

Original Article

## Retrospective analysis of clinicopathological characteristics and survival outcome of gastrointestinal stromal tumors: Real-world experience

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### ABSTRACT

**Objectives:** Gastrointestinal stromal tumors (GISTs) are the most common mesenchymal tumors of the gastrointestinal tract. Its true incidence, prevalence, and outcome have been less studied in the Indian subcontinent. We conducted the study to analyze the clinicopathological and survival outcomes of GIST patients to get a real-world scenario of a tertiary care hospital in India.

**Material and Methods:** A retrospective review was conducted of all newly diagnosed GIST patients presenting from January 2015 to December 2024 to the radiotherapy department of a tertiary care hospital in Kolkata. Data on demographic, clinical, pathological, treatment, and follow-up details were retrieved from case records. Patients were categorized as operable localized, unresectable non-metastatic, or metastatic GIST. Operated cases were risk-stratified using the College of American Pathologists (CAP) criteria. Survival analysis was performed with DFS calculated for upfront operated patients and progression-free survival (PFS) for those patients who presented with unresectable non-metastatic disease and metastatic disease.

**Results:** The cohort of 51 patients (mean age 50.7 years; 37 (72.5%) male, 14 (27.5%) female) had a median follow-up of 34 months. At presentation, 34 patients (67%) had operable localized disease, 8 patients (15%) had unresectable non-metastatic disease, and 9 patients (18%) had metastatic disease. The primary tumor originated in the small intestine in 21 patients (41%) and in the stomach in 19 patients (37%), with the remaining cases arising in the rectum, colon, or retroperitoneum. 5-Year DFS for localized operable cases was 89%. 3-Year PFS for unresectable non-metastatic GIST patients was 68%. Median PFS for metastatic cases was only 20 months, and 3-year PFS for metastatic cases was only 17%.

**Conclusion:** Our study revealed a nearly equal distribution of GISTs between the stomach and small intestine, despite the stomach being the most common primary site reported in the global literature. The occurrence of localized and metastatic GIST aligns with global literature findings, though our patients presented at a younger age with a higher male predominance. Survival outcome is at par with the Western data. Late recurrences are common after completion of adjuvant Imatinib, which warrants longer follow-up.

**Keywords:** Disease-free survival, DOG1, GISTs, Neoadjuvant imatinib

### INTRODUCTION

Gastrointestinal stromal tumors (GISTs) are the most common mesenchymal neoplasm of the gastrointestinal (GI) tract, accounting for 1 to 3 percent of all GI malignancies.<sup>[1,2]</sup> GISTs occur throughout the entire GI tract, the stomach and small intestine being the two most common sites, accounting

for 60% and 30% respectively.<sup>[3]</sup> Less than 5% of GISTs occur in the rectum, omentum, esophagus, and mesentery.<sup>[4]</sup> The annual incidence of GIST is between 11 and 14.5 cases per million.<sup>[5]</sup> GISTs usually occur between 65 and 69 years of age; however, they are relatively uncommon in individuals less than 40 years of age.<sup>[6,7]</sup> Incidence is almost similar among both sexes. The incidence of GIST varies across

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different geographical regions. In a systematic review of 29 studies, conducted across 19 countries, they showed that incidence from Northern Norway, Hong Kong, and Korea is approximately 9–22 cases per million inhabitants, while incidences are lower from North America, Slovakia, etc. (4.3–6.8 cases per million).<sup>[6]</sup> Approximately 69% patients with primary GIST arising from the gastrointestinal tract present with site-specific clinical symptoms. However, a small proportion of GISTs are asymptomatic and detected incidentally during imaging, clinical examination, or during autopsy.<sup>[8]</sup> The tumor size, mitotic index, and site of the tumor are reliable prognostic factors of the disease. Patients with tumors less than 2 cm in size have a better prognosis, thus leading to a conservative approach in their management in comparison to those more than 5–10 cm in size, which have a worse prognosis. In addition, stomach GISTs have a better prognosis in comparison to small intestinal or rectal GISTs.<sup>[4,9]</sup>

