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ORIGINAL ARTICLE

The Current Status of Peritoneal Surface Oncology in India

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Abstract
With the increasing acceptance of cytoreductive surgery and HIPEC as a potentially curative treatment for primary and secondary peritoneal surface malignancies, peritoneal surface oncology has emerged as a distinct sub-specialty of surgical oncology. In the last 10 years, the acceptance of a conceptually different approach towards the management of peritoneal metastases has increased in India. During this period, over 1000 combined procedures have been performed in the country and most of the major cities have centers performing offering this treatment. Indian surgeons have formed collaborative groups to promote research and development of this specialty across the country. This article provides a detailed account of current practices pertaining to peritoneal surface oncology in the country and a future perspective.

Keywords Peritoneal surface oncology · Peritoneal metastases · Cytoreductive surgery · HIPEC · India

Background

With increasing acceptance of cytoreductive surgery (CRS) and HIPEC as a potentially curative treatment for peritoneal surface malignancies (PSM), peritoneal surface oncology has emerged as a distinct sub-specialty of surgical oncology. In the last 10 years, the acceptance of a conceptually different approach towards the management of peritoneal metastases (PM) has increased in India. This manuscript describes the evolution of this specialty in the country—its development, current status, and a future perspective.

Surgical Oncology Practices in India

Surgical oncology was formally recognized as a specialty in 1977 with the formation of the Indian Association of Surgical Oncology (IASO). The practice of surgical oncology in the 1980s was carried out by general surgeons, gynecologists, otolaryngologists, and orthopedic surgeons who had variable amount of training and exposure to oncology. Structured surgical oncology training courses leading to the conferring of a degree by the Medical Council of India were started in 1989. The availability for trained specialists was far short of the need; training programs could accommodate few candidates every year, and hence, cancer surgeries continued to be performed by non-specialists. Currently, there is one qualified oncologist for every 2000 cancer patients in India compared to one for every 100 patients in the USA.

Surgical oncology has been taught and practiced as a "broad specialty" with surgeons being trained to operate on tumors arising from any part of the body except the brain and spinal cord. At the same time, many surgeons and institutions have adopted an organ-specific approach since the last decade of the twentieth century. With the growing needs of cancer care in the country, advances in both surgical techniques and technology and looking at global trends, policy makers have recognized the need for organ specific practice and hence not only the training capacity of institutions and number of training centers has been increased but, in the last 5 years, site-specific oncology training programs have been instituted [1]. There are independent training programs for head and neck surgical oncology, breast, and gynecologic oncology. However, gastrointestinal, hepatobiliary, and

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thoracic tumors are still treated by surgical oncologists, gastrointestinal surgeons, thoracic surgeons, and general surgeons.

Cancer treatment is provided by both the private and public sectors.

India is a large country with 1.3 billion citizens who have varying degrees of socioeconomic development, genetic composition, environmental exposures, and lifestyles, leading to a heterogeneous distribution of disease burden and its impact on quality of life [2]. And hence, the development of a specialty, peoples' acceptance of the treatment, and attitude of medical professionals vary greatly across different regions.

Peritoneal Cancer Burden

Most of the patients undergoing CRS and HIPEC have peritoneal metastases of colorectal, ovarian, appendiceal, and gastric origin. Some rare primary peritoneal tumors like primary peritoneal serous carcinoma, peritoneal mesothelioma, and desmoplastic small round cell tumor are also treated. According to a recent report, the number of incident colon and rectum cancer cases in India in 2016 was 63,000 (95% uncertainty interval (UI) 58,000–66,000) and the prevalent cases were 185,000 (171000–195,000) [3].

Ovarian cancer had the sixth highest incidence rate among females in 2016 in India (4.0 per 100,000, 95% UI 3.7–4.3), with 26,000 (95% UI 24,000–27,000) incident cases and 76,000 (69,000–80,000) prevalent cases [3]. The estimated number of incident stomach cancer cases in India in 2016 was 75,000 (95% UI 73,000–78,000) and the prevalent cases were 112,000 (95% UI 109,000–116,000) [3].

