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The “homemade” HIPEC machine – a cost-effective alternative in low-resource countries

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Abstract

Background: HIPEC using custom-made machines (CMM) remains unaffordable for many patients in low-income countries. We describe the assembly and use homemade HIPEC machine (HMM) as a cost-effective alternative.

Methods: We evaluated the cost of setting up the HMM, maintenance, expenses per procedure as well as technical aspects including target temperature and flow rate, safety aspects, technical failures and the technical support required. The comparison with CMM was based on the manufacturer information and published reports and not on personal experience.

Results: From 2011 to 2017, we performed HIPEC (Coliseum technique) in 81 patients using HMM. HMM was a cardiopulmonary bypass machine available in our institution, with an additional water bath. Flow rate was 2 L/min and target temperature between 41 and 43 °C could be achieved in all cases. There were no technical failures and there was no safety issue recorded. Routine maintenance was provided yearly by an in-house technician. Chemotherapy costs (between 20 and 500 USD) were independent from the devices used. Cost of consumables was 450 USD/procedure, as compared to 1800 to 3500 USD/procedure for commercially available products. Investment cost for CMM is between 70,000 and 1,35,000 USD.

Conclusions: The HMM is a cost-effective option allowing access to HIPEC to patients in low-resource countries without loss of efficacy or additional safety concerns. The initial cost and cost per procedure were substantially less for HMM while the maintenance of both systems was

similar in terms of complexity and cost. The CMM are more user-friendly and require less technical support.

Keywords: HIPEC machine, HIPEC technology, homemade HIPEC machine, low-cost HIPEC machine

Introduction

Cytoreductive surgery (CRS) and hyperthermic intraperitoneal chemotherapy (HIPEC) prolong survival significantly in selected patients with peritoneal metastases (PM) compared with systemic chemotherapy alone [1]. The role of HIPEC is established for pseudomyxoma peritonei (PMP) and malignant peritoneal mesothelioma and is under investigation for other indications [2–4]

The two main techniques of performing HIPEC are the “open abdomen” and the “closed abdomen” methods [5–7]. There is no difference in the outcomes between the two methods and the choice depends on the preference of the surgical team [8, 9].

There are several variables involved in HIPEC – choice of drugs, the carrier solution used and its volume, the duration of the procedure, the level of hyperthermia, the flow rate, and the technique –open or closed [10]. Though there is no ideal target level for the fluid volume, the degree of heat used or the flow rate- the procedure is performed using 1.5–3 L of fluid at a flow rate of 1–2 L/min maintaining an intra-abdominal temperature of 41–43 °C. Some variables like the technique of HIPEC, the degree of hyperthermia, volume of perfusate and the flow rate depend on the apparatus used that comprises of a roller pump and a heating device.

Several custom-made “HIPEC machines” are available for performing HIPEC [10].

In these, the heating device and roller pump all enclosed in one external covering. The inflow and outflow tubes, 2–4 temperature probes and a reservoir bag (in most machines) are available separately, are for single use and connected to the machine for the procedure [11].

Some centers use a homemade machine (HMM) that usually comprises of a cardiopulmonary bypass machine used in conjunction with a water bath [10].

This article describes the assembly and use of a homemade HIPEC machine, the results obtained with its

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use and compares the technical and financial aspects with some of the popularly used custom-made machine (CMM).

Materials and methods

From June 2011 to Jan 2017, CRS and HIPEC was performed at our center using a HMM (described below). All the procedures were performed by the coliseum technique. The temperature range maintained during each procedure, the volume of fluid and the flow rate was recorded and this was reviewed retrospectively for this study. We performed a comparison of the cost of setting up the machine, maintenance, expenses per procedure as well as technical aspects like achieving and maintaining target temperature and flow rate, safety aspects, technical failures and the technical support required to run the homemade machine with the CMM commercially available.

The comparison with CMM was based on the manufacturer information and published reports and not on personal experience.

