



Role and responsibility of operating room nurse in preparation operation theatre for HIPEC and cytoreductive surgery in the tertiary health center in north India

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Abstract

Hyperthermic (or Heated) Intraperitoneal Chemotherapy (HIPEC) is a surgical procedure that's giving new hope to patients with abdominal cancers. Immediately after removing visible tumors through cytoreductive surgery, surgeons give a dose of heated chemotherapy inside a patient's abdomen. The technique involves macroscopic resection of disease burden and metastases, followed by infusion of chemotherapy heated to 41°C–43°C into the peritoneal cavity through a special device. After 90 minutes of the infusion, the chemo is washed out and incisions are closed.

Chemotherapy: -In HIPAC (Intraperitoneal) mitomycin-c is the most common drug administered and platinum-based drugs, cisplatin, carboplatin, and oxaliplatin which have a synergistic effect with heat, and doxorubicin, paclitaxel, docetaxel, and 5-fluorouracil drugs are commonly less used.

The technique of Hyperthermic intraperitoneal chemotherapy Administration: HIPEC is administered by two classical methods, the open abdomen method, and the closed method.

Skin preparation of patient: Skin preparation is from the mid-chest to midthigh with the preparation of the genitalia and catheterization.

Safety guidelines for administration of HIPEC: A sign the HIPEC is in progress should be placed at the door and the entry of personnel not involved in the procedure should be restricted. N95 grade mask provides the best protection against surgical smoke produced during the use of electrocautery. Doors should be closed during the operation with pressurized closures. The temperature should be 18–26 degrees Celsius and air humidity 45–60 %. The Association for peri-Operative Registered Nurses (AORN) recommends that operating room air exchanges should be maintained at a minimum of 15 air exchanges per hour. Air inflow volume should be 15 % higher than the outflow, airspeed must be lesser than 0.3 m/s. Appropriate PPE (personal protective equipment) consists of an N95 face mask (a simple surgical mask does not provide adequate protection), gloves, protective gown, and overshoes or laggings to provide adequate protection to all involved team members.

Handling of the chemotherapy during HIPEC: it should be prepared in the bio-safety cabinet not in the ward because of the danger from spillage and contamination, while preparing cytotoxic drugs to wear nitrile or neoprene powder-free long cuff gloves and wear a gown non-permeable long sleeve, cuffed and solid fronted and use an aerosol-free mask. Every effort should be taken to avoid any spill. Hospital policies to prevent spills should be adopted by the surgical and operation theatre team members and written procedures must specify the team responsible for spill management. Health care institutions should develop a plan and policy for handling hazardous medications. Collection, labeling, storage, transport, and disposal of contaminated waste should be done as per hospital policy.

Cleaning the operating room after HIPEC: Soap water is adequate to clean the operating room after HIPEC three consecutive times. 70% of isopropyl alcohol is also safe and effective.

Conclusions: All available studies point out that the correct use of specific protective measures is a key factor to minimize exposure. Emphasis has to be also placed on educating and instructing the involved personnel in the hazards and safe use of chemotherapy, the importance of adherence to safety protocols, and the correct use of the recommended personal protective equipment.

Keywords: Safety considerations, cytotoxic agents, cytoreductive surgery, HIPEC

Introduction

Hyperthermic (or Heated) Intraperitoneal Chemotherapy (HIPEC) is a surgical procedure that's giving new hope to patients with abdominal cancers. Immediately after

removing visible tumors through cytoreductive surgery, surgeons give a dose of heated chemotherapy inside a patient's abdomen. The technique involves macroscopic resection of disease burden and metastases, followed by

infusion of chemotherapy heated to 41°C–43°C into the peritoneal cavity through a special device. After 90 minutes of the infusion, the chemo is washed out and incisions are closed.

