INTRODUCTION DE LA CHIMIOTHÉRAPIE HYPERTHERMIQUE INTRAPÉRITONÉALE PEROPÉRATOIRE (CHIP) AU PROGRAMME DE CHIRURGIE

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RÉSUMÉ :

La chimiothérapie hyperthermique intrapéritonéale peropératoire (CHIP) offre la possibilité de prolonger la survie, voire de guérir, les patients faisant face à des types spécifiques de cancers envahissants de l'abdomen. Cet article examinera les aspects peropératoires de la mise en œuvre d'un programme de lutte contre les cancers péritonéaux qui comprend le traitement avec la CHIP. En analysant ce traitement, nous en partagerons les expériences dans le but d'optimiser les soins au patient pour les programmes de chirurgie potentiels et le personnel périopératoire. Cette analyse illustrera les domaines respectifs de développement du programme, tels que la formation, les exigences budgétaires et les considérations en matière de soins au patient. De plus, le dialogue se penchera sur la sélection des patients, la préparation préopératoire et les considérations peropératoires. Pour terminer, cet article démontrera les résultats spécifiques à court terme et à long terme pour le patient en commençant par la phase postopératoire immédiate.

KEYWORDS: CHEMOTHERAPY, ABDOMINAL CANCER, HIPEC, CYTOREDUCTIVE SURGERY, PERITONEAL MALIGNANCY, HYPERTHERMIA, INTRAPERITONEAL.

INTRODUCTION OF HYPERTHERMIC INTRAOPERATIVE INTRAPERITONEAL CHEMOTHERAPY (HIPEC) TO THE SURGERY PROGRAM

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ABSTRACT:

Heated Intraoperative Intraperitoneal Chemotherapy (HIPEC) offers a chance for extended survival, or cure, to patients facing specific types of invasive abdominal cancer. This article will explore the perioperative facets of implementing a peritoneal malignancy program that includes the HIPEC procedure. In exploring this procedure, experiences will be shared with the intent of optimizing patient care for potential surgical programs and perioperative staff. The examination will illustrate the respective program development areas such as training, budgetary requirements and patient care considerations. Further, the dialogue will investigate patient

The goal of the procedure is to improve the cancer cell kill rate by circulating heated chemotherapy to the cancerous tissues.

selection, preoperative preparation and intraoperative considerations. Lastly, the article will reveal the specific short-term and long-term patient outcomes starting with the immediate post-operative phase.

INTRODUCTION:

Roman author Cicero once wrote, "While there's life, there's hope."[1] Heated Intraoperative Intraperitoneal Chemotherapy (HIPEC) offers hope to patients facing specific types of invasive abdominal cancer. This procedure provides a surgical possibility for abdominal cancer patients who previously had a minimum chance of survival. Patients may experience three to five more years of life and, in some cases, a cure.[2] The article will explore the administrative, preoperative, intraoperative and postoperative facets of caring for patients undergoing a HIPEC procedure for surgical tumour reduction. It includes such topics as the procedure's historical foundations, surgical technique, equipment and safety, and patient centered learning relating to care needs and family support. An extensive literature search and case experience from the Covenant Health Peritoneal Malignancy program at the Grey Nuns Community Hospital in Edmonton, Alberta, are used to illustrate the surgical introduction of HIPEC. In exploring this surgical procedure the author's experiences will be shared with the intent of optimizing patient care for other potential surgical programs and perioperative staff looking to introduce the HIPEC procedure.

Historical Foundation and Surgical Technique

The HIPEC procedure was pioneered in the early 1980s at the Washington Cancer Centre in Washington, DC, by Paul Sugarbaker, MD.[3] HIPEC involves the circulation of heated chemotherapy solutions through a circuit which follows a cyclical loop between the patient's abdomen and hyperthermia pump (includes pump, heat exchanger, temperature monitoring device and pressure monitoring system.[4] (See Appendix A). The goal of the procedure is to improve the cancer cell kill rate by circulating heated chemotherapy to the cancerous tissues. Cancer cells are more sensitive to heat than other tissue cells and so combining heat and chemotherapy results in higher cancer cell kill rate.[2] The procedure, and its applicable perfusion, can be performed as an open or closed procedure. The Covenant Health program, and its primary surgeon Dr. Erika Haase, uses the open system technique to facilitate the chemotherapy administration. The procedure involves surgically opening the patient's abdomen and debulking or cytoreducing tumours to a size no larger than 2mm. The strength of the procedure lies in its effectiveness against cancers that are too small to be seen – such as scattered small peritoneal tumours or cancerous cytology found in abdominal fluid.[5]

