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Original Research Article

Impact of delay due to the first wave of the COVID-19 pandemic on elective surgical patients in a tertiary care center: a prospective observational study

Reddy A. Pullagura, Vishnu Prasad N. R.*

Department of Surgery, Division of GI and HPB Surgery, Jawaharlal Institute of Postgraduate Medical Education and Research, Puducherry, India

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***Correspondence:**
Dr. Vishnu Prasad N. R.,
E-mail: vprasad285@gmail.com

ABSTRACT

Background: Elective services were withheld in most parts of the world to cope with the stress on the healthcare system caused by the Coronavirus disease 2019 (COVID-19). However, delaying elective services for more than a particular duration adversely affects disease outcomes. This study aimed to assess the effect on elective surgical patients due to delays caused by withholding elective surgical services to deal with the COVID-19 pandemic at our institution.
Methods: This prospective observational study included all the patients who planned and waited for elective surgery till the day elective services were withheld at our institution (24 March 2020) due to the COVID-19 pandemic. All patients were followed until the patients were operated on or three months after resuming elective operative services at our institution. These patients were assessed to determine the proportion of patients with worsening symptoms, stage progression, and needing emergency procedures or palliative surgery.
Results: Breast cancer was the most common cancer among malignancy patients awaiting surgery. Compared to Breast cancer, Gastrointestinal cancers had a significantly higher proportion of patients with stage progression (61.3% vs. 90%, p=0.016) and mortality (6.5% vs. 53.3%, p<0.001). In benign patients, symptom progression was seen in 45.9%, and emergency surgery/procedures were needed in 5.4 %.
Conclusions: Even though the so-called elective surgery, postponing these surgeries, particularly cancer surgeries, can compromise the outcomes of the patients if delayed for more than a certain point.

Keywords: COVID-19, Elective surgical procedures, Breast neoplasms, Gastrointestinal neoplasms, Delivery of health care

INTRODUCTION

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), a causative organism of novel coronavirus disease 2019 (COVID-19), has a high rate of human-to-human transmission compared to influenza, with a case fatality rate of 3.5%.[1,2] World Health Organization (WHO) declared COVID-19 as a global pandemic on 11 March 2020.[3] Subsequently, an exponential increase in emergency department visits, inpatient admissions, and healthcare workforce shortage due to viral exposure and respiratory illness had adversely affected the effectiveness and sustainability of the health care system worldwide.[4] As an emergency measure, all medical staff, including surgical staff, were reallocated to manage COVID-19 patients worldwide. Moreover, multiple incidences of near-lockdown situations imposed worldwide have affected people's mobility and access to healthcare services, especially in developing countries.[5] The term "elective surgery" (ES) implies that the procedure is not immediately indicated in response to a limb or life-threatening emergency. However, an estimated 50% of all

elective surgeries can inflict harm if delayed or canceled.[6] Therefore, the adverse impact of the blanket suspension of ES facilities has to be weighed against the morbidity and mortality inflicted by COVID-19 itself.[3] A variety of literature is available on the precautions to minimize the community and healthcare spread of COVID-19 infection, efficient management of limited health resources, perioperative planning, ES risk-stratification, and factors leading to poor outcomes in COVID-19 patients following surgery.[7-10] However, there is a paucity of data on the impact of COVID pandemic-induced delay in elective surgeries on the patient's outcome. To conserve the resources necessary to manage the COVID-19 pandemic, as done in other countries like the United Kingdom, suspended elective services and a nationwide lockdown in India. Ours is a tertiary care center designated as a COVID-care center, and all elective surgeries were withheld from 24 March 2020.[11] The present study was conducted to evaluate the impact of the delay due to the suspension of elective surgeries at our institution on patients' outcomes during the first wave of the COVID-19 pandemic.

Objectives

The primary objective was to determine the proportion of malignant patients with stage progression waiting for surgery. The secondary objectives were to determine. The proportion of patients with worsening symptoms in malignant and benign cases and the proportion of patients needing emergency surgery or procedure in malignant and benign cases.

METHODS

Study design

This prospective observational study was done in the department of surgery, of a tertiary teaching hospital in India from March 2020 to April 2021.

Study population and sampling technique

All planned ES services under the department of surgery were withdrawn (24 March 2020) at our institute because of the COVID-19 pandemic, and such patients scheduled for ES were included in the study. In addition, the patients receiving neoadjuvant therapy would have been generally included for surgery or operation if elective operative services would not be withdrawn at our institute. Convenient sampling was used to include all the patient's awaiting surgery during the study period.

