it accounts for 22% of all the hospital acquired infections.<sup>2</sup> Elective colorectal procedures are well known for their high rates of surgical site infections upto 30%. Surgeons have been dependent on mechanical bowel preparation for decades. However, there is controversy as some of the researches have shown that mechanical bowel preparation does not help to reduce the incidence of postoperative infections and may cause harm to the patient as it is often poorly tolerated by many of the patients.<sup>3</sup> Antimicrobial prophylaxis is the single most important means of preventing surgical site infection as intestinal micro flora is profoundly influenced by antibiotic therapy peri-

operatively.<sup>4</sup> But antibiotics can cause functional intestinal nuisances in the postoperative period due to its harmful effects on the gut microbiota which may require further treatment.<sup>5</sup> So it is assumed that infectious complications in the post-operative period may originate from gut derived micro-organisms, So based on this assumption perioperative stabilization of microflora is a potential alternative for reducing postoperative infectious complications.<sup>6</sup>

Probiotics are defined as ‘live microorganisms which when administered in adequate amounts confer a health benefit on the host’ by an expert panel of World Health Organization (WHO).<sup>7</sup> Probiotics are helpful to our system in many ways, it improves bowel microbial flora and activate the immune system, inhibits pathogenic strains by production of a physiologically restrictive environment, stimulate IgA secretion, elaborate release of bacteriocins and defensins. In previous studies it has also been revealed that oral preparations in perioperative period can prevent disruption of normal gut mucosa which helps in prevention of ileus after the surgery.<sup>8</sup> Recently several studies have been conducted which clearly establish that usage of probiotics in perioperative patients has significantly improved intestinal microflora and reduced infectious complications and improved surgical outcome.<sup>9</sup>

So, this study was conducted as observational follow up study to determine the burden of the elective colorectal surgery in our centre, also to calculate the incidence of surgical site infections in these elective colorectal cases and factors affecting the same.

## METHODS

This observational follow-up study was conducted in the Department of General Surgery, Himalayan Institute of Medical Sciences (HIMS), Swami Ram Nagar, Dehradun, over a period of 12 months from 1st January 2018 till 31st December 2018; the institutional ethics committee approval was taken prior to the commencement of the study. Written informed consent was taken from all the patients.

### Sample size and sampling methods

All patients admitted to our department and scheduled to undergo an elective open colonic surgery from 1st January to 31st December 2018 were eligible for participation in the study.

### Selection criteria

Inclusion criteria were age more than 18 years coming for elective large bowel surgery.

Exclusion criteria were age <18 years, lactose intolerance, immunodeficient previously, usage of

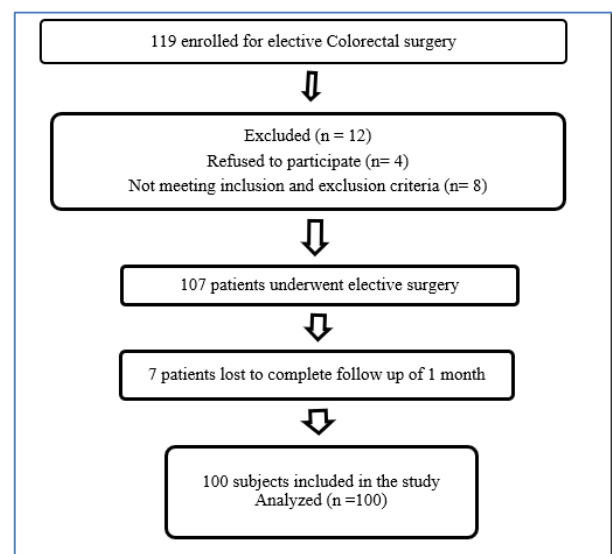
antibiotics for additional gastrointestinal disorders, and undergoing emergency OT.

### Study tools

Structured case record form, radiological studies such as X-ray, CT scan, contrast X-ray, MRI, pus culturing swabs. Probiotic - Baccelac PB capsules (*Lactobacillus Sporogens*- 50 million, *Streptococcus faecalis* 30 million, *Clostridium butyricum* 2 million and *Bacillus mesentericus* 1 million).

### Study protocol

Demographic and anthropometric indices were recorded and detailed clinical, haematological and microbiological assessment was done.



**Figure 1: Consort diagram of patient recruitment and analysis.**

All patients were given Becelac PB capsule in a thrice daily dosing for at least 3-6 days preoperatively and then restated the same day when the patient started drinking water and it was continued for at least 7 days postoperatively.

History taking and clinical examination of the population under study was done at the time of admission. All patients were given standard preoperative preparation as per hospital protocol.

