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Incidence of parastomal hernia in patients undergoing colostomy: A rural background study in West Bengal

Dr Dhrubajyoti Maulik[1], Dr Anil Kumar K[2]
[1](Department of General surgery, Bankura sammilani medical college and hospital /West Bengal university of health sciences, India)
[2](Department of General surgery, Bankura sammilani medical college and hospital /West Bengal university of health sciences, India)

***Abstract*:**
Background: *Parastomal hernia (PSH) is a very frequent complication after creation of a permanent colostomy. A parastomal hernia may be regarded as an incisional hernia related to an abdominal wall stoma. From the recent investigations, it is learnt that the development of hernia is not a single event rather involving multifactorial process linking an evolutionary anatomical weakness, predisposed defects, and increased abdominal pressure. It has been suggested that placing a mesh during the primary operation may reduce the rate of parastomal hernia. The aim of our study was to determine if parastomal herniation is prevented by the prophylactic placement during open surgery of a polypropylene mesh around a colostomy*.
***Materials and Methods*:** *In this prospective randomised controlled study in a rural background set up in west Bengal ,49 patients belonging to age group of 18-85years undergoing elective surgery under general anaesthesia were randomly allocated into 2 groups of 25patients each, Group A (with prosthetic mesh) and Group B (without prosthetic mesh). Considering certain predisposing factors(age, BMI, abdominal wall tensile strength, infection, smoking, diabetes, cancer & physical activity)which are more responsible to cause parastomal hernia in colostomy patients*
***Results*:** *Of the patients who were given prosthetic mesh 8% developed parastomal hernia and of the patients who were not given mesh, 33.3% developed parastomal hernia. All the patients who developed parastomal hernia , all had predisposing factors and associated between age of the patients was not statistically significant.*
Conclusion: *Prevention of parastomal hernia with prosthetic mesh has established good results when compared to the patients where prosthetic mesh is not given.*
Key word: *Parastomal hernia, Mesh, Abdominal wall stoma, Colostomy*

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I. Introduction

Parastomal hernia (PSH) is a very frequent complication after creation of a permanent colostomy. A parastomal hernia may be regarded as an incisional hernia related to an abdominal wall stoma. After the construction of a stoma, parastomal hernia has been reported to occur in up to 50% of patients, no matter what modification of the surgical technique is used(1). In 2 studies, a lower rate has been reported with the stoma brought out through the rectus abdominis muscle, although One third of parastomal hernias require surgical intervention, but even if there are many surgical options available, the results are very disappointing(2,3). Thus, recurrence rates of between 30% and 76% have been reported after local aponeurotic repair or stoma relocation. Better results have been produced with prosthetic mesh repair (4,5) .It has been suggested that placing a mesh during the primary operation may reduce the rate of parastomal hernia, but there is only1 nonrandomized study reported(6,7).

In general terms, hernia is described as a protrusion of intestine/abdominal fat (omentum) / urinary bladder, commonly through a weakness or opening in the muscle wall of the abdomen. Therefore it is detected commonly in the space under the skin. The mechanism behind such opening is still under debate in the direction of anatomical defect or connective tissue disorder. Although earlier reports pointed out the role of a mechanical disparity between visceral pressure and resistance of the structures within the myo-pectineal orifice as the cause for hernia development, it failed to explain the factors that contribute more for its development. From the recent investigations, it is learnt that the development of hernia is not a single event rather involving multifactorial process linking an evolutionary anatomical weakness, predisposed defects, and increased abdominal pressure. To date, the influence of each of these factors in the primary formation and recurrence of hernias is an area of significant dispute. As many number of abdominal wall hernias are reported and none of them are symptomatic but nearly all types have a potential risk of having their blood supply cut off, thereby developing severe

complications when they left untreated. For example, in case of inguinal hernia, intestinal loop get trapped in the weak area of the abdominal wall, leading to closer of the intestinal channel. This further result in severe pain, vomiting, or the inability to have a bowel movement and sometimes causes strangulation, or restriction, of the trapped intestine's blood supply and necessitates emergent surgery. In rare cases, strangulation of intestine considered as a life threatening since it results in death of a part of intestine.(8,9) This necessitates the importance of prompt diagnosis of hernia defect.