Exclusion criteria

Exclusion criteria for current study were patients below 18 years of age and patients who expired before the surgery due to causes unrelated to their diagnosis.

Study duration

From the time all elective surgeries were withheld at our institute, i.e., from 24 March 2020, all patients were followed up till the time they were operated on or a maximum period of three months after the elective operative services were resumed to pre-COVID-19 capacity at our institute.

Procedure

As per the inclusion criteria, all the patients from the departmental database were included in the study. The patients were communicated with using telecommunication services, and informed verbal consent was taken from all the participants. The patients were followed up for worsening previously existing symptoms, developing new symptoms, any emergency procedures done, or if operated outside. After resuming the ES services at our institute, the non-operated patients were followed up in the outpatient department. Informed written consent was taken from all the participants. The patients were assessed by a clinician other than the principal investigator for worsening or developing any new symptoms**.** Pain episodes were assessed in terms of severity using the visual analog scale (VAS) and frequency of pain episodes by the number of episodes per day or week; if the patient had suffered continuous pain, it was considered daily pain. Vomiting was categorized by the number of episodes per week and after taking a solid or liquid diet. Laboratory tests for parameters like bilirubin or hemoglobin were repeated. Swelling size progression was assessed by clinical examination or using an imaging modality based on the disease. Depending on the type of malignancy, stage progression was evaluated by clinical examination and imaging as required.

Statistical analysis

Data were assessed using SPSS 19 software. Continuous data were represented as mean±standard deviation or median with interquartile range based on normality of distribution. The categorical variables were expressed as percentages and compared using the Chi-Square or Fischer exact tests, p value <0.05 was considered significant for all the statistical analyses conducted.

RESULTS

The elective operative services were withheld at our institute on 24 March 2020 and were fully resumed on 25 January 2021. Therefore, non-operated patients were followed up till 25 April 2021. Among 88 malignancy patients enrolled in the study, 19 were lost to follow-up, and 69 were assessed (Figure 1).

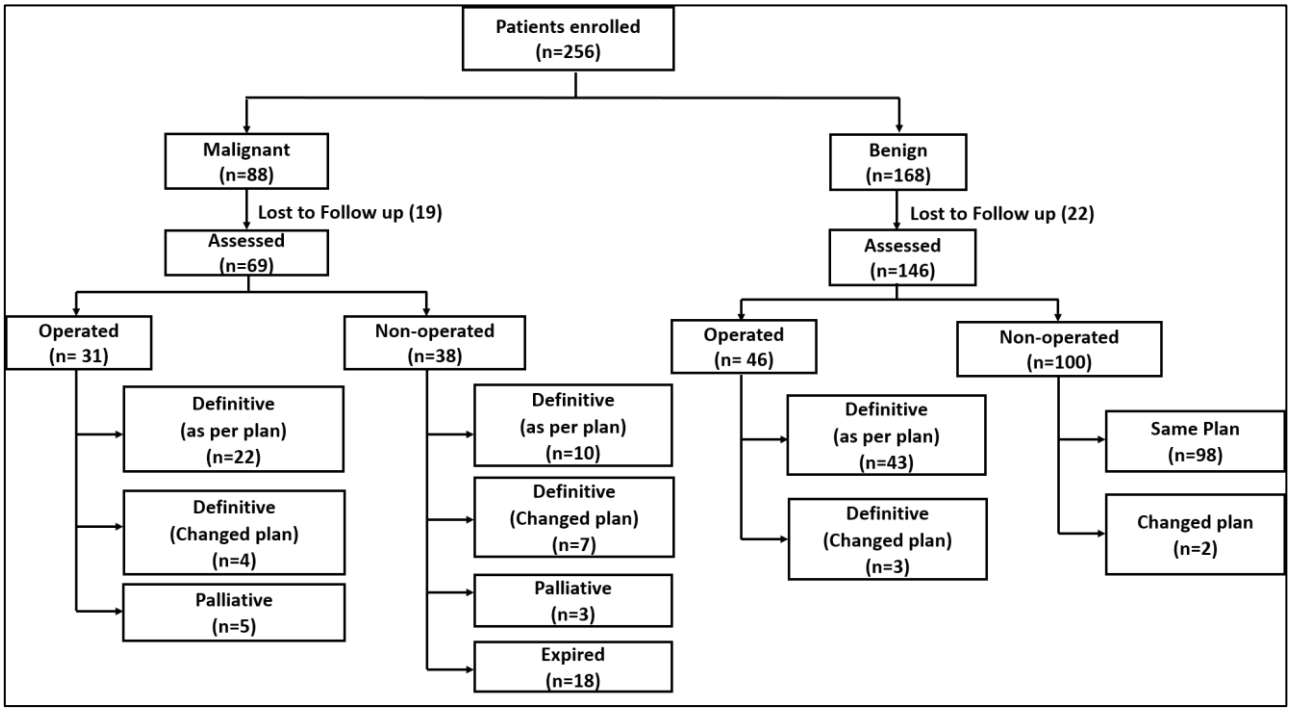

Figure 1: Enrolment, and follow-up of the patients in the study.