Development of SSI was inspected daily during the dressings and other complications were observed after the surgery including pneumonia, urinary tract infections, and bacterimia and after discharge patient was followed through post procedure OPD visits or telephonically till 30 days of postoperative period.

Interpretation and analysis of the data obtained was carried out after noting all the details in microsoft excel

sheet. The data thus collected was subjected to descriptive analysis (e.g. mean, frequency, ratio etc.).

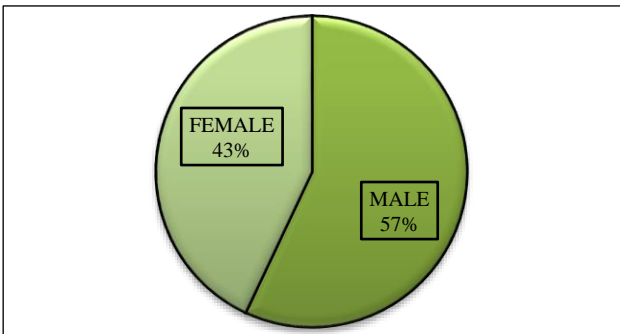
**Ethical approval**

The Institutional Ethics Committee approval was taken prior to the commencement of the study.

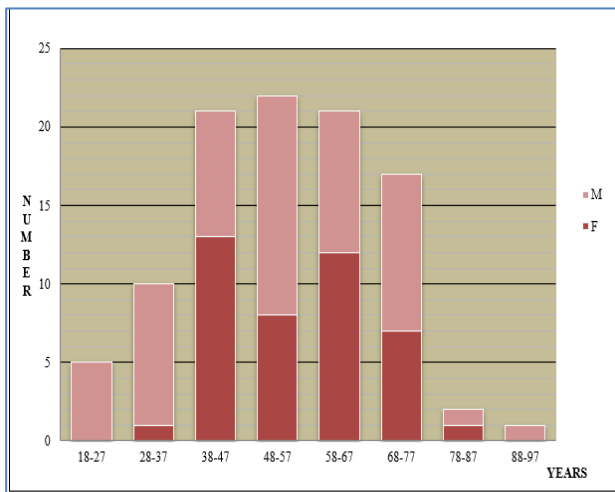
**RESULTS**

As given in Figure 2, 57% of the subjects were male and 43% females. Mean age was 53 years  $\pm$ 15.34 ranging from 18-95 years.

Most of the participants in the study were in 48-57 years of age group with least number of participants in 88-97 age groups (Figure 3). 10% of the participants were hypertensive and 8% were diabetics.

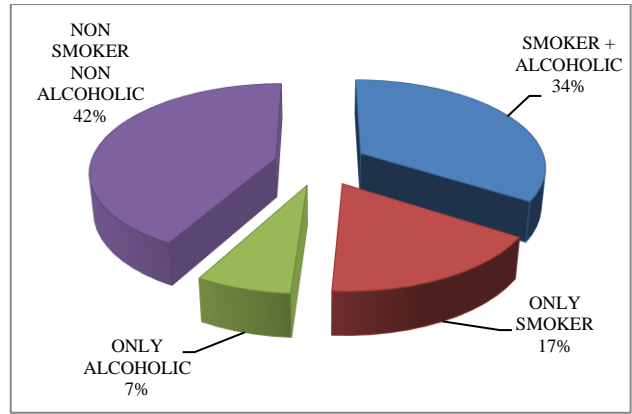


**Figure 2: Gender ratio of analyzed population (n=100).**



**Figure 3: Age distribution of analyzed population (n=100).**

51% of the total participants were smokers and 40% of the participants were alcoholics. So only 17 subjects included in the study were smoker only and 7 patients were alcoholics and do not smoke. 34% of the subjects were both alcoholics and smoker (Figure 4).



**Figure 4: Substance abuse in the study population (n=100).**

All patients underwent routine haematological and biochemical tests. Mean haemoglobin of the participants were 10.86 gm/dl  $\pm$ 2.0 (range 6.7-16) gm/dl. Mean leukocyte count was  $8.73 \pm 3.7 \times 10^9/l$  (range  $3.1-26 \times 10^9/l$ ). Mean albumin level was  $2.8 \pm 0.75$  g/l (range 1-4.33 g/l) (Table 1). Probiotics were given preoperatively for at least 3-6 days and was started postoperatively for at least 7 days. Mean duration of probiotics intake was 11.7 days  $\pm$ 2.8 (range 3-20 days).