Immunohistochemistry (IHC) is the cornerstone for confirming the histological diagnosis of GIST. The hallmark of most GISTs is their positivity for CD117 (kit) and DOG1(ANO1).<sup>[10]</sup> 70% to 80% of GISTs harbor a mutation in the KIT gene, and 8 to 10% have mutations in the PDGFRA gene; mutations in these genes are mutually exclusive. PDGFRA genetic mutations are usually found in GISTs originating from the stomach and those with epithelioid morphology, and have a less malignant course of the disease.<sup>[11]</sup> The main treatment approach in GIST is surgery and adjuvant targeted therapy with tyrosine kinase inhibitors, while chemotherapy and radiotherapy are rarely used approaches in the era of TKIs.<sup>[3]</sup> The incidence of GIST in the Indian population and the impact of its pathologic and histologic characteristics on management, including the treatment strategy, is largely derived from studies in other global populations.<sup>[12]</sup> Thus, there is a need for data regarding the clinicopathologic characteristics of GIST in the Indian population. The aim of our study is to identify the clinical and pathologic characteristics of GIST patients diagnosed at our center and impact on the treatment strategy in these varied clinical situations.

## MATERIAL AND METHODS

A retrospective review was conducted on all newly diagnosed patients of GIST who presented it from January 2015 to December 2024 to the radiotherapy department of a tertiary care hospital in Kolkata. Approval from the Institutional Ethics Committee with reference number (Memo no. IPGME&R/IEC/2025/0253 dated 05.08.2025) was obtained prior to the initiation of the study. Considering the retrospective record-based nature of the study, the Institutional Ethics Committee has granted a waiver for the informed consent requirement for the study. Patient

data pertaining to the demographic, clinical, pathological, treatment, and follow-up details were obtained from the case record forms. Clinical variables included age, sex, presenting symptoms, and status at presentation. According to clinical presentation, patients were categorized into operable localized GIST, unresectable non-metastatic GIST, and metastatic GIST. Pathologic variables included tumor site, size, morphological variant, necrosis, and mitosis. Statistical Analysis was performed using Statistical Package for Social Science (SPSS) software (Version 22.0, SPSS, Inc., Chicago, IL, USA).

Biopsy specimens of all the diagnosed cases of GISTs were rechecked from the oncopathology unit of the institution. Tissue blocks were checked for c-KIT (CD117) or DOG1 positivity, if not done previously, and only confirmed cases were included for analysis. For unresectable non-metastatic GIST & metastatic GIST cases, diagnosis was made by image-guided core needle biopsy from the primary tumor or from the metastatic lesion.

Operated cases were risk-stratified using the College of American Pathologists' (CAP) criteria based on tumor site, size, and mitotic rate. With this criterion, post-operative cases were categorized into very low risk, low risk, intermediate risk, and high risk of malignant potential. Based on the risk of recurrence, some patients were treated with adjuvant therapy using Imatinib. DFS was calculated from the date of surgery to the date of relapse or the date of last follow-up.

Patients with unresectable non-metastatic GIST were treated with neoadjuvant therapy followed by reassessment for surgery. Before initiating neoadjuvant oral Imatinib, Tru-cut biopsy followed by IHC confirmation using c-KIT (CD117) or DOG1 was performed. Patients with metastatic GIST were treated with oral Imatinib with a palliative intent. For patients with unresectable and metastatic disease, progression-free survival (PFS) was calculated from the date of initiation of treatment with oral Imatinib.

## RESULTS

A total of 51 patients were selected in our study for final analysis. 42 patients (82%) presented with localized disease, and 9 patients (18%) presented with metastatic disease. Of 42 patients with localized disease, 34 patients (67%) were found to have resectable disease and underwent upfront surgery. Whereas 8 patients (15%) were deemed unresectable by the Surgical Oncologist, and neoadjuvant oral Imatinib was started to downsize the tumor. The median duration of follow-up was 34 months (6 months to 85 months).