The incidence of mesothelioma (pleural and peritoneal) has increased by over 100% from 1990 to 2016 [3]. There are 42 population-based cancer registries in India that collect information at two time points—diagnosis and death [4]. Only a fraction of the population is covered by the registries, and these incidences are extrapolated from mortality reports. The major data inputs to determine cancer mortality in the above study included the nationwide Sample Registration System (SRS) cause of death data, the Medically Certified Cause of Death data, in addition to the information derived from registries [3]. It is not possible to determine the exact incidence of PM at present but extrapolating from the published reports, 15–20% of the patients with colorectal cancer, 30–50% of the patients with gastric cancer, and 75% of the patients with ovarian cancer would have PM at some point in their disease timeline [5–7].

The exact incidence of pseudomyxoma peritonei is not known, but is assumed to be similar to the reported incidence of 1–2 per million worldwide [8]. Thus, the absolute number of patients with PM is high in the country.

Evolution of Peritoneal Surface Oncology as a Specialty and Its Current Status

Across the World

Worldwide, the "founder" and promoter of peritoneal surface oncology as a specialty was Paul Sugarbaker from the Washington Cancer Institute, who systematically described the techniques of performing peritonectomy and visceral resections in the early 1990s [9]. He trained surgeons from all regions and has been instrumental in starting peritoneal surface malignancy (PSM) programs across the globe. Simultaneously, pioneers in Japan and France developed and integrated the use of intraperitoneal chemotherapy in the treatment of PM [10–13].

In India—the Past

In the late 1990s and first decade of this century, few Indian surgeons pursued fellowships at the Washington Cancer Center and at St. George's Hospital, Sydney, to learn this treatment. A couple of surgeons started performing HIPEC using homemade machines, but performed under five procedures a year. There were very few who performed peritonectomy alone without HIPEC. Peritoneal surface oncology received more focus in 2011, when a couple of surgeons started "HIPEC" programs, promoting peritoneal surface oncology as a sub-specialty of surgical oncology and educating patients and the medical fraternity about this treatment. The number increased to 8 in 2014, and currently, there is no account of the number of centers offering this treatment [14].

Current Scenario in India

Every metropolitan city has at least five centers performing the procedure and many second tier cities at least one center offering this treatment. The major metropolitan cities in the country are New Delhi, Mumbai, Chennai, Kolkata, Bangalore, and Hyderabad. The second tier cities include Ahmedabad, Pune, Jaipur, Nagpur, Indore, Coimbatore, Patna, Lucknow, Baroda, Mysore, and Chandigarh to list a few. The Medical Council of India accredits surgeons to perform cancer surgery, and in some instances site-specific cancer surgery. However, there is no accreditation for procedures like CRS and HIPEC. Surgeons' practices are governed by institutional policies. There are certified surgical oncologists, gynecologic oncologists, gastrointestinal surgeons, and even general surgeons who currently perform CRS and HIPEC depending on their experience and ability,