II. Material And Methods

Study Design: The study was institution based randomized controlled clinical trial study. The study is a design with blinded randomization of patients to two groups, namely mesh prophylaxis (study group) and no mesh prophylaxis (control group), in the creation of an end-colostomy. A 90% power estimation with a = 0.05, based on a published study suggested a sample size of 50 patients.

Study Location: The study was conducted at **General Surgery ward** of Bankura Sammilani Medical College & Hospital

Study Duration: January 2019 till January 2021

Sample Size: 49 patients

Sample Size Calculation: The sample size (SS) for the proposed study was calculated based on the following formula: $N=[(Z_\alpha+Z_\beta)^2 x\{(S_n)(1-S_n)\}]/[l^2 x(1-p)]$,where $Z\alpha=1.96$(two tailed) at 95% confidence interval (CI), $Z_\beta=0.84$ at 90% power of the test, S_n=Sensitivity , p=prevalence , q=complement of p=100-p.Putting values in the formula, $N=(7.8x0.31x0.69)/[(0.25)^2 x0.55]$, l=allowable error around the reported prevalence of event of interest, here it is assumed to be 25% i.e. 0.25. So, the SS=49. Considering 10% non-response rate the revised SS=54.

Subjects & Selection Method: The study population was drawn from patients who presented to Bankura Sammilani Medical College & Hospital before treatment initiation between from January 2019 to June 2020. Patients were divided into two groups (each group had 25 patients) With dyslipidemia were as follows: Group A(N=25 patients) -with prosthetic mesh ; Group B (N=24 patients) -without prosthetic mesh. Consecutive cases were included in the study as per predetermined inclusion and exclusion criteria. If there is less number of case per week the number of days for data collection was increased. In case of more than one case present on the day of data collection then one out of them was selected via simple random sampling.

Inclusion Criteria:

1. Patients undergoing formation of a permanent end colostomy in an elective setting regardless of benign or malignant disease.
2. Age between 18 and 85 years.
3. Signed informed consent.

Exclusion Criteria:

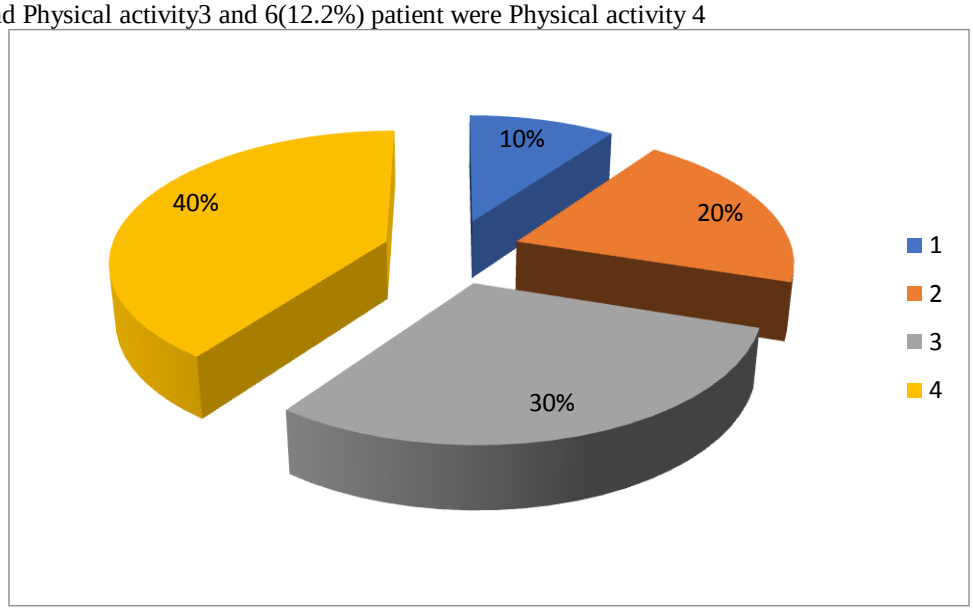
1. Expected survival <12 months.
2. Stoma formation in an emergency setting.
3. Formation of an ileostomy.
4. Correction of a previous constructed colostomy.