The clinicopathological profile of the patients is given in Table 1. The mean age of the study cohort is 50.7 years, with a minimum age of 16 years and a maximum of 80 years. Of the

total study population, there were 37 male patients (72.5%) and 14 female patients (27.5%). Location-wise, 21 patients had small bowel primary (41%), which was found to be the most common, followed by 19 patients with primary in the stomach (37%), the second most common site. 4 patients (8%) had colorectal GIST, and 7 patients (14%) had extra-intestinal GIST. Bleeding (19 patients, i.e., 37%) and pain (17 patients, i.e., 33%) constitute major presenting symptoms of our study population. Spindle cell variety was found in 45 patients (88%), which constituted the major histopathological subtype.

**Table 1: Clinicopathological profile of patients (n=51)**

Clinicopathological Factors	Category	Distribution
Age	Mean age (range)	50.67 years (16 to 80 yrs)
	40 Years and below	8 (16%)
	41 yrs to 50 yrs	16 (31%)
	51 yrs to 60 yrs	20 (39%)
	Above 60 yrs	7 (14%)
	Sex	Male
	Female	14 (27.5%)
Location	Stomach	19 (37%)
	Small bowel	21 (41%)
	Colorectal	4 (8%)
	Extra-intestinal	7 (14%)
Symptoms at presentation	Bleeding	19 (37%)
	Pain	17 (33%)
	Multiple symptoms	12 (24%)
	Abdominal lump	2 (4%)
	Bowel obstruction	1 (2%)
Mitosis	≤ 5/50 HPF	24 (47%)
	> 5/50 HPF	27 (53%)
Histopathological subtype	Spindle cell type	45 (88%)
	Epithelioid cell type	4 (8%)
	Mixed	2 (4%)
Necrosis	Present	12 (24%)
	Absent	20 (39%)
	Unknown	19 (37%)

HPF: High power field

### Operable localized GIST (n=34)

34 patients (67%) underwent upfront surgery [Table 2]. 17 patients (50%) were treated with resection and anastomosis, particularly for intestinal mass. Wedge resection was done in 5 patients (15%), and total gastrectomy was done in 3 patients (9%), who were used for smaller and larger gastric

masses, respectively. Wide local excision was performed in 8 patients (23%). The mean size of the resected tumor is 7.5 cm, with a minimum size of 3 cm and a maximum size of 17 cm. Postoperative margin is free from any tumor involvement in 21 (62%) cases, whereas in 6 (18%) cases margin is involved. In 7 (20%) cases, although the proximal and distal resection margins were free, we could not get the circumferential resection margin. In view of the exophytic growth of GISTs, the circumferential resection status constitutes an important parameter for R0 resection. Hence, we have categorized these cases as resection margin status unknown.

**Table 2: Type of surgery and histopathological characteristics of operable localized cases (n=34)**

Characteristics	Category	Frequency
Type of surgery	Resection and anastomosis	17 (50%)
	Wide local excision	8 (23%)
	Wedge resection	5 (15%)
	Gastrectomy	3 (9%)
	Multi-visceral resection	1 (3%)
Size of tumor	Mean size	7.5 cm
	Minimum size	3 cm
	Maximum size	17 cm
Margin of resection	Negative	21 (62%)
	Positive	6 (18%)
	Unknown	7 (20%)
Mitosis	≤ 5/50 HPF	20 (59%)
	> 5/50 HPF	14 (41%)

HPF: High power field

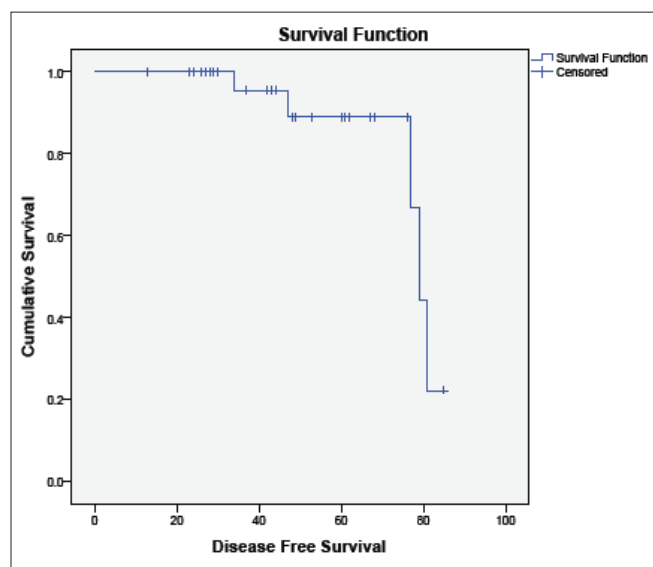
Based on location, primary tumor size, and mitotic rate, we have categorized each subject into very low risk, low risk, moderate risk, and high-risk using the CAP guideline [Table 3]. Although adjuvant Imatinib is indicated in intermediate and high-risk cases, adjuvant therapy with oral Imatinib was seen in 29 patients (85%). Adjuvant Imatinib therapy is usually started within one month following surgery.

