IOSR Journal of Dental and Medical Sciences (IOSR-JDMS)
e-ISSN: 2279-0853, p-ISSN: 2279-0861.Volume 17, Issue 11 Ver. 2 (November. 2018), PP 01-04
www.iosrjournals.org

Assessment of the patients for post procedure complications after Diagnostic Colonoscopy –A prospective multicenter study in Bangladesh.

Md. Masudur Rahman Khan[1], Madhusudan Saha[2], Malay Kumar Sur Chowdhury[3], ABM Safiullah[4], Mohammad Shoaib Chowdhury[5], Mahbubur Rahman[6], Mohammad Mahbubul Haque[7] , Md. Shakhawat Hossain[8]

***1.** Associate Professor, Department of Gastroenterology, BSMMU*
***2.** Professor, Department of Gastroenterology, North East Medical College, Sylhet*
***3.** Associate Professor, Sylhet MAG Osmani Medical College*
***4.** Assistant Professor, Department of Gastroenterology, BSMMU*
***5.** Assistant Professor, Department of Gastroenterology, BSMMU*
***6.** Consultant, Department of Internal Medicine, BSMMU.*
***7.** Associate Professor of Medicine, Sheikh Hasina Medical College, Jamalpur*
8. *Assistant registrar, Department of Gastroenterology, Rangpur medical college Hospital , Rangpur, Bangladesh*
Corresponding author – Md. Masudur Rahman Khan

Abstract: *Colonoscopy is a widely used procedure for diagnosis and treatment of colorectal disease as well as for colorectal cancer screening . But the procedure is not free of risk. The rate of serious complications was found about 0.28% and major complications mostly occur following interventional colonoscopy. In this prospective multicenter based descriptive study, adverse events after the procedure up to 30 days were recorded by telephonic conversation with patient on day 5, day 15 and day 30. Total 247 patients, age varying from 10 years to 90 years (mean 43.42 and SD 17.25) were included in this study for various indications. Of them 60(24.29%) patients complained pain and discomfort in abdomen during procedure, 06 (2.43%) patients developed bradycardia and 02(0.81%)patients developed respiratory distress preventing completion of procedure. Six patients (2.4%) required hospitalization within 05 days , 03 for respiratory distress, 01 for bloody diarrhoea and 02 for abdominal pain. None of the patients in this series had perforation, angina or shock. At the end of 30 days after procedure 205 (83%) patient agreed to undergo further colonoscopy if indicated. No death during or after procedure within 30 days was reported in our series.*

Date of Submission: 25-10-2018 Date of acceptance: 06-11-2018

I. Introduction:

Colonoscopy is a widely used procedure for diagnosis and treatment of colorectal disease as well as for colorectal cancer screening[1]. Over 14 million colonoscopies are performed annually in the United States, approximately half for screening indication [2]. It is generally safe and well tolerated procedure. But one third of patients complain of transient gastrointestinal symptoms [3,4]. According to systematic review of 12 studies, the rate of serious complications was found about 0.28% and major complications mostly occur following interventional colonoscopy [5]. Overall procedure related mortality was about 0.09%[6]. In Bangladesh colonoscopy has been performed in more than 100 institutions including outdoor setting and hospital based centers. And till now in most of the centers, sedation and analgesia are not used. But no data regarding complications during and within short period after procedure in our country is available. With this background this study was designed to see incidence and nature of complications of diagnostic colonoscopy performed in an outpatient setting during and within 30 days after the procedure.

II. Material and method:

This prospective multicenter based descriptive study was carried out in Department of gastroenterology of BSMMU, Dhaka and *North East Medical College*, Sylhet, Bangladesh from july 2016 to july 2017. Total 247 consecutive patients under-going diagnostic colonoscopy for variable indications were included in the study. Olympus GIF -160 & Olympus GIF-170 colonoscope was used for the study. All colonoscopy were performed by consultant gastroenterologist. Epidemiological features, indications, bowel preparation, findings and adverse events during procedure were recorded in a predesigned data sheet. Continuous monitoring of pulse rate and

oxygen saturation with pulse-oxymeter were done during procedue. Adverse events after the procedure up to 30 days were recorded after telephonic conversation with patient on day 5, day 15 and day 30. Mentally retarded and persons unwilling to participate the study were excluded. For bowel preparation 20% mannitol solution was used orally about eight hours before procedure. No sedation or analgesia were used during the procedure.