Statistical Analysis:

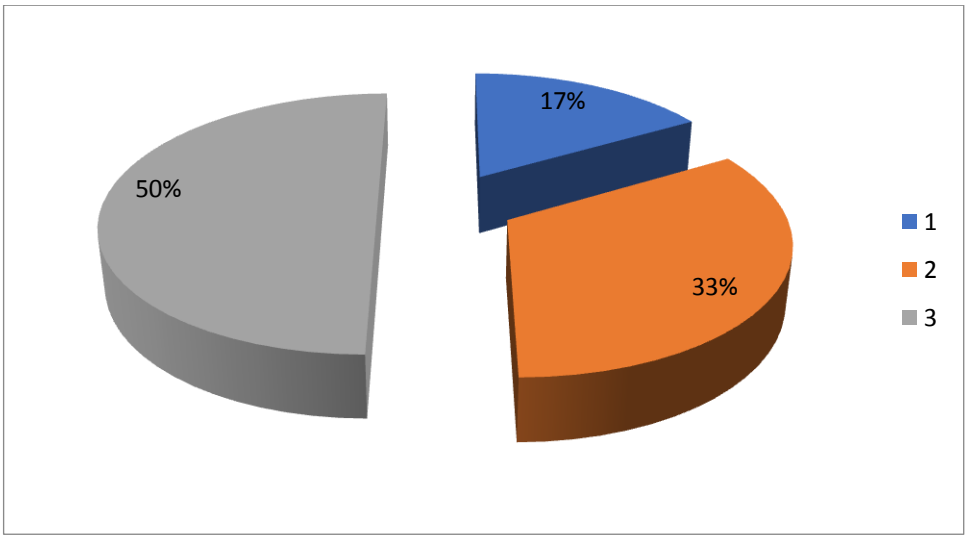
For statistical analysis data were entered into a Microsoft excel spreadsheet and then analysed by SPSS (version 27.0; SPSS Inc., Chicago, IL, USA) and GraphPad Prism version 5. Data had been summarized as mean and standard deviation for numerical variables and count and percentages for categorical variables. Two-sample t-tests for a difference in mean involved independent samples or unpaired samples. Paired t-tests were a form of blocking and had greater power than unpaired tests. A chi-squared test ($\chi 2$ test) was any statistical hypothesis test wherein the sampling distribution of the test statistic is a chi-squared distribution when the null hypothesis is true. Without other qualification, 'chi-squared test' often is used as short for Pearson's chi-squared test. Unpaired proportions were compared by Chi-square test or Fischer's exact test, as appropriate. Explicit expressions that can be used to carry out various *t*-tests are given below. In each case, the formula for a test statistic that either exactly follows or closely approximates a *t*-distribution under the null hypothesis is given. Also, the appropriate degrees of freedom are given in each case. Each of these statistics can be used to carry out either a one-tailed test or a two-tailed test. Once a *t* value is determined, a *p*-value can be found using a table of values from Student's t-distribution. If the calculated *p*-value is below the threshold chosen for statistical significance (usually the 0.10, the 0.05, or 0.01 level), then the null hypothesis is rejected in favour of the alternative hypothesis. p-value ≤ 0.05 was considered for statistically significant.

