Setting up of the Indian HIPEC Registry: A Registry for Indian Patients with Peritoneal Surface Malignancies

Aditi Bhatt¹ · Sanket Mehta² · Ramakrishnan AS³ · Pankaj Pande⁴ · Firoz Rajan⁵ · Ashvin Rangole⁶ · Avanish Saklani⁷ · Kayomarz Sethna⁸ · Shivendra Singh⁹ · Shabber Zaveri¹⁰ · K. S. Gopinath¹¹

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Abstract There are various registries for patients with peritoneal metastases (PM) that aid pooling of data and generate evidence that dictates current clinical practice. This manuscript describes the setting up of the Indian HIPEC registry that was set up with a similar goal by a group of Indian surgeons. This is a registry for patients with PM treated with CRS and HIPEC in India. It also acts as a database for storing treatment-related information. Patients with PM from colorectal ovarian, gastric, appendiceal tumors, and other rare peritoneal tumors/metastases from rare tumors are enrolled in the registry. A coordinator updates the disease status of patients on a yearly basis. A private organization maintains the database. A non-disclosure agreement is signed between the company and each surgeon contributing to the registry to maintain confidentiality. For enrolling patients, securing institutional permission depends on the requirement of each institute;

patient consent is mandatory. Data entry can be prospective or retrospective. To propose and conduct a study, the approval of a scientific committee linked to the registry is required. The Indian HIPEC registry is a practical database for Indian surgeons. There is no regulatory body that mandates collection and publication of scientific data in India. The onus is on each surgeon to capture valuable information pertaining to these common and rare diseases that could contribute to the existing scientific knowledge and guide the treatment of these patients in the future. The next challenge will be to enter data into the registry.

Keywords Registry · HIPEC · Cytoreductive surgery · Peritoneal metastases · Indian registry

Introduction

Peritoneal metastases are common. The incidence of PM is 90% in patients with ovarian cancer, 50% in pancreatic, and 32% in colon cancer patients, respectively [1]. With advent of the combined modality treatment of cytoreductive surgery (CRS) and hyperthermic intraperitoneal chemotherapy (HIPEC) that has been increasingly adopted by centers across the world over the past two decades, there has been a significant improvement in both the survival and quality of life of these patients who were previously offered either systemic chemotherapy alone or supportive care [2]. However, the percentage of patients who are actually candidates for this treatment is small and randomized trials in this field are lacking. Most of the evidence on which current treatment recommendations are based comes from pooled data from centers within a country or across the world [3, 4]. This has been made possible by national and international registries and collaborative groups like the Peritoneal Surface Oncology Group

✉ Aditi Bhatt
aditimodi31@gmail.com

¹ Department of Surgical Oncology, Fortis Hospital, 154/9 Bannerghatta road, Opposite IIM-B, Bangalore 560076, India

² Saifee Hospital, Mumbai, India

³ Cancer Insittute (WIA), Chennai, India

⁴ BLK Superspeciality Hospital, Delhi, India

⁵ Kovai Medical Centre, Coimbatore, India

⁶ Apollo CHL Hospital, Indore, India

⁷ Tata Memorial Hospital, Mumbai, India

⁸ Sion Hospital, Mumbai, India

⁹ Rajiv Gandhi Cancer Centre, Delhi, India

¹⁰ Manipal Hospital, Bangalore, India

¹¹ HCG Hospital, Bangalore, India

International (PSOGI), the RENAPE, the American society of peritoneal surface malignancies, etc. This manuscript describes the setting up of the Indian HIPEC registry.

The Need for a Registry for Peritoneal Surface Malignancies in India

In India, the combined modality treatment has been used for a few years only [5]. The patterns of healthcare vary from rural to semi-urban and urban areas [6]. Even in the urban areas, the healthcare delivery is not uniform nor is the record keeping. Most centers do not have allocated resources or personnel for record keeping, and even if records are maintained, there are deficiencies in the information stored. Almost all the centers currently offering this treatment are in major cities [5]. Patients from rural areas may come for a single time treatment and never return for a follow-up. Even patients from the same city may run out of resources to continue to follow up and obtain further treatment [7]. This was reflected in a combined analysis of 330 patients from eight Indian centers in which 43.1% of the patients were lost to follow up [5]. A system for tracking and follow-up of these patients is needed.