Study Design: Prospective observational study

Study Location: This was multicenter hospital based study done in Department of gastroenterology of BSMMU, Dhaka and *North East Medical College*, Sylhet, Bangladesh.

Study Duration: 01 year, from july 2016 to july 2017.

Sample size: 247 patients undergoing colonoscopy.

Sample size calculation: We assumed that the confidence interval of 10% and confidencelevel of 95%.

Subjects & selection method: The study population was drawn from consecutive patients under-going diagnostic colonoscopy for variable indications from july 2016 to july 2017.

Inclusion criteria:

1. Either sex
2. Aged ≥ 10 years,

Exclusion criteria:

1. Patients with previous history of angina, severe vascular disease, or other life threatening disease.
2. Patients with renal failure, active liver disease, bile duct problems, or ALT > 3 × ULN.
3. Patients taking concurrent Chemotherapeutic agents, ciclosporin, and/or hormone replacement therapy.
4. Patients who are physically inactive.
5. Patients not willing to take part in the study

III. Procedure methodology:

Total 247 consecutive patients under-going diagnostic colonoscopy for variable indications were included in the study. After written informed consent was obtained, a well-designed questionnaire was used to collect the data of the recruited patients retrospectively. Olympus GIF -160 & Olympus GIF-170 colonoscope machine were used for the study. All colonoscopy were performed by consultant gastroenterologist. Epidemiological features, indications, bowel preparation, findings and adverse events during procedure were recorded in a predesigned data sheet. Continuous monitoring of pulse rate and oxygen saturation with pulse-oxymeter were done during procedue. Adverse events after the procedure up to 30 days were recorded after telephonic conversation with patient on day 5, day 15 and day 30. For bowel preparation 20% mannitol solution was used orally about eight hours before procedure. No sedation or analgesia were used during the procedure.

IV. Statistical analysis:

Data was analyzed using SPSS version 20 (SPSS Inc., Chicago, IL). Mean and standard deviation were calculated for continuous data and percentage were calculated for categorical data. The level $P < 0.05$ was considered as the cutoff value or significance.

V. Result:

Total 247 patients, age varying from 10 years to 90 years (mean 43.42 and SD 17.25) were included in this study. Of them 143 (57.89%) were male and 104(43.1%) were female. Among them 82(33.2%) were housewives, 63(25.50%) were service holders and 39(15,79%) were businessmen respectively. Among them 131 ((53.03%) had education up to class five or below. Common indications were Bleeding per rectum 80(32.40%) and chronic diarrhoea 44(17.81%). Other indications were anaemia, abdominal lump, pain a abdomen, follow up of ulcerative colitis and carcinoma colon and screening for colorectal carcinoma. In this series, tissue biopsies were taken in 49(9.84%) patients. Sixteen patients had history of undergoing previous colonoscopy. Ileum was intubated in 121 (48.99%) while examination up to caecum was done in 61(24.7%) patients. Total colonoscopy could not be done in 38(15.38%). Of them in 24(9.72%) cases scope was withdrawn as patient had severe pain and discomfort, bradycardia and shortness of breath. In 14(5.67%) patents procedure could not be completed due to narrowing of lumen or mass lesion. During procedure 06 (2.43%) patients developed bradycardia and 02(0.81%)patients developed respiratory distress preventing completion of procedure. Although 60(24.29%) patients complained pain and discomfort in abdomen during procedure, of them procedure could be completed in 44((17.81%). Gut preparation was good in 72(28.7%) cases while average or acceptable and poor were in 92(36.7%) and 83(33.1%) cases respectively. In this series 222(89.87%) patients had positive idea regarding colonoscopy before undergoing examination. In this series neoplasm was found in 36(14.57%) cases. Other significant findings were normal in 111(44.93%), colorectal polyps in 30(12.14%), haemorrhoids in 38(15.38%) and ileo-caecal and colonic tuberculosis in 06(2.42%).

None of the patients in this series had perforation, angina or shock. Five (2.0%) patients had constipation and 04(1.62%) had diarrhoea after the procedure up to second telephonic conversations. Three (1.2%) patients had breathlessness and 03(1.2%) patients experienced fever for short period within 05 days of examinations. Six patients (2.4%) required hospitalization within 05 days of the procedure. Three of them had respiratory distress, 01 for bloody diarrhoea and 02 for abdominal pain and recovered uneventfully by conservative measures.
At the end of 30 days after procedure 205(83%) patient were agreed to undergo further colonoscopy if indicated.