**Table 3: Risk categorization and use of adjuvant therapy in operable cases (n=34)**

Variables	Category	Frequency
Risk categorization	Very low risk	5 (15%)
	Low risk	9 (26%)
	Moderate risk	6 (18%)
	High risk	14 (41%)
Use of adjuvant imatinib	Yes	29 (85%)
	No	5 (15%)

5-Year DFS for operated cases was 89% [Figure 1]. Most patients were treated with three years of adjuvant oral

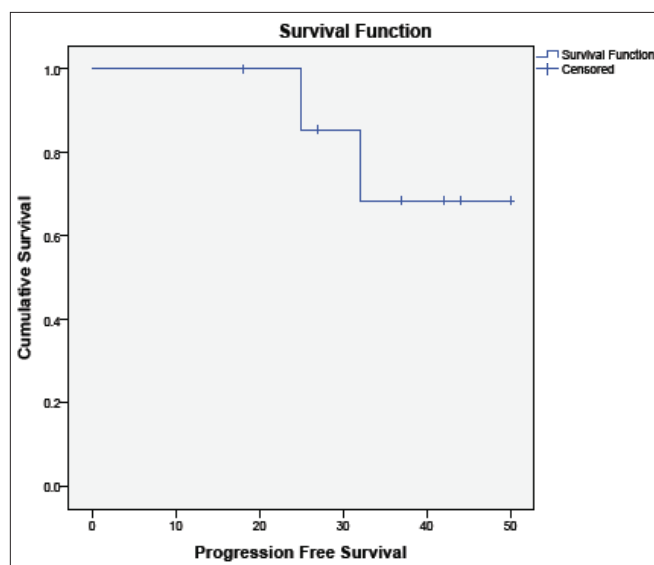
Imatinib (with a dose of 400 mg once daily), whereas some patients received oral Imatinib (with a dose of 400 mg once daily) for five years at the discretion of the concerned oncologist. Five patients developed recurrence during the follow-up period. All the recurrences, except one, developed after the completion of adjuvant therapy.



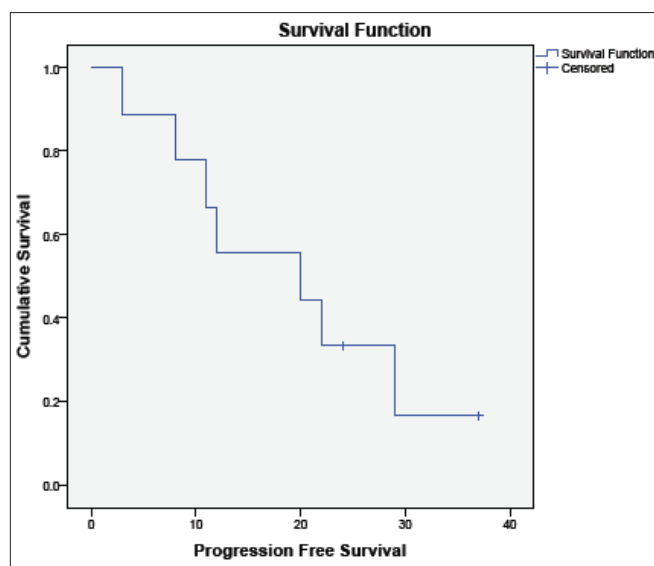
**Figure 1:** Disease-free survival of operable non-metastatic GIST (Gastrointestinal stromal tumors) (n=34)