Table 1: Baseline demographic variables and follow-up data of malignancy patients (n=69).

Parameter	N	%
Age (Mean 52.1 years, SD ±11.5)		
Sex		
Male	22	31.9
Female	47	68.1
Site of malignancy		
Breast	31	44.9
Oesophageal	7	10.1
Gastric	6	8.7
Colo-rectal	8	11.5
Hepatopancreatobiliary	9	15.9
Thyroid	3	4.3
Miscellaneous[†]	5	7.2
Operated patients (Median delay 135 days (IQR, 89-223)	31	44.9
Surgery done		
Definitive (as initially planned)	22	31.9
Definitive (Changed, when compared to initial plan)	4	5.8
Palliative	5	7.2
Non operated patients	38	55.1
Surgical plan of non-operated patients		
Definitive (Same as initial plan)	10	14.4
Definitive (Changed, when compared to initial plan)	7	10.1
Palliative	3	4.3
Expired	18	26
Symptom progression		
Yes	49	71
No	20	29
Stage progression		
Yes	47	68.1
No	22	31.9
Emergency surgery/procedure	9	13

Continued.

Parameter	N	%
Palliative surgery	5	7.2
Diversion	2	2.9
Biliary drainage	2	2.9

The demographic profile and outcome variables are tabulated in (Table 1). The Mean age of the patients was 52.1±11.5 years. Carcinoma breast accounted for most waiting-for cases (44.9%). The Median delay in surgery for operated cases was 135 days (IQR, 89-223), whereas 55.1% (N=38) of patients were not operated till the end of the study. Of these patients, 71% (N=49) had symptom progression, and 68.1% (N=47) had stage progression. In 4.3% (N=3) of patients, the treatment plan was changed to palliative based on disease progression, and 26% (N=18) expired, awaiting surgery.

On comparing the patients' outcomes based on their malignancy site (Table 2), there was a statistically significant difference in stage progression (p<0.001) and mortality (p<0.001), whereas, in symptom progression, no statistically significant difference (p=0.056) was seen irrespective of the site.

As breast and gastrointestinal (GI) cancers (Esophagus, Gastric, Colo-Rectal, and Hepatopancreatobiliary cancers) formed the significant bulk of the patients (88.4%), on comparing breast malignancy patients with GI cancers (Table 3), higher stage progression rate (61.3% vs. 90.0%, p=0.016) and mortality (6.5% vs. 53.3%, p<0.001) was seen in GI malignancies. Symptom progression was also higher in GI cancers (86.7% vs. 64.5%), but this difference was not statistically significant (p=0.073). A change in definitive curative surgical plan (25.8% vs. 10%) or down gradation to palliative treatment (20.0% vs. 6.5%) was seen in a higher proportion of patients with GI malignancy as compared to breast malignancy at follow-up, which was statistically significant (Table 4).

Among 168 patients awaiting surgery for benign conditions who were enrolled, 22 patients were lost to follow-up, and a total of 146 patients were assessed (Figure 1).

The demographic profile and other variables are tabulated in Table 5. The mean age of patients was 45.8±14.1 years. The median delay in surgery for operated cases was 332 days (IQR, 194-396), whereas 100 patients were not operated till the end of the study. 46% (N=67) patients had symptom progression, whereas 8.2% (N=12) had improvement in their symptoms due to conservative measures.

Table 2: Comparison of patient outcomes based on site of malignancy.

Outcome	Symptoms progression Frequency (%)		Stage progression Frequency (%)		Mortality Frequency (%)	
	Yes (N=49)	No (N=20)	Yes (N=47)	No (N=22)	Yes (N=18)	No (N=51)
Breast cancer (N=31)	20 (64.5)	11 (35.5)	19 (61.3)	12 (38.7)	2 (6.5)	29 (93.5)
Thyroid cancer (N=3)	1 (33.3)	2 (66.7)	0	3 (100.0)	0	3 (100.0)
Gastro-intestinal cancers† (N=21)	18 (85.7)	3 (14.3)	19 (90.5)	2 (9.5)	8 (38.1)	13 (61.9)
Hepatopancreatobiliary cancers (N=9)	8 (88.9)	1 (11.1)	8 (88.9)	1 (11.1)	8 (88.9)	1 (11.1)
Miscellaneous cancers‡ (N=5)	2 (40.0)	3 (60.0)	1 (20.0)	4 (80.0)	0	5 (100.0)
P value	0.056*		<0.001*		<0.001*	