The “homemade” system

A cardiopulmonary bypass machine (Terumo Sarns Modular Perfusion System 8000, Bloomfield, USA) in combination with a series of heating devices and a fluid reservoir was used. The machine has four roller pumps that can circulate fluid at a maximum flow rate of 7 L/min and an inbuilt temperature control mechanism that does not allow the fluid temperature to exceed 42°C. Initially we used two external heaters for heating the fluid (Figure 1). The fluid returning from the abdominal cavity is collected in a venous reservoir (Edwards vital venous reservoir,

Edwards lifesciences, Irvine, USA) that has a capacity of 5 L and an integrated heat exchanger which heats fluid to 44°C (Figure 1). This device can heat the fluid up to 44°C. The reservoir allows chemotherapy solution to be quickly extracted from the abdomen in case of a complication and can hold the excess volume of perfusate that cannot be accommodated in the patient's peritoneal cavity [11].

It was then pumped back into the abdominal cavity through a second pump and another heater was placed in its course (MYOthem XP® cardioplegia delivery system, Minneapolis, USA) which heated the fluid to 44°C. There is a heat loss of 1–2 degrees in the tubing depending on the length and flow rate (Figure 1). With this set up alone, an intra-abdominal temperature of 41–42°C was achieved. From 2014 onwards, a water bath (Huber, Offenburg, Germany) was used in addition that heated the fluid passing through the myotherm (Figure 2). With the water bath, that can heat fluid up to 100, an intra-abdominal temperature of 41–43°C was easily achievable, the inflow temperature being set at 45–46°C. The venous reservoir was connected to a third roller pump that constantly circulated the fluid accumulating in it to prevent stagnation and heat loss. We used one inflow channel that was hand held by one of the surgeons throughout the procedure and was constantly moved over different areas of the abdominal cavity. This was to prevent direct contact and overheating in one particular area and is a technique used by one of the pioneers of the open methods, Dominique Elias. When the water bath was not used, this was important for maintaining the target temperature all regions.

Fluid is sucked out of the peritoneal cavity using one roller pump and collects in the venous reservoir (blue circuit). From the venous reservoir it is pumped back to the peritoneal cavity using another pump (red circuit). It passes through a MYOthem where fluid from the water bath (orange circuit) flows around it to further heat it and raise the temperature to 45–46°C. The fluid in the venous reservoir is recirculated using another pump (green circuit).

Figure 1: The cardiopulmonary bypass machine with the venous reservoir and MYOthem.

Figure 2: Diagram showing the functioning of the homemade HIPEC machine.

Fluid is sucked out of the peritoneal cavity using one roller pump and collected in the venous reservoir (blue circuit). From the venous reservoir it is pumped back to the peritoneal cavity using another pump (red circuit). It passes through a MYotherm where fluid from the water bath (orange circuit) flows around it to further heat it and raise the temperature to 45–46 °C. The fluid in the venous reservoir is recirculated using another pump (green circuit).

We used one inflow and two outflow channels connect through a “Y” connector to a single roller pump which maintains the perfusion efficiently. It also prevented clogging of the outflow channels. The flow rate was fixed at 2L/min. All procedures were performed by the coliseum technique using 2.5 L of perfusate. We did not calculate the fluid volume based on the body surface area as done by some surgeons [7]. It is an approximation based on the quantity of fluid that would effectively maintain the perfusion and temperature at a desired flow rate. The minimum target temperature was 41 °C. We aimed to maintain the temperature between 41 and 43 °C. The choice of perfusate depended on the drug being used. Three temperature probes were used- 1 placed under each cupola of the diaphragm and one in the pelvis.

Sterilization and maintenance

There is no contact of any body fluid with the machine as it is contained in the disposable tubing throughout the procedure. The machine is cleaned externally with a disinfectant solution after every procedure. When the machine was used for patients who were reactive for human immunodeficiency virus (HIV) or hepatitis B or C viruses, the machine was left in the operating room during the post- procedure fumigation process. There is no other maintenance required for the machine. The center volume for HIPEC is 25–35

cases per year while that for cardiac procedures requiring the use of a cardiopulmonary bypass machine is 50–70 procedures per month and the same machine can be used for both procedures.