#### Unresectable non-metastatic GIST (n=8)

Though not metastatic, these patients could not be operated on upfront often due to the huge size of the mass or due to proximity or adherence to critical structures, thus making them not amenable to upfront surgery. Eight patients (15%) presented with unresectable disease at diagnosis. Six patients were deemed unresectable by surgical oncologists due to large tumor size (all had tumor sizes of more than 13 cm). Two patients had a smaller tumor size, but the location was in an eloquent area. One patient was having an anorectal mass, and another was having a posterior vaginal wall mass. Eight patients were started on neoadjuvant therapy with oral Imatinib at an initial dosing of 400 mg daily for 3 months. Clinically, all patients had symptom improvement with oral Imatinib therapy. After three months of neoadjuvant therapy, repeat imaging was performed to assess the response to treatment. Six patients had radiological partial response, and two patients had stable disease. Five patients underwent definitive surgery, and three patients remained unresectable after three months of neoadjuvant therapy. After definitive surgery, adjuvant oral Imatinib was continued. Three patients, who had symptom control, were continued on oral imatinib until disease progression. Upon disease progression, oral Sunitinib was administered as second-line therapy. 3-year PFS for these patients was 68% [Figure 2].



**Figure 2:** Progression-free survival (PFS) of unresectable non-metastatic GIST (Gastrointestinal stromal tumors) (n=8)



**Figure 3:** Progression-free survival (PFS) of metastatic GIST (Gastrointestinal stromal tumors) (n=9)

#### Metastatic GIST (n=9)

Nine patients (18%) were diagnosed with metastatic disease at presentation. Primary tumor size in metastatic cases ranged from 10 cm to 17 cm. Liver and peritoneum constituted major sites of metastasis in our series. Three out of nine patients had undergone surgery for the primary disease. All three patients had to undergo multi-visceral resection to remove large primary lesions. One patient with a large mass arising from the D2-D3 segment of the duodenum had to undergo D2-D3 resection along with right hemicolectomy, along with ileo-transverse anastomosis. After biopsy

confirmation of metastatic disease and surgical resection of primary mass in selected cases, all patients were started on therapy with Imatinib. Seven patients were started at a dosage of 400 mg once daily, whereas two patients were started on an initial dosing of 400 mg twice daily at the discretion of the concerned oncologist. Patients who experienced disease progression were subsequently treated with oral Sunitinib as second-line therapy. Median PFS for metastatic cases treated with Imatinib therapy was only 20 months, and 3-year PFS was only 17% [Figure 3].

## DISCUSSION

GISTs are the most common mesenchymal tumors of the gastrointestinal tract. We retrospectively reviewed the clinicopathological characteristics and management of all patients with GIST presenting to our department. The median age at diagnosis, as reported in world literature, is 60 to 65 years.<sup>[13]</sup> However, our study revealed an age predilection of around 10 years younger, which is in concordance with other reported series from the Indian sub-continent.<sup>[14]</sup> Our cohort had a male preponderance, with a male: female ratio of 2.8:1. Although male preponderance has been noted in other studies,<sup>[13]</sup> however our study reported almost 3 times male predominance. According to world literature, the most common site of origin is the stomach (55.6%), followed by the small intestine (31.8%), while uncommon sites are the colorectum (6%), the esophagus (0.7%), and the omentum/mesentery.<sup>[6,13]</sup> We found almost equal incidence of GIST in both stomach and small bowel (37% and 41%). Apart from these, colorectal and extraintestinal GISTs constituted 8% and 14% of the entire study cohort, respectively.

The clinical presentation of GISTs is variable, but the most common symptoms noted were abdominal pain and gastrointestinal bleeding.<sup>[6]</sup> A symptomatic tumor mostly presents with GI bleeding and anemia.<sup>[15]</sup> Studies also showed that about 70% of GIST were diagnosed depending on symptoms, 20% of GIST were incidentally found at surgery, and the remaining were found at autopsy.<sup>[8]</sup> In our study, the common presentations observed were gastrointestinal bleeding (37%), followed by abdominal pain (33%). No incidentally detected case was found. These deviations from international data may be explained by late presentation in the natural history of the disease among lower socio-economic groups (which comprises the majority of the study population) in India.