Cancer is not a notifiable disease in India. Cancer cases are primarily registered through active methods [8–10].

Cancer registration in India was initiated in 1964 and was expanded in 1982, through initiation of the National Cancer Registry Program (NCRP) by the Indian Council of Medical Research. The NCRP currently has 26 population-based registries and seven hospital-based registries [11]. Yet, these registries majority of which are located in urban areas, cover less than 15% of the population and covering a larger proportion of the population is the main challenge facing the NCRP [11]. Moreover, there are only two time points where cancer data is collected: at diagnosis (incidence) and at death (mortality). The data collected includes personal identifiers, demographic variables, date of diagnosis, the most valid basis of diagnosis, tumor site and morphology, and extent of disease and treatment(s) given up to 6 months after diagnosis [11]. If peritoneal surface malignancies are considered a separate entity, then more specific data needs to be collected and a more stringent follow-up is needed.

The initiative to have a registry specifically for patients with peritoneal surface malignancies/PM was taken by a group of Indian surgeons performing the combined modality treatment. The immediate goals of setting up this registry were as follows:

- The registry will be linked to an online database for data capturing and storage which is accessible to all users of the registry.
- Having a database will lead to a uniformity in reporting (preoperative evaluation, details of the procedure, follow-

up, etc.) and that information specific and relevant to CRS and HIPEC, like the common prognostic indicators are captured for each patient. Prognostic indicators that are used for selecting patients for the procedure are the imaging findings, peritoneal cancer index (PCI), completeness of cytoreduction score (CCR score), and the tumor grade [12, 13].

- Follow-up of patients: There is a coordinator who will contact all patients enrolled in the registry on a regular basis and update their disease status. This will ensure a follow-up of nearly all the patients.
- Assessment of outcomes: Each surgeon will be able to assess his/her individual outcomes. Analysis of pooled data will be possible as well.
- Collaboration: The registry provides an opportunity for surgeons to collaborate for clinical studies and publication of data.

Results

Setting Up of the Registry

The Indian HIPEC registry, a registry for patients with PM treated with CRS and HIPEC in India, was created in March 2016. The registry is linked to an online database, which is maintained by a private organization specializing in web-based software solutions. A group of five surgeons who have been trained in and regularly perform CRS and HIPEC funded this project. Subsequently, five other members who specialize in this treatment joined the group. For the maintenance, all the members pay a nominal annual fee.

Functioning of the Registry

Responsibility of Data Entry

Data entry is done by surgeons or any other person designated by the surgeon. Surgeons can seek the help of the registry coordinator for the same. Where required by the institute/hospital, surgeons need to obtain permission from the institutional review board. This requirement is not uniform across the country. It is not mandatory for surgeons to report all the cases treated by them.

Capturing Data

Cases will be registered under surgeons and not hospital/institutions.

Data entry can be prospective or retrospective provided all the mandatory requirements have been fulfilled.

Data entry is disease specific under the following divisions: colorectal cancer, gastric cancer, ovarian cancer, pseudomyxoma peritonei/appendiceal cancer, rare tumors/indications for cytoreductive surgery, and HIPEC.

There are separate forms for each of these in the database. The information that is captured in the database includes the demographic information, a detailed clinical history, imaging details, surgical details, and perioperative outcomes, further treatment taken and follow up of patients. Each patient's contact information is part of the demographic data collected. Details of common prognostic indicators like the peritoneal cancer index (PCI), tumor grade, and completeness of cytoreduction score (CC score) as well as the details of the cytoreductive surgery itself are recorded (Fig. 1). Specific details of the drug used during HIPEC, dosage and duration are also recorded (Fig. 2).

Authenticity of Data

To ensure that the data entered is authentic, it is mandatory to upload scanned copies of the pathology report and

discharge summary for each patient. This will also help in monitoring the quality of the surgery that is performed.

Patient Consent

Since each patient will be contacted by a coordinator regularly, patient consent is mandatory. The only exception is patients who are dead.

It is the surgeon's responsibility to provide adequate information to the patients and their kin about the registry in a language that they understand.

A consent form template is available on the website. Surgeons can download this form and use it.

Mandatory Requirements

For a case to be accepted, the following requirements need to be met:

- Patient consent
- Scanned copies of the hospital discharge summary and pathology report need to be uploaded.