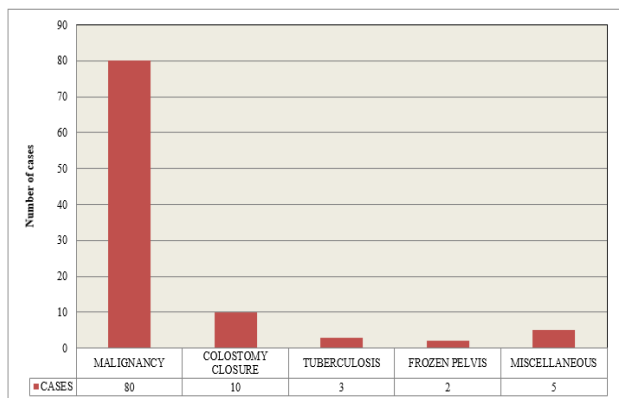
**Table 1: Preoperative blood indices of the analyzed population (n=100).**

| Preoperative blood index | Value           |
|--------------------------|-----------------|
| Haemoglobin (gm/dl)      | 10.86 $\pm$ 2.0 |
| Leukocyte ( $10^9/l$ )   | 8.73 $\pm$ 3.7  |
| Albumin (g/l)            | 2.8 $\pm$ 0.75  |

Colorectal malignancy was the most common indication for elective colorectal surgery. 2nd most common indication was colostomy closure in previously made colostomy for other reasons (trauma, covering stoma). Ileocaecal tuberculosis was the third common indication leading to right hemicolectomy. 2 patients underwent elective surgery for diversion in a case of frozen pelvis due to advanced cervical malignancy (Figure 5). In malignancies most common was carcinoma rectum comprising of 50% of all the malignancies and 40% of the total subjects included in the study. Other malignancies were localized at ascending colon (17.5%), anal canal (12.5%), caecum (8.75%), sigmoid colon (5%), appendix (2.5%) and transverse colon (2.5%) out of total malignancies.

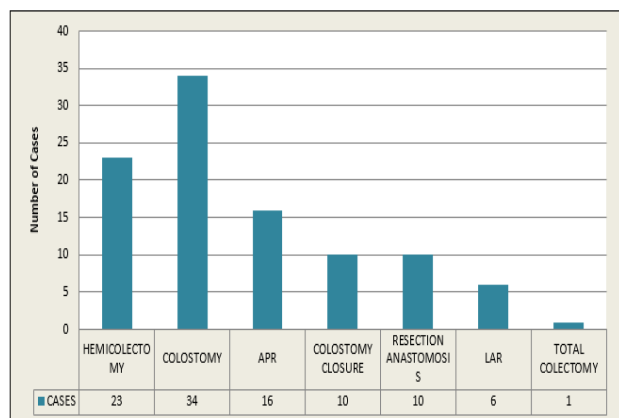
34 patients underwent elective diversion colostomy which was either ascending, transverse or descending loop or end colostomy done as a palliative procedure or for partial large bowel obstruction in case of distal colonic or ano-rectal mass. 23 patients underwent right hemicolectomy done for either malignancy or ileocaecal tuberculosis. 16 patients underwent abdomino-perineal resection for ano-rectal carcinoma. 10 patients underwent

colonic resection anastomosis for localized malignancy. 10 Patients underwent elective colostomy closure which was made earlier as a covering stoma or in case of trauma or in case of non healing perianal ulcers after complete healing of the ulcer. 6 patients underwent low anterior resection for carcinoma rectum and one patient underwent total proctocolectomy with end to end ileo-anal anastomosis for FAP (Figure 6).



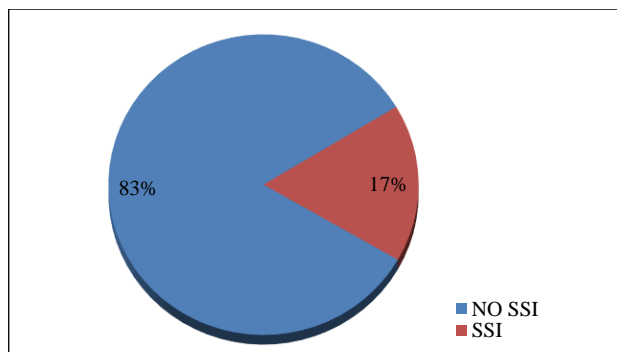
**Figure 5: Indications for elective surgery in study population (n=100).**

Surgical site infections were seen in 17% of the participants of the study (Figure 7). 6 were female and 11 were male participants. A breakdown of surgical site infections showed that 12 patients had superficial surgical site infections and 5 patients had deep/organ space SSI.



**Figure 6: Elective colorectal surgeries in study period (n=100).**

Culture isolates were taken all patients having surgical site infections and in 3 patients' culture was negative. Single isolate was present in 8 cases all of which were Escherichia coli. Double isolates were present in rest of the cases (35%). Urinary tract infections were seen in 2 patients (2%). Lower respiratory tract infections were seen in 2 patients (2%). Anastomotic leak was present in 2 cases out of 70 cases (2.8%). Mortality was seen in 2 cases (Table 2).