The mainstay of management in the case of localized operable GIST remains surgery. In our series, 34 patients (67%) underwent upfront surgery. Patients underwent resection anastomosis (50%) for intestinal and colorectal primary, followed by wedge resection and gastrectomy (24%) for stomach primary. Wedge resection (23%) and multivesicular resection were performed for extraintestinal GISTs. All patients underwent laparotomy followed by removal of the

primary lesion with the intention of achieving R0 resection. Postoperatively, margin was involved in 6 cases (18%), and in 7 cases (20%), the margin status was unknown. Re-excision was not attempted for patients with R1 resection. As per international consensus, re-excision for a microscopically positive margin is not routinely recommended.<sup>[13]</sup>

Risk stratification was done retrospectively, and classification of cases into risk groups was done based on the CAP guideline. This guideline is based on the studies conducted by Fletcher *et al.* in 2002 and Miettinen & Lasota in 2006.<sup>[16,17]</sup> In a study from Turkey done on 249 cases, 47% belonged to high risk category.<sup>[18]</sup> High-risk tumors comprised approximately 70% and 60%, respectively, of all cases in two studies from India.<sup>[14,19]</sup> Our study had approximately 41% patients in the high-risk category, which corroborates with the Turkish study.<sup>[20]</sup>

Adjuvant oral Imatinib given at the dose of 400 mg once daily has a definite role for patients in the intermediate and high-risk categories. All our patients of intermediate and high-risk category (which comprised 59% of the study population) received adjuvant oral Imatinib. Although not indicated in the low-risk category, some patients in our series received adjuvant oral Imatinib despite being in the low-risk group, as the margin of resection was involved or unknown. In total, 29 patients (85% of the operable localized group) received adjuvant oral Imatinib. Most of our patients received adjuvant Imatinib for 3 years; however, some patients in the high-risk category were continued on adjuvant oral Imatinib for 5 years as per the treating oncologist's discretion. The IMADGIST RCT compared 6 years of adjuvant Imatinib with 3 years and it showed an improvement of DFS (42% in the 3-year arm versus 72% in the 6-year arm).<sup>[20]</sup> In our study, 5-year DFS was 89%. Similar improvement of DFS was seen in other studies, too.<sup>[21]</sup> 5 patients (15%) developed recurrence during the follow-up period, of which 4 recurrences developed after the completion of adjuvant therapy. This is consistent with a recent report in gastric GIST also showing a high risk of relapse after the end of adjuvant oral Imatinib.<sup>[22]</sup> In the IMADGIST study, the relapse rate was close to 50%, 3 years after the end of the standard 3 years of adjuvant treatment.<sup>[20]</sup> The current recommendation suggests the duration of adjuvant oral Imatinib should be at least 3 years for high-risk cases.<sup>[13]</sup> Studies are ongoing to establish the optimal duration of adjuvant Imatinib treatment.

For patients with large, localized GIST that is unresectable due to the risk of unacceptable morbidity, preoperative Imatinib is indicated to downsize the tumor. This also facilitates organ or function-preserving surgery if the tumor is in a critical location. In 8 patients (15%), unresectable patients, neoadjuvant Imatinib was given for 3 months at the dose of 400 mg once daily. In the RTOG 0132 trial, they