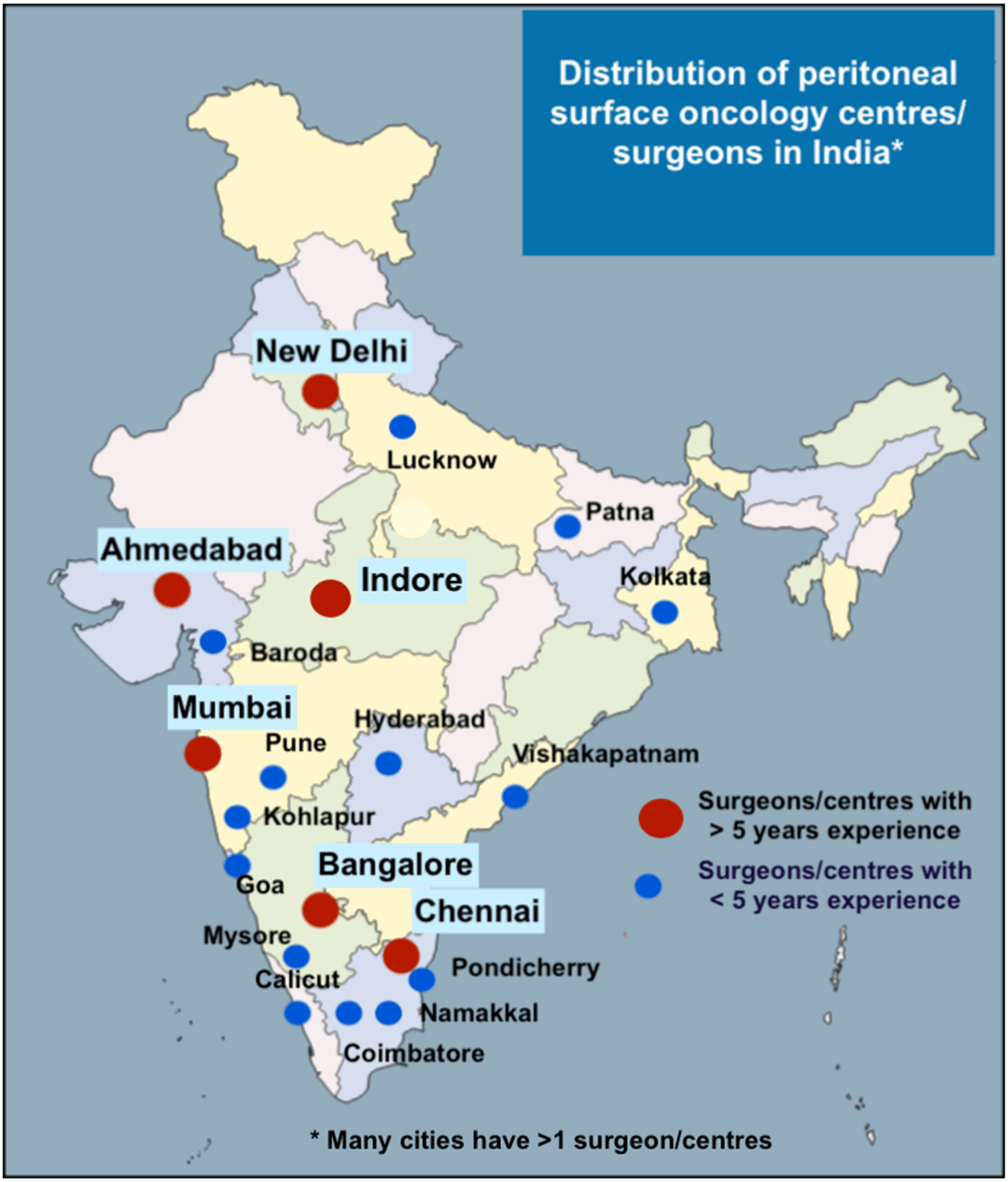

Fig. 1 Distribution of peritoneal surface oncology centers/surgeons in India

though majority of the procedures are performed by surgical oncologists. There are few surgeons whose practice comprises mainly of peritoneal surface oncology and high-volume centers performing over 50 procedures a year have emerged. There are less than five such centers at present. The distribution of surgeons and centers is provided in Fig. 1. This is based on the authors' personal contacts, information derived from industry personnel, and other surgeons, and some cities may not have

been covered. Surgeons perform HIPEC using home-made and custom-made machines. There are approximately 30 custom-made HIPEC machines which have been installed across the country. Many surgeons use custom-made HIPEC machines that are available on rent.