The screenshot shows a web-based data entry form. At the top, there is a search bar and a 'File Manager' dropdown. The main section is titled 'Tumor Markers' and contains a table for recording marker levels (CEA, CA 19-9) across four columns. Below this is the 'Imaging' section, which includes a table for recording findings from various imaging modalities (CT Scan, PET CT, MRI) across 13 regions (R0-R12). The 'Predicted PCI' column shows a value of 1. There are also sections for 'Diagnostic Laparoscopy', 'If Cytology Done', and 'Pathology' with a table for recording tumor characteristics like Type, Grade, Differentiation, LVI, and IHC.

Fig. 1 Calculation of the CT-PCI

Facilitating Data Entry

There is a help menu of the website, which provides a comprehensive systematic guide for users including the process of registration, data entry, and editing (Fig. 3). There is a supplementary material that can be downloaded from the website like the consent form, a list of complications, and their grades. The data forms can also be printed and used for personal record keeping. For assistance, surgeons can seek the help of the coordinator and/or service provider.

Contributing Surgeons

Surgeons performing the combined modality treatment can contribute to the registry. Surgeons can send a request at www.indianhipecregistry.com. The core group also invites surgeons to join the registry. The goal is to include most if not all the surgeons performing this treatment in the country.

Each surgeon is provided with a log in ID and password. An online registration form needs to be filled, and a non-disclosure agreement has to be signed with the service provider.

Data Security and Confidentiality

- Surgeons cannot view the data entered by other surgeons. Information entered by each surgeon can be exclusively seen by the surgeon alone and is password protected.

The system administrator and the registry coordinator have access to all the data entered.

- The domain is SSL certified (Secure Sockets Layer) which is the standard security technology for establishing an encrypted link between a server and a browser and is commonly used for online transactions. It ensures that the data cannot be viewed by a third person in the process of transfer from the browser to the server.
- The databases use the “Open clinic,” and application is used for handling the data, which is commonly used for sensitive information like medical records. The service providers have a list of security measures that are listed on the website. Surgeons are advised to follow these measures strictly.

Detailed Score	
Region	Score
R0	0
R1	0
R2	0
R3	0

Fig. 2 Capturing the surgical details, PCI, and CC score

Fig. 3 Help menu

- A non-disclosure agreement is signed between each user and the service provider and also between the coordinator and service provider essentially stating that both parties will consider the information confidential and will not share it with a third party.

Coordinator

- The coordinator is a qualified medical practitioner trained to use the system and familiar with peritoneal surface malignancies. The coordinator monitors the data being entered periodically. Any discrepancies and deficiencies in the data entered will be brought to the attention of the respective surgeon entering the data, and attempts will be made to rectify the data by the coordinator. All surgeons/users can directly contact the coordinator. All patients will be contacted on a yearly basis through phone calls, e-mails, or post, and the disease status will be updated.

Data Analysis and Publication

- Individual surgeons data or combined data can be analyzed by the service providers themselves.
- Any surgeon who has registered 25 patients or more can propose and conduct a study.
- A scientific committee will approve the study within a period of 15 days. Failure to respond within the stipulated time will imply that the members have no objection to the proposed study.

- Each study has to be completed within 3 months. Failure to complete it within the stipulated time will warrant cancelation of the study or transferring the charge to another person depending on the decision taken by the scientific committee. The duration can be extended on request.
- No permission is required for analysis of individual data. However, the cost will be borne by the individual surgeon.
- All contributors merit authorship irrespective of the number of cases contributed

Current Status

Currently 17 surgeons have been enrolled in the registry working at 16 different institutions.

Conclusions

The Indian HIPEC registry is a useful and practical database for Indian surgeons. The registry has been set up keeping in mind the problems faced in reporting clinical outcomes, the Indian scenario—for e.g., irregular follow-up or a lack of follow-up. This key element for setting up a registry described here can be followed to set up other similar registries. The next challenge would be to enroll maximum number of patients undergoing CRS and HIPEC into the registry. There is no regulatory body that mandates collection and publication of scientific data in India. The onus is on each surgeon to capture valuable

information pertaining to these common and rare diseases that could contribute to the existing scientific knowledge and guide the treatment of these patients in the future. The registry can be accessed at www.indianhipecregistry.com.

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