have used neoadjuvant Imatinib for 8 to 12 weeks, although at a higher dose of 600 mg once daily.<sup>[23]</sup> In our institution, 400 mg once daily was used as the preferred dose by the treating oncologist. Median time of response to Imatinib is 3 months, as reported in a phase II trial, which showed that response to Imatinib reached a plateau at 6 months in unresectable GISTs.<sup>[24]</sup> The optimal duration of neoadjuvant therapy thus ranges from 3 to 6 months. After neoadjuvant therapy, response assessment can be done by CT imaging (Choi criteria), which considers CT density.<sup>[25]</sup> Also, FDG PET CT is an attractive option as GISTs have high glucose metabolism. In our cohort of patients, response assessment was done by contrast-enhanced CT imaging after 3 months of neoadjuvant treatment, which is at par with published literature. Out of 8 patients, 6 patients achieved a partial response. However, surgery was feasible in 5 patients (62% of the unresectable GISTs). In the Asian study on large gastric GISTs (size>10cm), surgery could be achieved in 91% patients with 6 to 9 months of neoadjuvant therapy with oral Imatinib.<sup>[26]</sup> 3-year PFS for these unresectable non-metastatic GISTs treated with neoadjuvant oral Imatinib was 68%. In the ACRIN 6665 trial, patients were followed up for 5.14 years. 5-year PFS and OS was 57% and 77%, respectively.<sup>[23]</sup> In an Asian study on large gastric GISTs, 2-year OS was 89%.<sup>[26]</sup> 3-year PFS in our study corroborates the world literature.

The most common metastatic sites of GIST are the liver (65%) and the peritoneum (21%). GISTs rarely metastasize to lymph nodes (6%), bone (6%), and lungs (2%).<sup>[16]</sup> Our study results corroborated these data, as liver and peritoneum are the major metastatic sites. The advent of TKIs like Imatinib has greatly improved the survival of metastatic GIST patients, thus pushing surgery to take a backseat. Though there is no direct evidence to support the role of surgery, it is reasonable to deduce that the incidence of drug resistance is in proportion to the amount of tumor cells exposed and the duration of Imatinib administration. Thus, to combat Imatinib resistance due to continuous medication, surgical intervention to reduce or eliminate tumor burden is a viable option, in surgically respectable sites, even in this era of TKIs. In our study, the majority of patients in metastatic cases presented with a huge tumor burden not amenable to surgery, thus leading to surgery being offered to 33% of patients, and often, multivessel resection was offered. In our series, three patients who underwent multivesicular resection (MVR) at the diagnosis of metastatic disease had better PFS than the other six patients who did not undergo surgery. Two international, multicenter phase III trials proved the efficacy of oral Imatinib in delaying progression and prolonging life in patients with metastatic GIST.<sup>[27,28]</sup> One study reported a median PFS of 25 months.<sup>[27]</sup> In our study, the median PFS was 20 months, and the 3-year PFS was 17%. Similar PFS data were published in the SWOG intergroup trial.<sup>[28]</sup>

This study has several limitations, such as the retrospective nature of the study, small sample size, and heterogeneity of tumor site. Also, in most cases, surgery, which is the primary modality in operable GISTs, was not done by surgical oncologists, further limiting the survival of such patients.

The study has certain strengths, too. Treatment uniformity was maintained as this was single institutional study. The study duration was 10 years, thus allowing a longer follow-up period. Also, the size of the tumor varied from 3 to 17 cm and ranged from operable to metastatic cases. Such diversity gave a broader overview of real-world scenarios in a resource-limited country.

## CONCLUSION

In conclusion, it was evident from this study that surgery remains the mainstay of treatment in operable GISTs. With the advent of Imatinib, survival is favorably increased in operable and metastatic cases. However, in metastatic cases, median PFS with Imatinib is still dismal, hovering around 2 years. Further studies need to be conducted regarding the inculcation of molecular studies in categorizing GIST and exploring other TKIs to improve survival.

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**Author contributions:** HMS, BC, MP and NBP: This all authors read and approved this manuscript. We certify that we fulfill the ICJME authorship through our contributions to the study design, data analysis, manuscript drafting, critical revision, and approval. We affirm the honesty and validity of this work and accept responsibility for its content.

**Ethical approval:** The research/study was approved by the Institutional Review Board at IPGME and R Research Oversight Committee, number IPGME&R/IEC/2025/0253, dated 5<sup>th</sup> August 2025.

**Declaration of patient consent:** Considering retrospective record-based nature of the study, the Institutional Ethics Committee has granted waiver for the informed consent requirement for the study.

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**Use of artificial intelligence (AI)-assisted technology for manuscript preparation:** The authors confirm that there was no use of artificial intelligence (AI)-assisted technology for assisting in the writing or editing of the manuscript and no images were manipulated using AI.

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