Training of the perfusion team

Before the first procedure was performed, the perfusion team was educated about the procedure by the surgeon. The key technical points and clinical targets were discussed and defined and an experimental run was carried out. New recruits to the department are trained by the senior members of the perfusion team during the procedure. The service provided by the perfusion team is not charged to the patient.

Avoiding technical failures/breakdown

The two most important parameters dependent on the machine are the temperature and the perfusion. Despite the high flow rate that can be achieved by the HMM, clogging of the outflow tubes can lead to a break in the perfusion. In the homemade system this is prevented by using the “Y” connector. When the water bath was not used, under- heating of different regions is avoided by moving the inflow channel continuously, thus perfusing all

regions with the heated fluid. Similarly, this practice avoids overheating when the water bath is used. In, addition the temperature is constantly monitored during the procedure and the inflow temperature can be controlled to the accuracy of 0.1 °C by altering the temperature at which the water bath is set.

All the connections and tubes are checked for any leaks/breaks prior to starting the procedure to ensure there is no breakdown during the procedure.

Results

From June 2011 to Jan 2017, 134 patients were taken up for CRS and among these HIPEC was performed in 81 patients. The cardiopulmonary bypass machine was available at our center and there was no additional cost of purchasing the machine. Only a water bath which costs 500 (USD) had to be purchased. The cost involved in setting up the machine, the expenses per procedure and a comparison with the CMM is provided in Table 1. The prices provided in the Table are approximate prices and may vary according to time and other financial variables involved (taxes etc.).

Cost difference

The price of CMMs available in India ranges from 70,000–1,35,000 USD. The cardiopulmonary bypass machine costs around 80,000 USD and is already available in a center that performs cardiac surgery. The only expenditure in setting up the machine is that of the water bath which costs 5000 USD. For each procedure, a set of consumables, the procedure “kit”, mainly comprising of plastic tubing (inflow and outflow tubing) and a

fluid reservoir is required, which is for single use and costs 1800–3500 USD (that is the cost of a resection of colorectal primary tumor in a private hospital in India) for the CMM. The consumables which are for single use when the HMM is used are the inflow and outflow tubes, which are the same as used in a cardiopulmonary bypass procedure (also known as a “custom pack”) and cost around 70 USD, the myotherm which costs around 125 USD and the venous reservoir that costs around 270 USD.

The company and make of the individual components of the kit is similar to what is used in CMMs- the kits are assembled in Europe or the United States which substantially adds to the cost. In several major Indian cities, HIPEC machines are available on “rent” but result in an additional 10–15 % increase in the cost of the “kit” to the patient.

Chemotherapy costs (between 20 and 500 USD) were independent from the devices used and depend on the drugs used for the procedure. The total cost of a CRS and HIPEC procedure in India ranges from 10,000–15,000 USD depending on the hospital set up, machine used, the extent of surgery required and complicated versus uncomplicated procedure. In this scenario, the kit cost of 2000–3000 USD represents a substantial expenditure for the patient

Performance and efficacy

The time taken to set up the machine was 15 minutes and another 10–15 minutes was required for the intraperitoneal target temperature to be attained. The target temperature of 41–43 °C was attained in all regions of the peritoneal cavity, including the diaphragmatic cupolas

Table 1: Comparison of the initial cost, maintenance, sterilization and expenditure per procedure for the homemade system and custom-made machines.

Machine	Cost of the machine, USD	Sterilization	Annual maintenance	Cost of consumable per procedure, USD	Cost of each consumable, USD	Technical assistance during the procedure/ additional charge
Homemade machine (HMM)	80,000 + 5000 (water bath)	External cleaning with disinfectant solution	Nil	450–500	Myotherm- 125 Venous reservoir-270 Custom pack –70	Perfusion medicine team/ none
Custom-made machine (CMM)	70,00–1,35,000	External cleaning with disinfectant solution	Nil	1800–3500		For some machines a technician from the manufacturer’s side remains present for the procedure/none

with a flow rate of 2 L/min. The same temperature was maintained throughout the procedure. There was a temperature difference of $<1^{\circ}\text{C}$ among the three regions that were monitored. A flow reversal is not possible using this machine and hence the closed method cannot be performed with it.