Table I: Demographic Data

Age Range (years)	Percentage
11-30	23
21- 40	35
41-60	160
61-80	22
≥81	7

Age range: 10- 90 years, mean 43.42 y SD ± 17.25

Gender	Percentage
Male	143(57.9%)
Female	104 (42.1%)

Occupations	**Number**	**Percentage**
Student	21	8.5
Service	63	25.5
Housewife	82	33.2
Business	39	15.79
Farmer	29	11.74
Labour and unemployed	13	5.26
Education	**Number**	**Percentage**
Illiterate	45	18.22
Primary	86	34.82
Up to SSC	60	24.29
Up to HSC	30	12.15
Above HSC	26	10.53
Indications	**Number**	**Percentage**
Per-rectal bleeding	80	32.39
Anaemia	09	3.64
CRC screening	4	1.62
Chronic diarrhoea	44	17.81
IBS	21	8.50
Others	89	36.03

Table II: Colonoscopy findings

Findings	**Number**	**Percentage**
Normal	111	44.93
Colorectal neoplasm	36	14.57
Colorectal polyps	30	12.14
Haemorrhoids	38	15.38
Tuberculosis	6	2.42
Proctitis	5	2.04
Ulcerative colitis	4	1.62
Solitary rectal ulcer	3	1.21
Others(fissure, nonspecific colitis, Crohn's disease, etc)	11	4.45
Extent of examination	**Number**	**Percentage**
Up to terminal ileum	121	48.99
Up to caecum	61	24.70
Up to ascending colon	26	10.52
Up to hepatic flexure	15	6.07
Up to splenic flexure	08	3.24
Distal to splenic flexure	16	6.48

Table III: Complications of colonoscopy procedure

Complications	**During procedure**	**First 5 days**	**6-15 days**	**16-30 days**
Abdominal pain	60 (24.29%)	6 (2.42%)	6(2.42%)	0
Breathlessness	02(0.80%)	3(1.21%)	0	0
Bradycardia	6(2.42%)	0	0	0
Altered bowel habit	0	9(3.64%)	9(3.64)	0
Bleeding per rectum	0	1(0.40%)	0	0

Fever	0	2((0.8%)	0	0
Hospitalization	0	6(2.42%)	0	0

VI. Discussion:

In our study, most common complication of colonoscopy during and after procedure was abdominal pain. Multicentre study from the USA[4] also found abdominal discomfort and pain as most common adverse event after colonoscopy. But our study incidence was lower. Pain and discomfort may be due to excess air insufflation, manipulation of colonoscope and therapeutic interventions during procedures. In addition, ours is a two centres report with small sample size. Other report shows that pain is rare after colonoscopy performed with sedation[7].

During procedure abdominal pain was the commonest complication in our study. No sedation was used during procedure in our cases which may explain the pain. Bradycardia (although incidence was low) was the second most common complication in our study which may be due to fear and vagal stimulation. Another complication was respiratory distress which was also of lower incidence, might happen due to abdominal distension due to excessive air insufflation. In our series, only 01 patient had developed post procedural bleeding per rectum which is lower than other reports[4]. Chance of bleeding increases with intervention like polypectomy- specially large polyps[8,9,10]. Levin et al. reported chance of bleeding to be 3.2/1000 colonoscopy[11]. But in our study sample size was small and no therapeutic intervention was done.

Alteration of bowel habit both constipation and persisting diarrhoea were noted in our study but incidence was low. This may be related with use of drugs for bowel preparation and or procedural gut manipulation. In our study, 06 patients required hospitalization for short period within first week of procedure for respiratory distress and abdominal pain but recovered uneventfully. But cause of respiratory distress could not be confirmed over telephone. In our series, no patient had perforation. But incidence of perforation is 0.9/1000 colonocopies[11]. No death during or after procedure within 30 day was reported in our series. It may be due to small sample size, no use of sedation and absence of therapeutic intervention in our series.

VII. Limitations:

Sample size is smaller. No therapeutic intervention was done. Further study with larger sample size, including cases of both diagnostic procedure and cases with therapeutic intervension with or without sedation at multiple centres may be done in future for proper conclusion.

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