Appendix A:

Apon completion of tumour cytoreduction the technique then

Figure A1: The Intraoperative Hyperthermic Chemotherapy Circulation Circuit

As the operating room is traditionally not an area that employs chemotherapy certified nurses, specialized training is required prior to the introduction of a HIPEC program.

involves inserting inflow and outflow catheters into the patient's abdomen. These are used to circulate the chemotherapy solution (see Appendix B). During catheter placement, intra-abdominal temperature probes are also positioned. Smoke evacuation is used to remove any potential cytotoxic fumes that may be aerosolized during the procedure. (See figure B2 - purple tubing shown in figure B2) The abdomen is draped with a plastic cover to reduce OR staff exposure to the heated chemotherapy agent fumes while it is being circulated. A trained operating room nurse, with chemotherapy certification, infuses the patient's abdomen with heated dialysate until it reaches 42 degrees Celsius. At this point, concentrated chemotherapy is added to the circulating heated dialysate solution until it reaches the desired concentration of chemotherapy. Chemotherapy agent selection and related concentration are primarily reflective of the type of cancer being treated and its suitability for intraoperative hyperthermic administration. The solution is then circulated for one to two hours while the nurse monitors the patient, the solution temperatures, and maintains a balanced inflow/outflow rate between 750ml-1L/min. During the circulation phase, the surgeon passes a double gloved hand through the port created in the plastic covering to manipulate the solution and abdominal structures (see Figure B1 and B2). The surgeon's intent is to ensure that the peritoneal cavity is uniformly exposed to the heat and chemotherapy.

Figure B1: Surgeon manual manipulation of abdominal structures via hand port

Appendix B:

Upon completion of the circulation phase, the dialysate solution is drained from the abdomen and disposed of following applicable cytotoxic disposal procedures which are discussed in the postoperative section of this article. The surgeon then irrigates the patient's abdomen with copious amounts of saline and repairs or reconstructs any remaining bowel components. The saline is also treated as cyto-contaminated fluid and disposed of appropriately. The patient's incision is then closed in the customary fashion, dressings are applied and the patient is transferred to the relevant post operative unit where postoperative care and monitoring is performed. The patient may require time in the facility's intensive care unit as the HIPEC procedure can take many hours and is physically demanding on the patient.

PROGRAM DEVELOPMENT CONSIDERATIONS:

Training and Safety

As the operating room is traditionally not an area that employs chemotherapy certified nurses, specialized training is required prior to the introduction of a HIPEC program. In order to ensure that there is a team of highly qualified staff who can adequately care for the patient and handle the cytotoxic materials, senior team members who have advanced knowledge of perioperative care should be considered first for this training. In addition, the operating team must be directed to use the correct steps to prepare and protect the extremely vulnerable HIPEC patient. The processes must be systematic, logical and organized in a way that optimizes safety. Imagine the horrific