There is no law that prohibits the use of cardiopulmonary bypass machine for performing HIPEC. The Drug Controller General of India (DCGI) is a regulatory body that approves certain devices for clinical use and HIPEC machines are not on this list [15, 16].

Training for Peritoneal Surface Oncology

Exposure During Surgical Oncology Residency

In the last three decades, the treatment of PM has seen a change in paradigm—what was treated with a palliative intent with supportive care alone or systemic chemotherapy is now treated with radical surgery [17]. This is unlike other cancers where the role of surgery has been long established and new developments comprise of a refinement of existing techniques and/or introduction of new technology [18]. A similar situation was seen in the case of liver metastases. But surgical resection of a liver SOL is a surgery most liver surgeons are accustomed to. Peritonectomy procedures were not performed till the organization of peritoneal surface oncology as a specialty, and thus, surgeons may have never seen such a procedure during their training. The oncological concepts have not been systematically taught to trainees as most older surgeons have a limited knowledge and experience of the same. The oldest peritoneal surface malignancy (PSM) units in the country are 7 years old, and most surgeons experienced in this treatment are still on the learning curve of around 120–150 procedures [19, 20]. Many institutions running surgical oncology training programs have not started a PSM program; thus, exposure to surgical treatment of PM is not uniform during surgical oncology residency.

Focused Training Programs in Peritoneal Surface Oncology

Most Indian surgeons have pursued training at a European or American center for 1–24 months. The European Society of Peritoneal Surface Oncology which was instituted in 2015 has laid down the guidelines for training and started a structured fellowship program, offered at centers across Europe [21]. In Asia, a similar fellowship is offered by the Japanese school of peritoneal surface oncology in conjunction with the Peritoneal Surface Oncology Group International (PSOGI). A few Indian centers have started offering fellowships but still recommend spending some time at a more experienced center abroad. Thus, surgeons who wish to pursue this specialty seriously train at one of the expert centers abroad. Most surgeons self-fund such training or avail of a UICC (Union International Cancer Centre) ICRETT fellowship [22].

Training Programs for Other Specialists

Management of PM requires a multidisciplinary approach. From a purely surgical perspective, the role of the anesthesiologist and critical care team is very important. Special training programs in the form of 2–3-day workshops are conducted in Europe and few teams have availed of these programs. Similarly, the pathological diagnosis and classification of these tumors has a significant bearing on the treatment and its outcomes. Expertise in radiological diagnosis and interventional radiology services are needed for a successful PSM program as well. There are no training programs for these specialties, and available expertise at different centers is variable.

Health Care Structure and Its Impact

Cost of Treatment

Out-of-pocket payments account for more than 75% of the cancer care expenditures in India [23]. Private insurance covers roughly 15% of the population [24]. Since 2007, several health insurance schemes have been initiated by the central government and individual states. However, the maximum coverage provided by these schemes barely covers the cost of consumables of a HIPEC procedure which ranges from 1500 to 3000 US dollars [25]. Even in public hospitals, CRS and HIPEC remains an out-of-pocket expenditure for patients and only a fraction of the population can afford it. An alternative would be to use a home-made machine in which the cost of consumables is 500 US dollars [25]. But this would only partially solve the problem. Complications will occur in 30–50% of the patients [26]. A preliminary analysis of data from two centers showed that grade 1–2 complications increased the procedure cost by 10–15% and grade 3–4 complications by 25–50% (unpublished results).

Referral Pattern

The timing of surgery has an impact on survival in peritoneal surface oncology [27]. Most of the patients are first diagnosed/treated by gastroenterologists, general surgeons, and medical oncologists. As the awareness about the availability, benefit, and results of the procedure is increasing, the number of patients referred for the

procedure is increasing. During the early experience, patients themselves approached specialists when the treating oncologist had run out of treatment options. This has changed with many patients now being referred at the time of diagnosis. There is no structured referral program in the country in oncology.

There are some states that have no centers offering surgical treatment for PM and patients travel/to other state regions or do not receive surgical treatment.