**Figure 7: Surgical site infection in analyzed population (n=100).**

**Table 2: Surgical complications in the analyzed population (n=100).**

| Complications                   | N (%)   |
|---------------------------------|---|
| <b>Surgical site infections</b> | 17 (17)   |
| Superficial incisional          | 12 (70.5)   |
| Deep, organ space               | 5 (29.5)  |
| <b>Urinary tract infections</b> | 2 (2)   |
| <b>Pneumonia</b>                | 2 (2)   |
| <b>Anastomotic leak</b>         | 2 (2.8) out of 70 cases in which anastomosis was done |
| <b>Mortality</b>                | 2 (2)   |
| <b>Total (n=100)</b>            | 25 (25)   |

Mean days to passage of first flatus was  $3.13 \pm 1.33$  days. Mean days to passage of first defecation was  $4.6 \pm 1.64$  days. Mean days to first solid diet was  $4.42 \pm 2.02$  days. Mean duration of postoperative care was  $10.88 \pm 7.4$  days. Mean duration of total length of hospital stay was  $14.7 \pm 8.7$  days.

**DISCUSSION**

Mean age of the patients included in this study was 53 years  $\pm 15.34$  which ranges from 18-95 years. The proportion of cases diagnosed in individuals younger than age 50 increased from 6% in 1990 to 11% in 2013.<sup>10</sup> There are several reasons for younger age group of patients of colorectal cancer in India. India has a broad-based population pyramid with a large proportion of young population. Other reasons can be an increased sedentary lifestyle and a higher prevalence of obesity in children and young adults.<sup>11</sup> In our study 57% of the subjects were male and 43% females. This can be explained by the fact that CRC incidence rates are approximately 30% higher in men than in women.<sup>12</sup>

Colorectal malignancy was the most common indication of elective colorectal surgery in this study and it is the most common indication for elective colorectal surgery throughout the world. In our study also most of the malignancies were of left side comprising of 70% of all

malignancies. Left-sided tumors are more likely to be symptomatic earlier because they present with overt bleeding per rectum and pain. Whereas in right sided disease the symptoms are milder with only mild localized pain due to distensibility of caecum and ascending colon. That's why the prognosis of right sided colonic cancers is worse than that of left sided colorectal carcinomas.<sup>13</sup>

Several studies have supported the positive benefit for maintaining the intestinal microbiota balance by perioperative probiotics (Table 3).

Many other randomized controlled trials were done prior to the study but many were of them are clinically insignificant because of either of the low sample size or usage of prebiotics with probiotics for better results. The above study was limited by the fact that in this study the control group was not taken because of which the statistical significance of the used probiotics cannot be evaluated. Also, there are large numbers of factors which are responsible for the postoperative infectious complications but it is difficult to tease out the exact contribution of probiotics without using large number of patients.

**Table 3: Percentage of incidence in placebo group.**

| S. no. | Study                           | Year | Place  | SSI (%) | UTI (%) | Pneumonia (%) | Anastomotic leak (%) | Other (%) | Mortality (%) | Total (%) |
|--------|---------------------------------|------|--------|---------|---------|---------------|----------------------|-----------|---------------|-----------|
| 1      | Liu et al <sup>14</sup>         | 2010 | China  | 10      | 12      | 10            | -                    | -         | -             | 32        |
| 2      | Mangell et al <sup>15</sup>     | 2012 | Sweden | 18      | -       | -             | -                    | 6.5       | 6.5           | 31        |
| 3      | Sadahiro et al <sup>16</sup>    | 2014 | Japan  | 23.2    | -       | 2.1           | 7.4                  | -         | -             | 32.7      |
| 4      | Aisu et al <sup>17</sup>        | 2014 | Japan  | 24.6    | -       | -             | -                    | 3.7       | -             | 28.3      |
| 5      | Kotzampassi et al <sup>18</sup> | 2015 | Japan  | 20      | 7.5     | 11.3          | 8.8                  | -         | -             | 48.8      |
| 6      | Mizuta et al <sup>19</sup>      | 2015 | Japan  | 34.4    | -       | -             | 17.2                 | -         | -             | 51.6      |

## CONCLUSION

In this study we have concluded that perioperative usage of probiotics can lead to decrease in incidence of infectious complications but cannot be statistically proved due to insufficient data. Also due to early bowel functioning there is decrease in the mean hospital stay which contributed to better surgical outcome and better quality of life. There is need of large size studies on large population scale with proper matching with standardized probiotic intervention (type, dosage, combination vs. single agent, length of treatment) to check the statistical significance of the given probiotic. Also, the side effects of probiotics also need to be addressed to calculate the risk benefit ratio

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