Cytoreductive surgery and Hyperthermic intraperitoneal chemotherapy (CRS-HIPEC) for primary peritoneal malignancies or peritoneal spread of malignant neoplasm are being done at many centers worldwide. HIPEC is currently an established treatment option for selected patients with peritoneal dissemination of gastrointestinal cancer, ovarian cancer, or primary peritoneal malignancies. Dr. Paul Sugarbaker showed that surgical removal of visible tumors for peritoneal mesothelioma combined with locoregional heated chemotherapeutic drugs improved the quality of life and survival of these patients.

The administration of HIPEC offers the combination of the pharmacokinetic advantages of intraperitoneal delivery of cytotoxic chemotherapy, with the direct cytotoxic effects of hyperthermia. In combination with complete cytoreductive surgery, it can offer significantly improved outcomes, with acceptable morbidity and mortality in experienced centers. Handling, and management of chemotherapeutic agents in the operating room for HIPEC, poses an additional risk to staff involved in the procedure. Personnel exposure during HIPEC procedures may arise from different routes, such as air contamination and pulmonary absorption, contact contamination, manipulation of perfusates, or manipulation of objects or biological tissues exposed to chemotherapeutic agents. These safety considerations have been taken into account since HIPEC was initially described. As the number of institutions adopting this therapeutic strategy for the prevention and treatment of peritoneal surface malignancy increases, concern regarding the safety of this technique in the operating room has grown.

Cytoreductive Surgery-

| Drug | Type | Common Uses | Common Toxicities |
|----------------|-----------------------|---|---|
| Mitomycin C | Antitumour antibiotic | Appendix, PMP, colorectal, gastric, ovary | Nephrotoxicity, pulmonary toxicity, myelosuppression |
| Oxaliplatin | Alkylating agent | Colorectal, appendix, gastric | Neurotoxicity, GI bleeding, nephrotoxicity, peripheral neuropathy, myelosuppression |
| Cisplatin | Alkylating agent | Ovary, colorectal, gastric, PMP | Nephrotoxicity |
| Carboplatin | Alkylating agent | Appendix, ovary | Myelosuppression |
| Doxorubicin | Antitumor antibiotic | Appendix, PMP, colorectal, ovary, malignant ascites | Cardiotoxicity, myelosuppression |
| Irinotecan | Plant alkaloid | Colorectal | Myelotoxicity |
| Paclitaxel | Plant alkaloid | Ovary | Myelosuppression, peripheral neuropathy |
| Docetaxel | Plant alkaloid | Gastric | Myelosuppression, pulmonary toxicity |
| 5-fluorouracil | Antimetabolite | GI | Myelosuppression, neurotoxicity |

Source- <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6921319/table/T2/?report=objectonly>

The technique of Hyperthermic intraperitoneal chemotherapy Administration: HIPEC is delivered in the operating room, after completion of cytoreductive surgery. HIPEC is administered by two classical methods, the open abdomen method, and the closed method. Sugar baker performed these open abdomen methods by using the “coliseum” technique. Hybrid semi-open or semi-closed methods were also reported by different groups.

1. Open abdomen technique
2. Closed abdomen technique

CRS consists of a great many surgical procedures depending on the extent of peritoneal tumor manifestation. Surgery may include parietal and visceral peritonectomy, greater and lesser omentectomy, and single organ as well as multi-visceral resection. Described the following five basic procedures:

1. Right hemicolectomy, greater and lesser omentectomy, and splenectomy
2. Right and left diaphragmatic peritonectomy
3. Cholecystectomy and resection of Glisson’s capsule
4. Partial gastrectomy
5. Anterior rectal resection, pelvic peritonectomy, hysterectomy, and ovariectomy.

Cytoreduction score

The goal of CRS is to remove all visible intraperitoneal tumor nodules. The completeness of cytoreduction can be determined by the completeness of the cytoreduction score.

1. CC-0 indicates no visible residual tumor and
2. CC-1 residual tumor nodules) 2.5 mm.
3. CC-2 and CC-3 indicate residual tumor nodules between 2.5 mm and 2.5 cm and >2.5 cm, respectively.

