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Original article

Application of hyperthermic intraperitoneal chemotherapy at the University Clinical Center of Republic of Srpska

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Summary

Introduction. Cytoreductive surgery (CRS) combined with hyperthermic intraperitoneal chemotherapy (HIPEC) is an advanced treatment modality for peritoneal malignancies, including ovarian cancer, appendix adenocarcinoma, colorectal cancer, and peritoneal metastases. This approach offers potential benefits in managing these complex conditions.

Methods. The effectiveness of CRS with HIPEC depends on the selection of cytostatics, their pharmacokinetics, and pharmacodynamics. Although these complex surgical procedures are associated with certain risks, they typically result in fewer complications and shorter hospital stays.

Results. The first CRS-HIPEC procedure at the University Clinical Center of Republic of Srpska was conducted on February 26, 2020. From February 2020 to February 2023, 42 CRS-HIPEC procedures were performed with favorable postoperative outcomes. The treatment led to a lower incidence of intraoperative (0%) and postoperative complications (11.9% in five patients), reduced side effects of local chemotherapy compared to systemic chemotherapy, and a decrease in mortality rates (2.4% in one patient). The patients were aged between 40 and 70 years. A multidisciplinary team of surgeons, gynecologists, anesthesiologists, oncologists, and perfusionists carried out the procedures.

Conclusion. Local intraoperative chemotherapy through HIPEC represents a modern and effective treatment approach that improves both surgical and oncological outcomes. Our institution and the Clinic for General and Abdominal Surgery should continue to adopt innovative procedures to enhance treatment and patient care.

Key words: hyperthermic intraperitoneal chemotherapy (HIPEC), cytoreductive surgery (CRS), ovarian cancer, peritoneal metastases (PC)

Introduction

Peritoneal carcinomatosis can be a consequence of primary peritoneal malignancy, gastrointestinal malignancies, gynecological cancers (ovarian cancer). Ovarian cancer accounts for 5% of all gynecological malignancies. Ovarian cancer is one of the leading causes of death

in women with malignant diseases. Annual incidence of ovarian cancer in the world is 192,400, prevalence 507,500 and mortality 114,100 women. The incidence rates are on average twice as high in developed countries (10/10,000 women) compared to developing countries (1/100,000 women). The most common type of ovarian cancer is adenocarcinoma (40–45%), followed by endometrial cancer. It is usually diagnosed in FIGO stages III and IV, when 75% of peritoneal metastases are already present. In the past, peritoneal metastases were considered an incurable and terminal stage of the disease, and patients were treated only palliatively (systemic chemotherapy or palliative surgery). With such a procedure, the average patient survival is only two months. In the 1990s, such an approach changed significantly. Some researchers have argued that peritoneal metastases are, in some cases, only a type of locoregional disease and that treatment is possible [1, 10].

Cytoreductive surgery (CRS) combined with intraperitoneal application of cytostatics (HIPEC) is the method of choice for the treatment of ovarian tumors. The purpose of cytoreductive surgery is to remove a macroscopically visible tumor. Depending on the stage of the disease, various surgical procedures are performed to remove cancer, peritonectomy, omentectomy, resection of the rectosigmoid part of the large intestine, right hemicolectomy, splenectomy, adnexectomy, hysterectomy. Another important part of treatment is locoregional chemotherapy (hyperthermic intraperitoneal application of cytostatics), which is applied during surgery. Hyperthermic intraperitoneal application of cytostatics is a procedure in which cytostatics are introduced and heated during surgery. The purpose is to remove the microscopic remnants of cancer cells. The applicability of this therapeutic approach assumes that cancer cells are still released from the lymphatic vessels or venous blood that remained after the operation. There is also the possibility that cancer cells are left behind at the resection margin, which creates a layer of cancer tissue that adapts to other anatomical structures [2, 6].

The most basic inclusion criteria for surgery with intraperitoneal application of cytostatics are the absence of systemic metastases or metastases in the liver (apart from 2 to 3 limited focal lesions) and exclusively locoregional progression of the disease on the peritoneum [3].

A multidisciplinary approach is necessary, involving a team made up of surgeons, gynecologists, anesthesiologists, oncologists and perfusionists. Cytoreductive surgery (CRS) combined with intraperitoneal chemotherapy (HIPEC) did not prove to be effective as separate methods, but in combination they are currently the most effective methods of treatment for patients with peritoneal metastases due to ovarian cancer, appendix adenocarcinoma, and colorectal cancer [4].