†Gastro-intestinal cancers: Oesophageal cancer, Gastric cancer, Colo-Rectal cancer, ‡Miscellaneous: Carcinoma Penis, Retroperitoneal tumor, Pleomorphic adenoma of the parotid gland, Malignant Melanoma, Adrenal Tumour, *Fischer exact test

Table 3: Comparison of patient outcomes of breast cancer and gastrointestinal malignancies.

Outcome	Symptom progression Frequency (%)		Stage progression Frequency (%)		Mortality Frequency (%)	
	Yes (N=49)	No (N=20)	Yes (N=47)	No (N=22)	Yes (N=18)	No (N=51)
Breast cancer (N=31)	20 (64.5)	11 (35.5)	19 (61.3)	12 (38.7)	2 (6.5)	29 (93.5)
Gastro-intestinal cancers† (N=30)	26 (86.7)	4 (13.3)	27 (90.0)	3 (10.0)	16 (53.3)	14 (46.7)
P value	0.073*		0.016*		<0.001*	

†Gastro-intestinal cancers: Oesophageal cancer, Gastric cancer, Colo-Rectal cancer, Hepatopancreatobiliary cancers, *Fischer exact test

Table 4: Comparison of surgical plan in patients with breast cancer and gastrointestinal malignancies.

Surgical plan	Follow-up				P value
	Plan as per admission (definitive)	Plan changed At follow up (definitive)	Plan changed to palliative	Expired	
Breast cancer (N=31)	19 (61.3)	8 (25.8)	2 (6.5)	2 (6.5)	<0.001*
Gastro-intestinal cancer† (N=30)	5 (16.7)	3 (10.0)	6 (20.0)	16 (53.3)	

†Gastro-intestinal cancers: Oesophageal cancer, Gastric cancer, Colo-Rectal cancer, Hepatopancreatobiliary cancers, *Fischer exact test

DISCUSSION

In this study, we prospectively followed the patients planned for ES from when elective surgeries were withheld at our institution due to the first wave of the COVID-19 pandemic. Malignant patients had poor outcomes. In malignancy cases, when compared to carcinoma breast, GI malignancies had a significantly higher percentage of patients with stage progression and mortality and underwent palliative surgeries. While in benign patients, although symptomatic progression was noted in 45.9% of patients, their surgical plan remained the same in almost all the patients, and none of the patients expired due to underlying disease during the follow-up. It is estimated that around 28 million elective surgeries were postponed or canceled globally during the pandemic's peak, and 90% of these are benign diseases.[12] In our study, benign cases formed the significant bulk of patients (66%) waiting for surgery when elective surgeries were withheld in our institution. Reasons for such extreme measures were to limit in-hospital transmission and adverse postoperative pulmonary complications and to optimize and divert healthcare infrastructure, workforce, and medical supplies for COVID-19 management. Elective surgeries were categorized into elective essential and elective discretionary by Sathel et al. Elective essential (cancer surgery, Hernia repair, Subacute cardiac valve prolapse, hysterectomy, and reconstructive surgery) being time-sensitive, are at an increased risk of adverse outcomes if such surgeries are delayed for an indeterminate period (more than one to three months).[3]

Moreover, surgical management remains the mainstay of curative treatment in managing many cancers. Even though the exact delay for malignancy patients following which the outcomes will be compromised is unknown, Fligor et al. systematically reviewed the literature between 2005 and 2020. They concluded that a delay of more than 30-40 days would adversely affect patients with GI malignancies.[13] In our cohort, the median delay in patients operated on for malignancy was 135 days (more than three months); therefore, a significant number of malignant patients had their surgical plan changed to palliative (11.6%) or expired due to delay in surgery (26%). Moreover, many patients were still awaiting (55.1%) surgery by the time this study was concluded.

Table 5: Baseline demographic variables and follow-up data of benign patients (n=146).