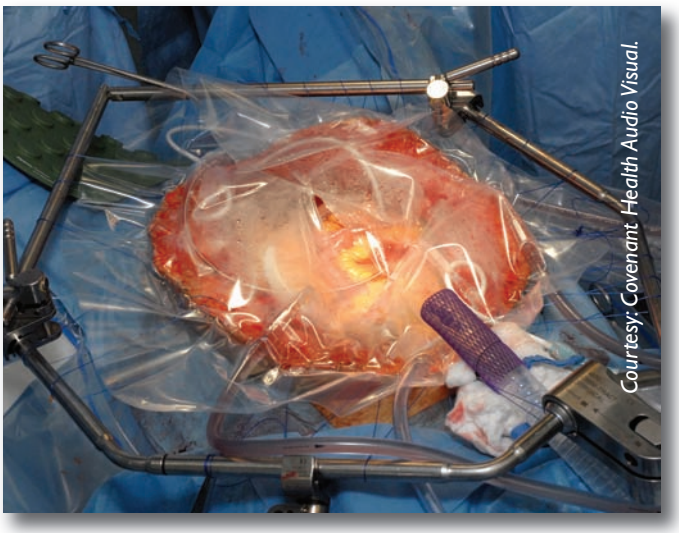

Figure B2: Open HIPEC approach with plastic cover

scene of an ill managed patient whose circulating chemotherapy has overflowed spilling cytotoxic agents onto (would it spill on to the patient? If so include the risk to patient safety as well as to staff) poorly protected patient and staff. It is imperative, for all concerned, that practice standards be strictly enforced. In the spirit of championing safe and competent care, a three pronged strategy for teaching HIPEC fundamentals should be utilized. The three initiatives include an in-service with a post-in-service test, surgical simulation scenarios, and preceptored peer-review.

Teaching Strategies

Wright advocates that post-in-service tests work well to measure cognitive skills in the technical domain.[7] As the majority of training areas for this technique are of a cognitive nature a post-training test provides a strong measure of the HIPEC knowledge retained by the trainee. All candidates must successfully complete the post-in-service exam prior to proceeding to the simulation component of the training.

Simulation is often viewed as a safe way to allow learners to work through the cognitive materials at their own pace. Jeffries discusses the importance of using simulation to replicate clinical crises in a safe climate allowing learners to assimilate information without compromising real patients.[8] Alinier illustrates, however, that one best not become falsely secure as simulation cannot fully replicate the robust dynamics of actual patient care.[9] It is proposed that the mock scenarios allow staff to work on building strong team dynamics and learning the steps in the process while not facing the risks posed by real cytotoxic materials. Staff can focus on the proper way to wear personal protective equipment (PPE), setting up equipment, and prioritizing the complex aspects of the procedure. Once the staff have mastered the basics of the mock simulation, the educator can introduce potential emergencies for the newly formed team to deal with. These encounters may range from

chemotherapy spills to equipment failure or even a patient crisis, such as heat stroke. These simulations provide a realistic progression toward their own peer-preceptored clinical experience.

Having the opportunity to work with a senior preceptor allows staff the ability to integrate into the team without being fully responsible for having senior knowledge. The use of clinical teaching opportunities ensures that staff members are presented with the chance to work in actual patient situations in order to solidify the knowledge they have already obtained and to acquire new skills under experienced supervision. As some criticize patient simulation training as not providing enough "real world" skills and information assimilation the ability to supplement it with a structured mentorship program allows students to transition their simulated skills into actualized patient care and to build the strength of the team dynamic. These learning progressions must be honoured in order to foster a safe environment and cannot be compromised for any reason – including dealing with staff shortages or other competing priorities. The operating room clinical educator needs to assess students based on the specific HIPEC teaching measures and provide them with regular "action plans" on how to improve and work toward the desired goals.

Figure C1: Example of nurses operating hyperthermia pump and administering chemotherapy agent.

The teaching strategies were built in such a way that they can be tailored to several different job classifications while still having all participants accountable to the same standard of educational information. Documentation of the training strategies provides a legal record that the staff member has been given all of the required regulatory safety based information. Management holds a legal responsibility to ensure staff members comply with regulatory and site-based procedural requirements.

Budgetary Considerations

HIPEC procedures have one-time and ongoing cost implications which should be recognized before proceeding with program development. The equipment used during the procedure is the HIPEC pump, high volume smoke evacuator, and heating/cooling blanket. In most operating rooms the HIPEC pump is likely not already present and thus is the paramount purchasing consideration (see Appendix C). In the Covenant Health program, there are duplicates, on standby, of the major pieces of equipment in case of any equipment failures. Handling equipment malfunction was a significant portion of the team's training during the simulation exercises. As the procedure requires the delivery of heated chemotherapy for the required period of time it is essential to have backup equipment readily available.