Hyperthermic intraperitoneal application of cytostatics (HIPEC) is a procedure in which a cytostatic solution, heated to 41–44°C, is pumped through the peritoneal cavity via catheters (depending on the type of cytostatics). The solution is then aspirated from the peritoneal cavity through a catheter into a temperature management Hyperthermia Pump (Figure 1). The concentration of cytostatics in the peritoneal cavity is seven times higher when administered intraperitoneally than when administered intravenously. Hyperthermia itself has an antitumor effect because it causes protein degradation, lysosome activation and apoptosis. If the cytostatic solution is heated, complex chemical reactions are triggered further increasing the efficiency and the penetration of the cytostatic into the tumor tissue. The laparoscopic HIPEC technique is also used with a palliative indication (significantly reduces ascites), especially in patients with cancer that cannot be treated surgically. The duration of hyperthermic intraperitoneal application of cytostatics (HIPEC) depends on the type of cytostatics and ranges from 30 minutes to 3 hours. The drug must not cause

local toxicity and must not bind to free water. In addition, it must have a direct cytotoxic effect and satisfactory pharmacokinetic and pharmacodynamic properties [5].

Only patients with limited metastases and no systemic metastases can be candidates for this procedure. This is crucial, as it may act as a limiting factor for the application of this therapy.

The combination of cytoreductive surgery (CRS) and hyperthermic intraperitoneal application of cytostatics has shown to be an effective treatment in female patients with ovarian cancer. The optimal treatment regimen has not yet been established. Cisplatin, oxaliplatin, mitomycin and doxorubicin have been used in various studies. In one study, 70 mg/m2 of cisplatin and the application of HIPEC at 42°C for one hour was confirmed as the most appropriate protocol. It has been proven as the longest survival time when using cisplatin [7].

Cisplatin is associated with an increased incidence of nephrotoxicity, occurring in 5-15% of patients. Diuresis and required urine output greater than 1mL/kg/h will reduce the risk of nephrotoxicity [8].

Methods

This retrospective clinical study was conducted in the Clinic for General and Abdominal Surgery of the University Clinical Center of Republic of Srpska. A total of 42 patients who underwent surgery and who underwent hyperthermic intraperitoneal application of cytostatics (HIPEC) were monitored. The patients were from the entire Republic of Srpska. The study was conducted from March 26, 2020, to February 13, 2023.

Data were collected from council findings, medical history, operation lists, discharge letters and histopathological findings.

Eighteen parameters were monitored in the research such as age, sex, pre/postoperative diagnoses, pH verification, duration of chemotherapy, number of chemotherapies, multidisciplinary approach, type of chemotherapy, method of diagnoses, intraoperative and postoperative complications, hospital mortality.

Results

Fourty-two patients were treated: 40 (95.24%) female and two (4.76%) male patients.

The youngest patient was 40, and the oldest 74. The average age of patients was 57.76 years (patients treated in 2020 had an average age of 58.27, patients treated in 2021 had the average age of 58.36, patients treated in 2022 had the average age of 55.64, while patients treated in 2023 had the average age of 65.5 years) - table 1.

Figure 1. shows the age of patients (in years) and years of treatment.

Table 1. Patient age (in years) and years of treatment

Year of treatment	n	Minimum	Maximum	Median	Mean	Std. Deviation
2020.	15	41	74	57.00	58.27	8.956
2021.	11	40	68	60.00	58.36	8.767
2022.	14	36	72	58.50	55.64	10.426
2023.	2	57	74	65.50	65.50	12.021
Total	42	36	74	59.00	57.76	9.422

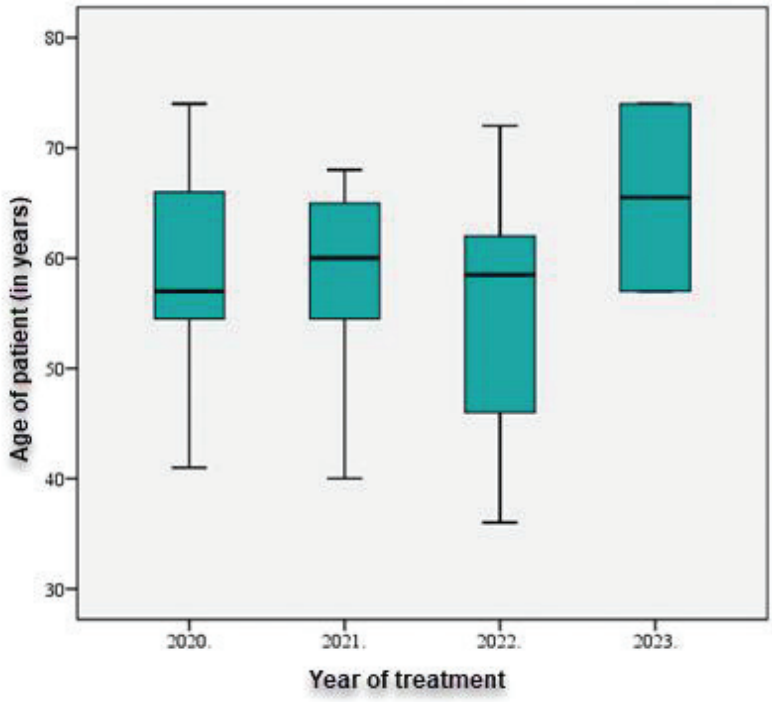

Figure 1. Age of patients (in years) and years of treatment

Applying the Kruskal-Wallis test, no statistically significant difference was obtained ($\chi 2 = 1.386$, $p = .709$) testing the age of the patients (in years) in relation to the year of treatment. Only one of the patients was nulliparous. Three out of four (32 or 76.2%) patients had comorbidities. Two (4.76%) patients had no previous surgery. In two out of three (28 or 66.7%) patients, the diagnosis was made intraoperatively, and in 14 (33.3%) patients, the diagnosis was made by another method.