In comparison, most CMM achieve a flow rate of 2 L/min and can heat the fluid to a minimum 44°C to maintain a temperature of $41\text{--}42^{\circ}\text{C}$ inside the peritoneal cavity. The time taken for the desired temperature to be reached varies and some machines take one hour to reach the desired temperature.

Some of the apparatus may be more appropriate for open administration (Belmont, SunChip) whereas the others are more appropriate for the closed system (Rand Performer, Thermasolutions).

Technical and safety features

The HMM requires a perfusion medicine specialist to be present throughout the procedure. The bypass machine is not intended for performing HIPEC; the in-built safety systems do not apply to HIPEC. The heating of fluid occurs after it has been pumped out of the machine and hence a constant monitoring of the temperature is essential. There are no pressure sensors and alarms for temperature and pressure and temperature monitoring is done manually on different screens. Constant monitoring is required to ensure that over-heating and under-heating does not occur in any area.

In contrast, most CMMs have a user friendly interface and temperature adjustment and monitoring is done through a single screen that is computer controlled. There are alarms for temperature and pressure to avoid overheating and clogging of the system. Some machines provide a record of the intraperitoneal temperature throughout the procedure. Some of the machines are designed to function automatically and adjust the fluid volume according to the patients' body habitus.

There was no disconnection of tubes or breakdown of the circuit during any of the procedures and no failures to obtain the target temperature and flow rate.

Spontaneous bowel perforations were seen in two patients during this period both had had extensive electro-evaporative surgery for removal of tumor nodules on the small bowel surface, anastomotic leaks in 3 patients of which one was a delayed leak.

A comparison of the technical and practical aspects of the homemade and CMM is provided in Table 2.

Regulations and approvals

The various CMM are US Food and Drug Administration (US FDA) or European community (EC) approved for HIPEC [10]. HIPEC involves off-label use of chemotherapy drugs that are intended for intravenous use. In India, the existing regulations do not mandate the registration or approval of HIPEC machines with or by any regulatory body. 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 [12, 13]. There is no law that prohibits the use of cardiopulmonary bypass machine for performing HIPEC. In this situation, patient information becomes important and all our patients were informed that a HMM would be used for the procedure. Though most CMMs are marketed as "FDA approved" such an approval is not mandatory for a HIPEC machine.

Discussion

The first heated intraperitoneal chemotherapy perfusion was performed by John Spratt in 1980, using a roller pump with a heater and filter [14]. The equipment used for delivery of heated chemotherapy required to be assembled for each procedure and consequently, CMM were developed in which the heater and the pump were integrated and enclosed in a cabinet thus, simplifying the process. The heat and perfusion parameters could be chosen from a range of options at the press of a button. Surgeons worked with engineers to develop systems in which homogeneous maintenance of temperature and perfusion was possible with relative ease. The ideal parameters remained undefined however, and the commercially available machines have a lot of variability.

It has been demonstrated that the outcomes of CRS and HIPEC vary with the surgeon and center where the procedure is performed and improve with experience [15–17]. The impact of the quality of HIPEC on these outcomes has not been shown because of the questionable benefit in a large proportion of the cases, the multitude of variables involved and the lack of a quantifiable endpoint (e. g. complete cytoreduction for CRS). Hence, there are no ideal parameters to monitor the quality of HIPEC. However, a flow rate of 1–2 L/min maintaining an intra-abdominal temperature of a minimum of 41°C (preferably $42\text{--}43^{\circ}\text{C}$) for 30–90 minutes are the commonly accepted standards for the procedure [10]. Over

Table 2: Technical and practical aspects of various HIPEC machines.