Chemotherapy

In HIPAC (intraperitoneal) mitomycin-c is the most common drug administered and platinum-based drugs, cisplatin, carboplatin, and oxaliplatin which have a synergistic effect with heat, and doxorubicin, paclitaxel, docetaxel, and 5-fluorouracil drugs are commonly less used. The ideal carrier solution should improve the exposure of the peritoneal surface, have slow clearance from the peritoneum, maintain high intraperitoneal volume and not have any adverse effects on the peritoneal membranes. Nowadays isotonic saline or dextrose-based peritoneal solutions are recommended.

3. **Open abdomen technique**

The wound is partially covered by a disposable hipec drape to decrease possible vaporization and escape of abdominal liquids and four closed suction drains are placed and secured through the abdominal wall. The surgeon performs continuous manual stirring during the 30-90 min of perfusion. In this procedure, the open method allows direct manipulation of the abdominal contents and better distribution of the perfusate but in this method risk of

environmental contamination is higher. It directly exposes the surgeon and scrub nurse to contact of chemotherapy.

Closed abdomen technique

After cytoreduction is complete, 2 inflow catheters and 2 outflow catheters are placed in a watertight fashion. Temperature probes are appropriately placed, and after the temporary closure of the skin, the preheated solution is allowed to fill the peritoneal cavity. The closed technique provides the lowest exposure of cytotoxic drugs, it protects the surgeon and scrub nurse to contact chemotherapy. However, it's restricted to the surgeon to directly manipulate the heat and distribution of chemotherapy.

Preparation of Patients

Skin preparation is from the mid-chest to midthigh with the preparation of the genitalia and catheterization should be done for patients scheduled for HIPEC.

It is the responsibility of Pre-operative nurses to ensure appropriate preparation of skin before posting patient to the operation theatre.

Instruments and equipment's

Following instruments should be ready for cytoreduction surgery -

1. General Instruments Set.
2. Abdominal Set
3. Vascular Set
4. Thompson Retractor
5. Electrosurgical Ball tip (3mm).

Before receiving the patients in the operation theatre scrub nurse and circulating nurses should ensure that the above-mentioned material should be available, it is the responsibility of scrub nurses to inform the surgeon in case of non-availability of any instruments before surgery.

Incision

The abdominal cavity is opened by the surgeon or surgery team and a midline incision is done from the xiphoid to the pubis. The old abdominal incision is often excised, quite often, these patients have had previous surgeries and caution needs to be exercised to prevent injury to intestines opening the abdomen. For better exposure of the abdomen using a self-retaining retractor. In the case of diaphragmatic stripping, a xiphoidectomy will help in better exposure and placements of Thompson retractor blades. When the disease is extensive, thorough exploration is performed to look for contraindication for CRS and no bowel should be resected till the surgical plan is finalized. Thompson retractor placed for better exposure.

Role and responsibility of Nurses in Safely administration of HIPEC

Preparation of the operation theatre: Nurses should ensure that a sign of the HIPEC is in progress should be placed at the door of an operating room and the entry of personnel not involved in the procedure should be restricted.

Protection against surgical smoke:-Cytoreduction surgery is performed with high voltage electrocautery using pure cutting current which produced a large amount of smoke for prolonged periods. Inhalation of this smoke has health

hazards. Electrocautery smoke increases the risk of headache, watery eyes, coughs, burning throats, nausea, drowsiness, sneezing, etc. The scrub nurse should wear PPE with an N95 grade mask during the procedure, they should be aware of the long-term health risks.

Air conditioning and humidity: - Air conditioning should be working throughout the surgical procedure, and positive pressure should be maintained in the operating room at all times. Positive pressure is maintained between the operating room and adjoining areas to prevent outside air entry into the operating room. Positive pressure producing a slightly higher pressure to the surrounding area. Doors should be closed during the operation with pressurized closures. The temperature should be 18–26 degrees Celsius and air humidity 45–60 %.