Appendix C:

The ongoing costs for HIPEC are related to the medication and supplies needed and the related PPE. These are in addition to the usual costs involved in performing a major abdominal general surgery case. The HIPEC case will involve additional costs of approximately CAD$5,000 per procedure -- with four-fifths of this cost being for the chemotherapy drug. The remaining costs are for the procedure's consumables such as the HIPEC tubing circuit, the disposable protective equipment (e.g. impervious disposable gowns) and the prescribed chemotherapy agent.

Collaborative Approach

In the development of a Peritoneal Malignancy Program, it is necessary to create and foster key collaboration among the staff. Mohamed & Moran offer that teamwork is essential in HIPEC and that a multidisciplinary team

Theatre personnel review their volunteer patient's medical profile.

is required to optimize outcomes, minimize risks, and deal with problems as they arise.[10] They illustrate that HIPEC should be implemented in "high volume centers" that are mindful of the learning curve and are willing to learn from the mistakes of others. The team must learn to work together as a highly developed group that is willing to train together through a variety of patient simulated scenarios. The HIPEC program interfaces with many areas including pharmacy, housekeeping, supply chain, surgery and the intensive care unit. The program lead should foster interdisciplinary collaboration so that the respective surgeons, anaesthetists, and hospital staff can work together to meet the patients' perioperative needs. Working together will result in the creation of processes that allow for the successful mixing, transportation, use and disposal of chemotherapy that reflect safe practice and are fiscally responsible. Intraoperatively, as not every patient will be deemed suitable for the HIPEC procedure, a collaborative process can save pharmacy time, by avoiding mixing drugs needlessly, and save the operating room thousands of dollars in potentially wasted drug costs.

The program may also need to develop external relationships with oncology centres that can work in collaboration with the surgeon, in regards to chemotherapy selection, and be used to support the ongoing post-operative patient care and follow up. The oncology centre can also be approached to assist in the oncology training of the surgical staff. As an example, the Covenant Health HIPEC Program and a local oncology centre worked in reciprocating collaboration to teach each other's staff various components of patient care. Each site benefited from this approach and ultimately patients at both sites reaped the benefit. The HIPEC program also sent representatives to another hospital site where HIPEC procedures are performed on a regular basis. The numerous site visits gave the intraoperative, postoperative, and anaesthesia representatives a greater understanding of the procedure and helped to better prepare the program for a successful implementation.

PREOPERATIVE CONSIDERATIONS:

Patient Selection and Booking

Cotte et al. propose that cytoreductive surgery and HIPEC is most beneficial in young patients, under 65, who present with low volume of disease being treated intraoperatively and when the procedure is performed in a centre that specializes in treating peritoneal malignancy.[11] Once the patient selection process has been completed it is vital that the pertinent booking information be submitted so that the many areas impacted can begin

EVACUATING AN OR cont. on page 28

The HIPEC program interfaces with many areas including pharmacy, housekeeping, supply chain, surgery and the intensive care unit.

Surgeon's manual manipulation of abdominal structures via hand port.

planning for the procedure. The booking should include details of the chemotherapy agent that will be required and should clearly identify the proposed post-operative bed plan. The patient should attend a preadmission clinic for routine preoperative testing and to allow for an assessment of the patient's social network. Within the Covenant Health program the unit supervisor from the applicable post-care unit meets the patient and their respective family/support system, provides them with an overview of the pending experience, and assesses the patient's support network. HIPEC is not only physiologically taxing but also carries with it many of the mental burdens that result from a lengthy hospital stay, dealing with invasive cancer, and the potential end of life. A percentage of candidates will, during the procedure, be deemed unacceptable for HIPEC therapies. It is vital that the patient has strong support, from both their family and the hospital staff, as they confront a confirmed palliative diagnosis.