Machine	Maximum flow rate, L/min	Maximum temperature, °C	Heating mechanism	Precision in Temperature control, °C	Approvals	Technique of HIPEC
Homemade machine	7	100	Coil with heat exchanger	0.1	None (for HIPEC)	Open
Belmont® Hyperthermia Pump, Billerica, MA, USA	1	48	Electromagnetic induction warmer	0.1	EC	Open; closed
Rand Performer® HT, Modena, Italy	2	46	Plate heating	0.1	FDA, EC	Closed; open
ThermoChem™ HT-2000® ThermaSolutions, White Bear Lake, MN, USA	2.4	47		0.1	FDA, EC	Open; closed
SunChip®, Eaubonne, France	2	55	Heat exchanger with coil	0.1	FDA, EC	Open; closed
Eight Medical, Bloomington, IN, USA	2.1	46	Medical grade anodized aluminum heat	0.1	FDA, ec	Open; closed
Exiper Hyperthermia, Medolla, Italy	2	46	Heat exchanger with coil	0.1	EC	Closed; open

heating $>44^{\circ}\text{C}$ and under-heating $<41^{\circ}\text{C}$ should be avoided. Breaks in the perfusion due to clogging of bowel loops/debris at the ends of the tubes should be avoided.

Both HMMs and CMMs achieve these parameters effectively with the latter being more user friendly- with easy assembly and monitoring of the procedure. The HMM requires manual monitoring by a perfusion team and is not suited for the closed method. The clinical benefit of having a more “refined” system remains to be proven; safety standards can be maintained with equal accuracy using a HMM. The cost of setting up the HMM is nominal where a cardiopulmonary bypass machine is available and the same machine can be used to perform both procedures (HIPEC and cardiac procedures) on the same day. The maintenance and sterilization is simple. There were no technical failures in our experience. There is no additional charge for the services of the perfusion team. The HMM has an overall lower initial cost and significantly lower cost per procedure for the consumables used. One of a most feared consequences of overheating is bowel related complications and we did not experience any such complications that could be attributed to high temperature.

Out of pocket spending is common in health care in India, ranging from 70–90 % [18]. Despite the introduction of government-funded schemes, more than 80 % of outpatient care and 40 % of inpatient care provided by the private sector [19]. Out of pocket payments are known to cause impoverishment in patients and families [20].

Government and private insurance only partially cover or do not cover procedures like CRS and HIPEC. Though the amount spent on the procedure-related consumables is not the only expenditure that can be minimized, it is still a significant amount for a large majority of the patients. The HMM can make this procedure more “affordable” by reducing the average cost by 15–20 % for a fraction of patients who would otherwise be deprived of the potential benefits solely because of the high cost. For PMP and mesothelioma, the cost-effectiveness of HIPEC has been demonstrated in an Australian study [21]. The benefit was comparatively less for patients with colorectal and other primary tumors. 80 % of the cases of colorectal PM recur. These patients require additional treatment; it is not a one time expenditure but a continuous one.

The HMM is still used in 20 % of the centers in the United States, at a high volume center in Australia and at a few centers in India [10, 22]. In France, all centers use CMMs [23].

The description of the HMM provided in this manuscript should make it simpler for surgeons and perfusion teams to set up such a system and optimize the procedure from the very beginning. Some of the important points that need to be taken care of are

1. The abdominal should be stretched tightly when the skin edges are sutured to the table mounted retractor. The perfusion is better than when the wall is lax
2. Temperature should be monitored at both diaphragmatic cupolas separately

3. The inflow tube should be constantly moved over the whole exposed area to ensure even distribution of the hot fluid and prevent overheating in one area
4. Using a “Y” connector prevents clogging of the ends of the outflow tubes and maintains a constant perfusion.

The drawbacks of this study are that it is a retrospective, single institution study and the comparison with CMM is made based on manufacturer information and published reports and not on personal experience or a direct comparison. A constant record of the intraperitoneal temperature was not maintained and only the temperature range was recorded in the case records.

Conclusions

The homemade HIPEC machine is an efficacious, safe and low-cost alternative to CMM. The cost of consumables for each procedure for CMM is a financial burden for Indian cancer patients and precludes certain patients from undergoing this procedure. The use of a homemade system requires a perfusion medicine team, a thorough knowledge of the procedure and constant monitoring to ensure that the minimum acceptable standards for the procedure are maintained.

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