Patients' Attitudes

The education level of patients has an impact on their seeking treatment for what is still perceived in many parts of the country as "advanced" incurable malignancy worthy only of palliative care. Many patients are illiterate or have never attended high school. And many do not understand the nature of the surgery and its potential risks. This calls for even more careful patient selection, since the perception of an average Indian about life, death, and longevity differs greatly from that of Western patients. The wishes of patients and their understanding of the nature of surgery need to be considered before subjecting them to a complex procedure. For, e.g., a 72-year old patient with low volume, low-grade PMP may prefer to not take any treatment than undertake even a 1% risk of mortality.

Collaborative Groups, Research, and Audit

Societies and Collaborative Groups

Surgeon specializing in PSM have since 2016 organized themselves into two collaborative groups resulting in the formation of two societies officially registered under the Registries Act of India (1960). Workshops and meetings have been organized on a yearly basis by each of these groups to disseminate knowledge about this specialty and collaborate on research. Eminent members of the PSOGI constitute the lead faculty for these workshops.

HIPEC/PSM Registry

Based on the lines of the RENAPE network in France, the Indian HIPEC registry which registers patients with PM undergoing surgical treatment was established in 2016 and has since then enrolled nearly 600 patients from 12 centers across the country [28, 29]. This registry is maintained by an independent software solutions company and functions through a web-based application. Over 50 surgeons have enrolled in the registry since its inception in March 2016 and the registry is recognized internationally [30]. However, participation in the registry is voluntary and many surgeons performing such procedures have not joined it. The distribution of patients according to disease is provided in Fig. 2. These patients have been enrolled by 14 surgeons from 12 centers.

The outcomes in the first 300 patients registered were recently published [31]. The analysis of registry data helped us identify both clinical and operational problems that need improvement and also validated the existing practices [31]. The survival outcomes in patients compared well with published reports except in colorectal cancer (Fig. 3).

Scientific Output and Prospective Studies

The collaboration between surgeons started even before the institution of the registry with evaluation of the pooled results as well as single-institution studies [14, 32–35]. The analysis of retrospective data has provided the background for some innovative prospective studies [36, 37].

Surgeons participating in the registry are collaborating on prospective studies as well, which are conducted under the aegis of the Indian Network for DEvelopment of Peritoneal Surface Oncology (INDEPSO) [31]. This organization of surgeons is voluntary and is between surgeons working at both private and public hospitals, which is unusual in the country [38]. Though there is some level of collaboration among the regional cancer centers and other public institutes, the private sector is seldom involved in it.

PIPAC

Pressurized intraperitoneal chemotherapy is a new method of intraperitoneal drug delivery that has shown promising results in patients with PM and is being evaluated in