Preoperative Preparation

Prior to the patient being received in the OR, it is recommended that the circulating nurse place a heating/cooling blanket on the OR table to prepare for the possibility of body temperature variations that the patient may experience. A urinary catheter is inserted in order to give the anaesthesia team the ability to monitor fluid imbalances that may result from variances in hydration and medications administered to enhance urine output. A smoke evacuator should also be present during the procedure in order to remove any potential aerosolized chemotherapy. White proposes that the circulating nurse also perform a double check protocol with the surgeon in order to verify the correct chemotherapy agent that should be used.[12] This check can be performed in the same fashion as is used on blood products or medications that are prepared for the scrub nurse's back table. The circulating nurse's primary role is related to safety, spill management and assisting the anaesthesia team should the patient become hyperthermic. The circulating nurse must, in addition to the regular responsibility of assisting the sterile scrub nurse in the preparation of the back instrument table, take on the role of safety advocate by ensuring that the room's regular trash receptacles have been replaced with appropriate biohazardous containers, that spill kits are readily accessible in the room, that the doors to the theatre have proper "HIPEC protocols" signage posted, and that any support staff that may be involved in the surgical case (i.e. housekeeping, operating room attendants) are aware of the HIPEC procedure.

The scrub nurse prepares the surgical back table for major abdominal surgery but also adds the supplies needed for the HIPEC circulation and the protective clothing that the team will wear during the procedure. White proposes that the scrub nurse ensure that all the supplies for the procedure (such as the proper catheters, temperature probes and pump tubing) are available.[12] Upon commencement of chemotherapy circulation all instruments and the sterile field are to be considered "chemo" contaminated. Staff need to change their gloves every thirty minutes. Double gloving using

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HIPEC (cont.)

> Double gloving using "non powder" latex gloves is a standard of care throughout the procedure and its cleanup.[13]

"non powder" latex gloves is a standard of care throughout the procedure and its cleanup.[13] Chemotherapy rated nitrile gloves are also a suitable glove choice. The scrub nurse should be a diligent advocate for appropriate PPE and the use of safety precautions once cytotoxic agent circulation begins and should continue monitoring safety compliance until the case is completed.

Preoperatively, the surgeon is responsible for preparing the patient's position and abdomen for the procedure. The surgeon needs to be prepared to withstand the lengthy procedure, which includes performing the laparotomy, tumour debulking, and placement of the inflow and outflow catheter and temperature probes. The surgeon works with the staff running the chemotherapy HIPEC pump to ensure the proper circuit of tubing is primed and available for placement intraoperatively.

A dedicated trained chemotherapy certified nurse or anaesthesia technician is responsible for ensuring that the HIPEC pump is in working order and that a secondary system is available in the event of an equipment failure. White proposes that the pump staff member check the medication label on the chemotherapy agent, perform the "rights" of drug administration (right patient, right medication, right dosage), and follow the hospital chemotherapy protocols.[12] Another responsibility of the pump staff member is to assist the anesthesiologist in maintaining proper patient fluid balances and ensuring adequate urine output. Anaesthesia staff also monitor the patient's endotracheal temperature and respond, as needed, with appropriate measures.

INTRA-OPERATIVE CONSIDERATIONS:

The team works, intra-operatively, to mitigate four major patient risks during the procedure. They are:

1. Nerve damage or deep vein

During this 48 hour period all body fluids are to be treated as cytotoxic and appropriate precautions should be taken.

thrombosis resulting from lengthy surgery;
2. Fluid and temperature imbalances from the surgical procedure and hyperthermic solutions;
3. Potential pulmonary complications from anaesthesia; and
4. Renal toxicity related to chemotherapy.

The surgeon will, during the procedure, be gently agitating the fluid in the abdomen to help circulate the chemotherapy within the peritoneal cavity. All staff must be aware of the chemotherapy spill risks and be ready to administer spill protocols as required. The pump staff monitor the HIPEC circulation and record all pertinent data, such as the patient's height, weight, and body surface area; chemotherapy dosages; temperatures; and urine output levels.[12]

Laboratory staff and pathologists need to be alerted to the potential of receiving specimens from the operative procedure and need to have an understanding of how to process cytotoxic body fluids or tissues. The scrub and circulating nurses are responsible for ensuring all specimens that leave the operative field and OR theatre are appropriately labeled including cytotoxic warnings.[14]

POSTOPERATIVE CONSIDERATIONS

Theatre Cleaning / Chemotherapy Disposal

The OR theatre should be cleaned, postoperatively, using strict routine precautions and all trash should be clearly identified as chemotherapy contaminated and display appropriate warning labels. Protective impervious barrier garments should be worn by all staff involved in post-op cleaning and chemotherapy disposal.[12] The main risks of exposure are from medication dust or droplets, absorption via the skin, or ingestion through food and other oral contact. Protective eye-wear must be worn in order to minimize the risk from potential splash. Wearing proper personal protective equipment (PPE) is every staff member's responsibility and should not be taken lightly.