III. Result

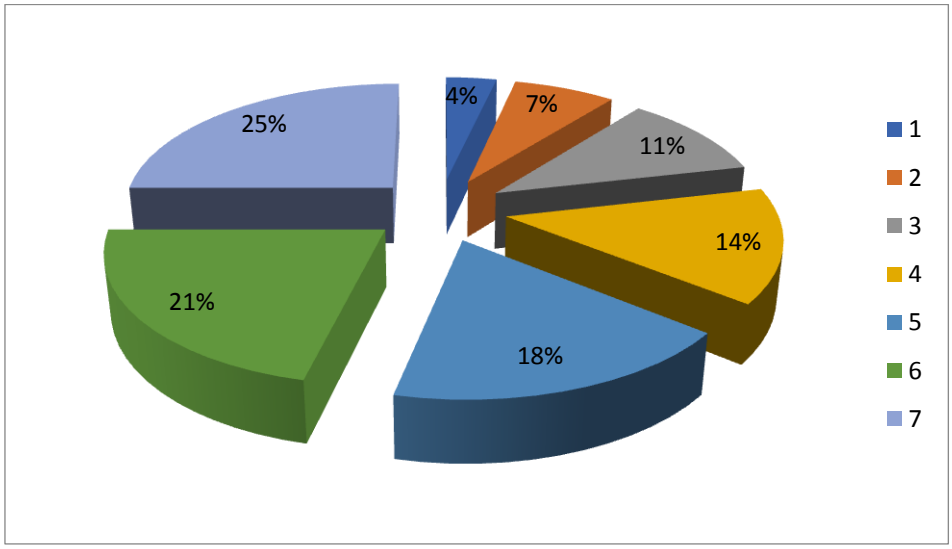
In our study, 4(8.2%) patients had Physical activity 1, 21(42.9%) patients had Physical activity 2, 18(36.7%) patients had Physical activity3 and 6(12.2%) patient were Physical activity 4



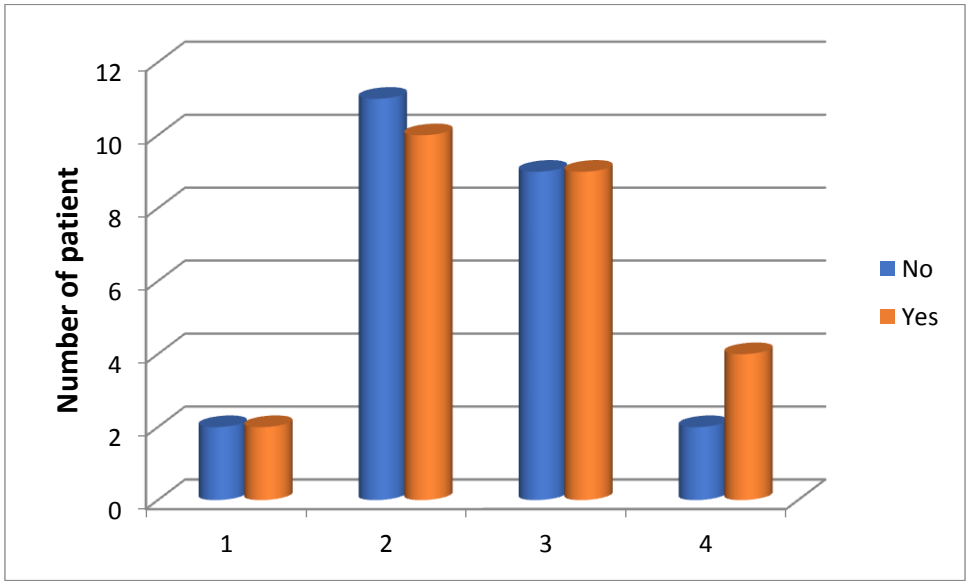
9(18.4%) patients had body mass index kg/m2 were Normal, 13(26.5%) patients had body mass index kg/m2 were Overweight and 27(55.1%) patients had body mass index kg/m2 were Obese