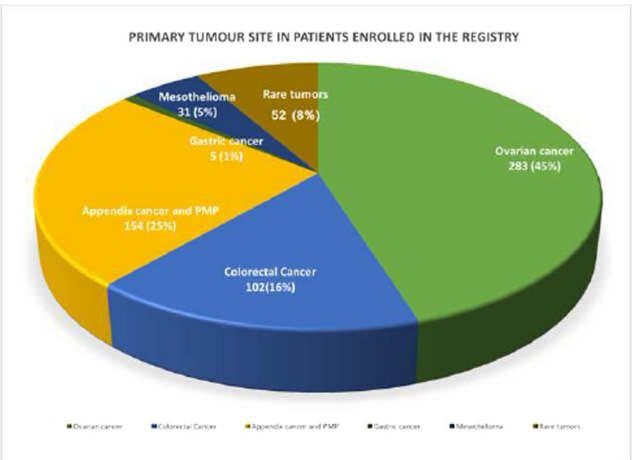

Fig. 2 Primary tumor site in 590 patients enrolled in the registry

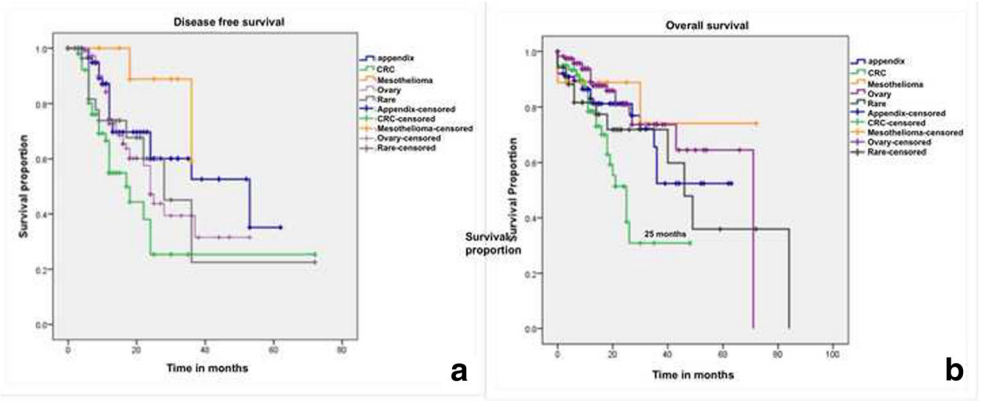

Fig. 3 Disease-free and overall survival in 332 patients enrolled in the Indian HIPEC registry according to the primary disease site (from reference [31] with permission)

clinical trials in Europe. The first PIPAC procedure in India was performed in May 2017 [39]. Since then, there are 23 surgeons who have undergone the compulsory certified training and over 100 procedures have been performed so far. Currently, PIPAC is used in the palliative setting and cost of the device which is to be used only once is the main barrier to more patients availing of this procedure.

Future Perspective

In a country falling in the category of "low and middle" income countries harboring a quarter of the world's population and having a heterogeneous healthcare system, peritoneal surface oncology has come a long way in a short period. Over 1000 procedures (this is an estimation derived from the authors' own experiences and those of other surgical colleagues as well as information derived from company personnel) have been performed in the last 7 years, and surgeons continue to make efforts to beat the odds and provide this treatment to patients. The lack of organization can be a boon as it provides room for innovation. Looking at the future, developing innovate ways of reducing the cost of the procedure is one of the main needs. Involvement of NGOs and charitable organizations is one such solution.

The second issue is the quality of surgical treatment. It has been shown that the surgeon/institution is a strong prognostic factor affecting the outcomes of cytoreductive surgery and HIPEC [40]. The quality of the surgery is determined not just by a controlled morbidity and mortality but also by the rates of early recurrence which depend on proper patient selection and completeness of surgery both [40, 41]. It is recommended that such procedures are performed in specialized centers since the quality of surgery and perioperative management can vary vastly among surgeons and centers.

In this regard, the high-volume centers need to establish themselves further, improving their results and increasing the number of patients treated each year. And in future, such centers should emerge in all regions. The onus is on the surgical oncology community to take organ specific practice to the highest level and refer patients to each other rather than perform surgeries for cancers of all organ systems. And to make such level of care available to every socioeconomic strata of society should not be considered a far-fetched but an imperative goal.

The third impending need is a quality of life analysis in these patients to determine the impact and benefit of the procedure. The collaboration to institute a registry and conduct multi-institutional studies is just the first step. More studies that have a direct impact on clinical practice need to be conducted with a much larger participation of surgeons/institutions.

Conclusions

Peritoneal surface oncology has developed at a rapid pace in the last decade in India. To truly pass on the benefit to patients, further development of specialized centers with multidisciplinary expertise, regular audit of surgical results and survival outcomes, and quality of life analysis is essential. The ongoing research needs to be more impactful and focused on issues specific to each disease, taking country specific concerns into consideration.

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Compliance with Ethical Standards

Conflicts of Interest The authors declare that they have no conflict of interest.

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