

Editorial

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Medical devices for treating peritoneal metastasis in low-income countries: is less more?

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Offering new effective treatments and improving survival is an ongoing challenge in medicine. This is also true for treating peritoneal metastasis with innovative solutions. With growing evidence from randomized control trials, cytoreductive surgery (CRS) and hyperthermic intraperitoneal chemotherapy (HIPEC) are increasingly offered to peritoneal metastasis patients [1]. A value-based review of the clinical outcomes and cost-effectiveness of CRS and HIPEC concluded recently that such option is a valuable therapy for selected patients and that the use of healthcare resources is meaningful [2]. Further technological advances such as Pressurized IntraPeritoneal Aerosol Chemotherapy (PIPAC) could offer new alternatives for controlling peritoneal surface malignancies [3]. However, in industrial countries, the absolute number of patients treated with the above technologies remains low, and the vast majority of affected patients in the world do not have access to such advanced treatments.

Against this framework, patient access to modern, combined therapies of peritoneal, surface malignancies must be considered as suboptimal. There are several reasons to explain this unfavorable situation. The first reason is related to the limited number of surgeons trained, and the learning process until a multidisciplinary team (including anesthesiologists) is able to apply complex techniques safely and effectively. To master such challenge, surgeons have first to consent a major personal and financial investment by taking prolonged time off from their home and from their hospital to learn the theoretical background and the practical aspects in reference centers abroad. For example, a large number of surgeons from Russia, Argentina, Brazil, India, Algeria, Morocco, Tunisia, Lebanon and many others countries have learned the concept of CRS and HIPEC in French pioneers centers including Paris Descartes/Paris Sorbonne University. As a proud member of the Peritoneal Surface Oncology Group International (PSOGI) and of the European Society of Surgical Oncology (ESSO), I am grateful to these societies for having developed complementary

educational programs for interested cancer surgeons worldwide. As an example, I would like to acknowledge the important educational efforts consented by the surgical oncology community in India [4, 5].

A second limitation in the acceptance of modern therapies of peritoneal surface malignancies is that it is difficult to disseminate knowledge outside the community specialized in peritoneal malignancies. Transmitting the message that peritoneal metastasis is a treatable disease is indeed a fundamental precondition for patients being referred to specialized therapy centers. It will need many more years and a lot of efforts until the old concept that peritoneal carcinomatosis cannot be treated effectively is abandoned [6]. Early referral of peritoneal metastasis to reference centers is the precondition for therapeutic success in this challenging disease. In practice, most patients with peritoneal surface malignancies are not referred, showing that it is difficult to “export” the positive experience gained to other medical (sub)specialties. Convincing the medical oncology community that surgery combined with locoregional chemotherapy can cure selected patients with peritoneal metastasis might even take more time: this paradigm change is not only driven by scientific evidence, it is also associated to fears, including loss of control and revenue. Overcoming these barriers will require significant communication efforts.

The third limitation is indeed the access to advanced medical technologies such as HIPEC in low-income countries. In the present issue of “Pleura and Peritoneum”, A. Bhatt et al. present their results obtained with a “home-made” HIPEC machine [7]. Considering the increasing regulatory requirements in the USA, in the EC and elsewhere, this article might appear an anachronism. However, it delivers an important message: the authors show that this home-made machine was safe and allowed access to effective care for many patients for whom the cost of a certified, custom-made machine was not affordable. Thus, this article also rises following question: in low-income countries, the additional safety provided by the additional quality control measures of the custom-made machines has to be balanced with the associated increase in costs preventing access to therapy

for many patients. In the light of the results presented (in particular of absence of technical pitfalls), it seems ethical to use a home-made machine – without regulatory certification – when healthcare resources are limited. Of course, such home-made machines should remain the exception and are only acceptable if an internal quality control audit shows that therapy is effective and that patient's health is not harmed. Such audit should include not only the operative results but also machine maintenance, sterility checks, etc. Moreover, a prospective critical incident reporting system register should be implemented in order to detect early possible incidents and to be able to react to such incidents rapidly.

There might also be indirect, undesirable effects of using home-made medical devices instead of purchasing custom-made machines from the industry. Only a small proportion of public grants is devoted to surgical oncology research, in spite of the high incidence of solid tumors and of the major role of surgery in outcome of these cancers. For example, in my research laboratory specialized on peritoneal surface malignancies, public funding from the University and from the French government is covering only part of the costs incurring. Without additional industrial research funding, development and validation of next-generation HIPEC or PIPAC technologies would simply not be possible in my laboratory. Unfortunately, HIPEC and PIPAC are niche markets with small volume for the industry – and therefore limited research and development budget. This situation has to be contrasted with the major public funding granted for cancer drug development. Sadly, this funding might have not delivered the expected return on investment: in Europe, most anticancer drugs entered the market without demonstrated benefit on survival or quality of life [8].

An additional dilemma for HIPEC or PIPAC devices is that, in contrast to cancer drugs, such single-use devices can be and are obviously reused. On the one side, repeated application of single-use medical devices can reduce the costs of the procedure and might make access to therapy easier. On the other hand, reusing such devices might be illegal (for example, reusing medical devices used for administering chemotherapeutic drugs and radioisotopes is prohibited in most European countries). Reusing medical devices is harming the legitimate financial interests of the industrial provider, its ability to refinance regulatory costs (including safety studies), to finance the development of next-generation devices and finally its capacity to survive on the market. Furthermore, reusing and re-

sterilizing medical devices can potentially harm patient's health and/or of the medical team involved in the procedure. Finally, in the worst-case scenario of an intraoperative accident, the medico-legal consequences of an inadmissible repeated use might become a personal and professional disaster for the physician in charge.

Taken together, it appears legitimate that physicians from low-income countries try to decrease the costs of new medical technologies in order to facilitate therapy access for their patients. On the other side, patients' and physicians' expectations for medico-technical progress and optimal safety can only be met if the legal, regulatory and economic framework conditions are respected. What is the solution to this area of conflict? The jury is still out. As the physicians responsible for the health of our patients, should we accept low-cost devices, at the cost of performance, safety, training, research and customer service? Should we consider that offering HIPEC with a home-made machine is better than to offer no HIPEC at all? Or should we consider that to give anything less than your best is to sacrifice the gift?

Further medico-technical advances for treating peritoneal surface malignancies are unrealistic without a strong industrial and financial backbone. Is there a solution? Experience from the airline industry could show us the way: in the future, medical devices companies might offer safe, non-reusable, low-cost technical solutions to treat peritoneal disease. Such scenario would be ethically acceptable (by multiplying the number of patients treated) and compensate for potential loss revenues for the industry (by multiplying the number of devices sold). Physicians are not used to reflect about the industrial and regulatory framework conditions of medical device development, and this is probably the first thing we should change - now.

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