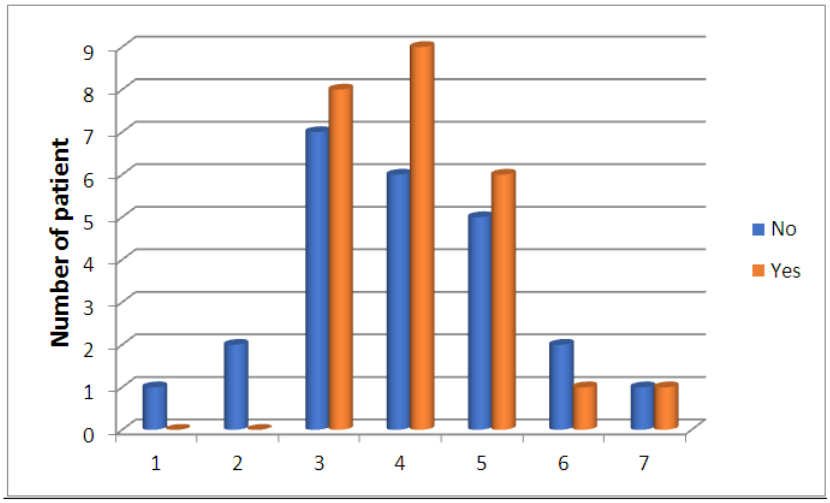
1(2.0%) patients had STRENGTH OF ABDOMINAL WALL 1, 2(4.1%) patients had STRENGTH OF ABDOMINAL WALL 2, 15(30.6%) patients had STRENGTH OF ABDOMINAL WALL 3, 15(30.6%) patients had STRENGTH OF ABDOMINAL WALL 4, 11(22.4%) patients had STRENGTH OF ABDOMINAL WALL 5, 3(6.1%) patients had STRENGTH OF ABDOMINAL WALL 6 and 2 (4.1%) patients had STRENGTH OF ABDOMINAL WALL 7.



Association of physical activity vs. prosthetic mesh was not statistically significant (p=0.8746).



Association of strength of abdominal wall vs. prosthetic mesh was not statistically significant (p=0.6669).



Association between development of parastomal hernia and Prosthetic Mesh

Patients who developed parastomal hernia	No. of patients who were given Mesh (25)	No. of patients who were not given Mesh (24)	Total (49)
Yes	2	8	10
No	23	16	39

IV. Discussion

Our Study showed that 15(30.6%) patients were ≤40 years old, 16(32.7%) patients were 41-50 years old, 12(24.5%) patients were 51-60 years old and 6(12.2%) patient were 61-70 years old. 10(20.4%) patients were Female and 39(79.6%) patient were Male. 4(8.2%) patients had Physical activity 1, 21(42.9%) patients had Physical activity 2, 18(36.7%) patients had Physical activity3 and 6(12.2%) patient were Physical activity 4. 22(44.9%) patients had diabetes. 36(73.5%) patients had smoking. 9(18.4%) patients had body mass index kg/m2 normal, 13(26.5%) patients had body mass index kg/m2 overweight and 27(55.1%) patients had body mass index kg/m2 obese and 27(55.1%) patients had infection. It was found that in Prosthetic mesh, 9(36.0%) patients were ≤40 years old, 7(28.0%) patients were 41-50 years old, 5(20.0%) patients were 51-60 years old and 4(16.0%) patient were 61-70 years old. Association of Age in Years vs. prosthetic mesh was not statistically significant (p=0.6084).

V. Conclusion

In our study, 25(51.0%) patients had prosthetic mesh.
Out of 25 people who were given prosthetic mesh ,2 of them developed parastomal hernia (8%)
and out of 24 who were not given prosthetic mesh 8 of them developed parastomal hernia (33.33%).
Out of 49 patients in the sample size 10 of then developed parastomal hernia and 39 patients did not.
Of the 10 patients who developed parastomal hernia, all 10 were diabetic, all 10 had history of smoking, all 10 had a predisposing infection. Out of the 10 patients who developed parastomal hernia 7 of them had colorectal cancer /metastases. Out of the 10 patients who developed parasternal hernia, 8 of them had high BMI (overweight/obese)

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