Ventilation of Operating room: The National Institute for Occupational Safety and Health (NIOSH) recommends a combination of general room ventilation and LEV (Local exhaust ventilation) as the first line of protection for controlling surgical smoke. The general room ventilation should be a high-efficiency particulate air (HEPA) filter or equivalent for trapping particulates. It also is important to ensure that the filters for the general ventilation system are maintained and changed as recommended by the manufacturer of the system. Dirty air filters will impede room air exchanges. The Association for peri-Operative Registered Nurses (AORN) recommends that operating room air exchanges should be maintained at a minimum of 15 air exchanges per hour. Air inflow volume should be 15 % higher than the outflow, airspeed must be lesser than 0.3 m/s.

Before the start procedure provides a comprehensive briefing to all operation team members.

- In cytoreduction and HIPEC procedures, pregnant females should be excluded.
- Inside and outside of the operation theatre safety signboard should be available there.
- The OR entrance should be labeled appropriately, and access to the OR should be restricted.
- The cytotoxic drugs should be prepared with an appropriate biological safety cabinet.
- The hazardous drugs should be transported by a sealed and leakproof container with appropriate labels.

Personal protective equipment (ppe) during administration of HIPEC

- Appropriate PPE (personal protective equipment) consists of an N95 face mask (a simple surgical mask does not provide adequate protection), gloves, protective gown, and overshoes or laggings to provide adequate protection to all involved team members.
- Certified surgical gowns should be used in CRS and HIPEC. They are made up of water-repellent material (e.g. Spun-bond/melt-blown) and long sleeves with elastic closed cuffs.
- Overshoes or special shoes should be used in HIPEC. Overshoes should be closed and easy to clean.
- In HIPEC procedure always wear double gloves. Gloves made of non-latex materials are effective in protection. Nitrile or neoprene rubber and polyurethane

gloves have also been successfully tested.

Handling of the chemotherapy during HIPEC

Chemotherapeutic drug dilution is an important part of cancer chemotherapy. It should be prepared in the bio-safety cabinet not in the ward because of the danger from spillage and contamination.

Drug dilution under laminar flow. Biosafety cabinets are part-recirculation laminar airflow enclosures with HEPA filtration of exhaust air and an air barrier at the work opening. Separate fan/HEPA filter systems are provided for exhaust and laminar airflow. They provide environmental and product protection.

Cytotoxic drugs precaution must be reduced contact through skin exposure, inhalation, and ingestion. Adequate techniques for drug preparation are essential to reduce the exposure risk.

1. While preparing cytotoxic drugs to wear nitrile or neoprene powder-free long cuff gloves and wear a gown non-permeable long sleeve, cuffed and solid fronted, and use an aerosol-free mask.
2. Work over a suitable container to prevent the spread of any spillage.
3. The use of cytotoxic ampoules should be away from the face and always covered with cotton or a suitable pad when broken open.
4. Diluent fluids should be introduced slowly into open-ended ampoules or vials, running it down the vessel wall and ensuring the drug powder is moist before shaking.
5. When excess air is expelled from a filled syringe it should be exhausted into a pad and not straight into the atmosphere
6. If the excess drug is to be expelled from a filled syringe it should be removed first and sterile Safe Handling of Chemotherapeutic Drugs cotton wool was placed over the end of the syringe to prevent the possible expansion of aerosol droplets.
7. Luer lock fittings syringes should be used. To connect I.V. set and tubing.
8. Label all prepared bottles.
9. Check the reconstitute or diluents for the particular drug and the concentration in which it is reconstituted.

Chemotherapeutic drug spillages management: Every effort should be taken to avoid any spill. Hospital policies to prevent spills should be adopted by the surgical and operation theatre team members and written procedures must specify the team responsible for spill management.