A spill kit and respirator masks need to be readily available to the staff, in case a spill occurs, as surgical masks do not provide enough protection against an aerosolized agent. Garbage and laundry bags must be removed following cytotoxic hospital policies and disposed of in the appropriate regulatory fashion as applicable in a designated hazardous waste facility. The patient is transferred to the applicable postoperative unit where the same precautions continue to be applied. The patient may still have cytotoxic fluids being released from

Patient Wound Closure Post HIPEC Procedure.

surgical sites and, therefore, precautions must continue until at least 48 hours after the surgery.[12] During this 48 hour period all body fluids are to be treated as cytotoxic and appropriate precautions should be taken. These precautions impact on the patient's post-operative care as all ward staff must have chemotherapy training and adhere to the required PPE protocols.

Post-operative Care

Post-operative HIPEC patients present with similar complications as patients who have undergone other major general surgical procedures. Esquivel illustrates that the three main complications that resulted in re-operation were fistula, anastomotic leak and bleeding. He further adds that these complications were only seen in 11 percent of the 356 HIPEC cases that had been studied. Esquivel also reports the median length of stay was 21 days.[15] It is only during the first 48 hours, of the three week post-operative stay, that the patient and his/her bodily fluids must be treated with chemotherapy precautions. Signage should be applied and appropriate PPE be worn during this 48 hour period. Special information sharing is required during hand-off from one department to another. Within the Covenant Health program, for example, the intraoperative team places a unique chemotherapy alert wristband on the patient to identify the chemotherapy status to all postoperative teams. The intensive care unit, or post-operative ward, track the period of time following chemotherapy administration and place the patient in a "chemo hot" status until the conclusion of the 48 hour period. Nurse to patient ratios may need to be increased, during the immediate post-operative period, to support patient acuity and in recognition of the increased time required to properly put on and take off the required PPE.

Outcomes

Glockzin et al. report that, as reflected in numerous studies, cytoreductive surgery and HIPEC provide a promising therapeutic option for selected patients with a variety of cancers. They add that a number of studies have demonstrated that cytoreductive surgery and HIPEC may improve oncologic outcomes as compared with palliative chemotherapy alone.[16] Both Glockzin et al. and Esquivel propose that the procedures' optimized success is a result of the combined approach of complete cytoreduction and HIPEC.[15,16] Esquivel adds that results support 60% success at 2 years and approach 40% success at 5 years. Tuttle et al. reported that in a prospective study, of 35 HIPEC patients, those surviving had functional assessments done at four month intervals, over the course of the first year post-op, with results demonstrating that quality of life measurements had returned to baseline after four months and shown significant improvement after 8 and 12 months. Rather than reporting that "I am sad" or "I worry about dying" the patients stated feedback such as "I am able to

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work again" and "I am content with my quality of life." These results lend support to the belief that HIPEC, with tumour cytoreduction, will continue to play a role in the treatment of peritoneal malignancy.

CONCLUSION:

The HIPEC procedure offers select patients, with peritoneal malignancy, a surgical opportunity to increase their survival and the possibility of a cure. During this article's exploration, the many facets of the HIPEC program were explored including the administrative, preoperative, intraoperative and postoperative phases. The discussion also revealed the critical importance of safety, training and team collaboration when planning to undertake a procedure that includes intraoperative chemotherapy. The article outlined the vital importance of establishing strong patient supports as they face the myriad of challenges including a lengthy hospital stay, a physiologically taxing procedure, and the potential end of life. The provided overview empowers surgical programs considering HIPEC to build a peritoneal malignancy program that respects the safety considerations, fiscal stewardship and the collaborative nature required for success. Clinicians and administrators need to apply this knowledge to continue on the journey toward improving hope and extending life for these vulnerable patients.

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