Parameter	N	%
Age (Mean 45.8 years SD±14.1)		
Sex		
Male	104	71.2
Female	42	28.8
Diagnosis of benign patients		
Inguinal and ventral hernia	65	44.5
Varicose vein	25	17.1
Fistula in ano and haemorrhoids	22	15.1
Gall Stone disease	14	9.6
Benign breast disease	5	3.4
Hydrocele	5	3.4
Ileostomy/colostomy (awaiting closure)	3	2.1
Benign thyroid disorders	3	2.1
Miscellaneous†	4	2.7
Operated (Median delay 332 days, IQR, 194-396)	46	31.5
Definitive as per plan	43	29.4
Changed plan‡	3	2
Non-operated patients' surgical plan	100	68.5
Same as initially planned	98	67.1
Plan changed when compared to the initial plan	2	1.3
Expired	0	0
Symptom progression		
Yes (symptomatically worsened)	67	45.9
No (same as initial symptoms)	67	45.9
Improved (symptomatically better)	12	8.2
Emergency surgery/procedure	8	5.4
Definitive	5	3.4
Biliary drainage (endoscopic biliary drainage)	3	2

According to Cancer statistics 2020, breast cancer is the most common malignancy and the fifth most common cause of cancer deaths after lung, colorectal, liver, and stomach cancer.[14] In our study, breast cancer comprises the majority of cancer patients (44.9%) awaiting surgery. Although it is difficult to compare the aggressiveness of different malignancies, survival statistics can be used to determine cancer prognosis.[15] Based on five-year survival rates, breast cancer (86%) has a better prognosis when compared to aggressive GI tumors (colorectal-65%,

pancreatic-39%, stomach- 32%, oesophageal- 20%, hepatic- 20%).[16] Similarly, due to delay caused by the first wave of COVID-19, stage progression and mortality were significantly more in GI cancers when compared to breast cancer. Perioperative COVID-19 infection has deleterious postoperative outcomes in the form of increased pulmonary complications and mortality.[17] But, the delay in curative surgery will lead to poor outcomes. Recent studies showed that, by taking appropriate perioperative precautions, COVID-19 free pathway, even the surgeries with a high risk of transmission could be performed safely with minimal cross-infection and post-operative outcomes similar to the pre-COVID-19 period.[18-20]

Moreover, any delay in curative surgery led to poor outcomes in symptom worsening, stage progression, and, at worst, mortality, as seen in our study. Therefore, a balanced approach is required to manage the COVID-19 pandemic and patients seeking treatment for non-COVID illness by following the COVID-19-free pathway. Closure of elective services to optimize health resources utilization and fear of poor perioperative outcomes for elective surgeries are only some factors responsible for the delay. Certain factors like lockdown-induced travel restrictions, accommodation, and food availability made it difficult for patients to reach healthcare facilities. Economic constraints caused by the loss of livelihood by the COVID-19 pandemic also affected healthcare access and spending. Finally, patients' apprehension due to fear of Covid-19 cross-infection played a significant role as a hindrance to seeking health care.[21]

The delay in resuming elective services in our center was much more than the global average of 12 weeks, as ours being a tertiary COVID-19 care center, caters to a large population of sicker COVID-19 patients referred from other centers as well.[12] Therefore, even after the peak had passed, we had a sizeable number of COVID-19 patients in our hospital, leading to a slow escalation of regular services. Complete services were resumed only on 25th January 2021. But, due to the surge of COVID-19 cases in March 2021, elective surgeries were again withheld from 10 April 2021. As the pandemic continues to evolve, to avert the poor outcomes caused by delaying elective essential surgeries, instead of blanket suspension of elective services, surgery decisions should be made on a case-by-case basis, and by following COVID free pathway, a balance should be reached to minimize the cross-infection and optimize surgical outcomes. The main strength of our study is that we, in reality, noted the impact on patient outcomes caused by delays due to the first wave of the COVID-19 pandemic on both malignant and benign patients. In contrast, the previous studies could only envisage the poor outcome caused by the delay.

Limitations

Limitations of current study were; firstly, the study design is observational and descriptive without a control group; hence the conclusion of poor outcomes on delay due to the first wave of COVID-19 cannot be made. Secondly, the delay was considerably more than that noted internationally, an average of 12 weeks during the pandemic's peak. Thirdly, our study included a smaller study sample size. To know the real impact caused by delaying elective services on elective surgical patients, a multicentric study including broader surgical diseases can be done with the historical data as a control group.

CONCLUSION

The COVID-19 pandemic has drastically changed the usual way of life and work of almost all individuals and organizations. Public and private healthcare systems are the worst affected among them. Some elective Surgeries (elective essential) are time-sensitive and delaying, which results in poor outcomes, as could be noted more in malignancy patients than in benign. Even in malignancy, aggressive GI cancers had deleterious outcomes compared to breast cancer. With appropriate precautions, elective surgeries can be continued. Priority should be given to cancer surgery, especially GI cancers, for better cancer outcomes.

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