Chemotherapeutic drug spillage kits must be available. If a spill happens, it should be contained and cleaned up immediately. A large spill is defined as a drop of more than 5 g or 5 ml of the pure drug. During HIPEC, chemotherapy is diluted, and drug doses are essentially minimal so that it is not likely to have a major spill.

Management of Spillage

Operating room nurses should do the following in case of spillage-

- Restrict access to the spillage area.
- Inform other members of staff in the ward and inform a senior member of staff.

- New and expectant mothers should not have direct involvement in the management of a chemotherapeutic drug spillage.
- Open a spill kit.
- In case of contamination of protective clothing during the spillage, remove the contaminated items and put on fresh protective clothing from the spillage kit.
- Place all contaminated items in the designated chemotherapeutic waste bin.

Handling of waste after HIPEC

Health care institutions should develop a plan and policy for handling hazardous medications. Collection, labeling, storage, transport, and disposal of contaminated waste should be done as per hospital policy. The objects which have only little contact with chemotherapy are treated as domestic waste in most of the countries and require no specific disposal e.g. High-temperature incineration. Hazardous waste is defined as items with a content of more than 3% by weight of the respective compounds in the USA and more than 20 ml in Germany.

Cleaning the operating room after HIPEC

Bactericidal cleaning solutions may react with the cytotoxic agents and do not inactivate them that way should not be used to wash contaminated areas. Soap water is adequate to clean the operating room after HIPEC three consecutive times. 70% of isopropyl alcohol is also safe and effective. The instrument should be dealt with similarly. Standard protective clothing should be worn during the cleaning.

Dealing with exposure and personnel contamination

Instruction for management if protective equipment or clothing, or direct skin or eye is contaminated

- Removing the gloves or gown as early as possible.
- Cleansing of the affected skin with soap and water as early as.
- Washing an affected eye at an eyewash fountain or with water or isotonic eyewash designated for that purpose for at least 15 min, for eye exposure.
- Calling for medical help. Record incident as per hospital policy
- Documenting the exposure in the employee's medical record.
- Spill Kits - Spill kits should always be ready to use in the operation theatre.

The material safety data sheets (MSDS) include sections on emergency procedures, including appropriate personal protective equipment.

The ASHP recommends that kits include: chemical splash goggles, two pairs of gloves, utility gloves, a low-permeability gown, 2 sheets (12" × 12") of absorbent material, 250-ml and 1-l spill control pillows, a "sharps" container, a small scoop to collect glass fragments, and two large waste-disposal bags for cytotoxic drugs.

Training for staff involved in HIPEC

Training must be given to all people involved in any aspect of the handling of cytotoxic drugs. The training must be given to physicians, nurses, pharmacists, housekeepers working in the HIPEC administration area. This information

should be provided in induction training and routine training program.

Training to employees must be given the following elements:

- Education about the potential hazards of electrosurgical smoke and cytotoxic drugs must be given to all in respect of gender.
- The importance of avoiding exposure to cytotoxic drugs in early pregnancy must be taught to women.
- Monitoring to be done to detect a breach in the safe handling practices of cytotoxic drugs and managing spills.
- Personal protective equipment to be used, not just for handling cytotoxic drugs but also protecting themselves from electrosurgical smoke.
- Reporting exposure to cytotoxic agents.

Conclusions

Currently, available evidence indicates that CRS and HIPEC is a procedure that can be safely performed concerning occupational exposure of healthcare personnel. All available studies point out that the correct use of specific protective measures is a key factor to minimize exposure. As these procedures progressively gain acceptance and new centers adopt, the implementation of safety guidelines, including the development of additional policies and procedures for the safe handling of cytotoxic agents and potentially contaminated items in the operating room, is of paramount importance. Emphasis has to be also placed on educating and instructing the involved personnel in the hazards and safe use of chemotherapy, the importance of adherence to safety protocols, and the correct use of the recommended personal protective equipment.

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