Table 2. presents the diagnosis methods.

Table 2. Method of diagnosis

	n	%
CT	23	54.8
MRI	12	28.6
PET CT	3	7.1
Abdomen ultrasound	1	2.4
MSCT	1	2.4
Other methods	2	4.8
Total	42	100.0

After pH diagnosis, the decision of the oncology team to continue treatment was made for 40 (95.2%) patients, and chemotherapy was performed for 39 (92.9%) patients.

The duration of chemotherapy was from two to eight months. In 16 patients, chemotherapy was carried out for four months, while in nine patients chemotherapy was carried out for six months. Three months of chemotherapy was carried out in seven, two months of chemotherapy were carried out in three, while five months of chemotherapy was carried out in two patients. Chemotherapy was carried out for seven months in one of the patients and eight months in another patient, while for three patients, chemotherapy was not carried out (Table 3).

Six cycles of chemotherapy were given to 20 patients, four cycles of chemotherapy were given to seven patients, while eight cycles of chemotherapy were given to four patients. Seven cycles of chemotherapy were given to three patients, and five cycles of chemotherapy were given to two patients, while three, nine or 10 cycles of chemotherapy were given to each of the remaining patients (Table 4).

Table 3. Duration of chemotherapy (months)

	n	%	Valid (%)	Cumulative (%)
2	3	7.1	7.7	7.7
3	7	16.7	17.9	25.6
4	16	38.1	41.0	66.7
5	2	4.8	5.1	71.8
6	9	21.4	23.1	94.9
7	1	2.4	2.6	97.4
8	1	2.4	2.6	100.0
Total	39	92.9	100.0	
	3	7.1		
	42	100.0		

Table 4. Number of chemotherapy cycles

	n	%	Valid (%)	Cumulative (%)
3	1	2.4	2.6	2.6
4	7	16.7	17.9	20.5
5	2	4.8	5.1	25.6
6	20	47.6	51.3	76.9
7	3	7.1	7.7	84.6
8	4	9.5	10.3	94.9
9	1	2.4	2.6	97.4
10	1	2.4	2.6	100.0
Total	39	92.9	100.0	
	3	7.1		
	42	100.0		

Taxol/Carbo, as a type of chemotherapy, was used in nine out of 10 (38 or 90.5%) patients, Folfox + Xelox in three, and Carboplantin in one of the patients (Table 5).

Table 5. Type of chemotherapy

	n	%
Taxo/Carbo	38	90.5
Karboplatin	1	2.4
Folfox + Xelox	3	7.1
Total	42	100.0

After chemotherapy, the decision of the oncology team to continue treatment was made for 35 (83.4%) patients. Operations were performed by a team in two out of three (28 or 66.7%) patients. Cisplatin was used as a cytostatic agent in all patients. The dose (mg) of cytostatics used is shown in table 6.

There were no intraoperative complications during the operation and eight (19%) patients received intraoperative transfusions.

Postoperative complications were registered in five (11.9%) patients namely: Haemorrhage intraabdominalis gravis; Shock haemorrhagicus; Bleeding; Neurological complications. CVI; Perfpratio intestini tenui and Recidiv localis. Infiltratio v. urinariae.

Seven (16.7%) patients received a postoperative transfusion (three patients received four doses, two patients received eight, and each of the remaining two patients received six or two doses).

Table 6. Used dose (mg) of cytostatics

	n	%	Cumulative (%)
50	1	2.4	2.4
80	4	9.5	11.9
90	1	2.4	14.3
100	3	7.1	21.4
120	3	7.1	28.6
130	1	2.4	31.0
140	1	2.4	33.3
150	13	31.0	64.3
160	5	11.9	76.2
170	1	2.4	78.6
180	6	14.3	92.9
200	3	7.1	100.0
Total	42	100.0	

Hospital mortality was recorded in one (2.4%) of the patients on March 11, 2020, and the reason was: II63 Infarctus cerebri. Ex. Lethal.

On average, 71.32 days passed from the decision of the oncology council after chemotherapy to admission to the Clinic. Six days (during 2021) is the minimum time from the decision of the oncology council after chemotherapy to admission to the Clinic, and 426 days is the maximum time from the decision of the oncology council after chemotherapy to admission to the Clinic (2021) - table 7.

Table 7. Time elapsed since the decision of the oncology council after chemotherapy and admission to the Clinic (days) and years of treatment

Year of treatment	n	Minimum	Maximum	Median	Mean	Std. Deviation
2020.	13	12	167	40.00	63.62	48.955
2021.	8	6	426	36.50	112.88	149.170
2022.	11	27	112	46.00	57.36	30.765
2023.	2	20	44	32.00	32.00	16.971
Total	34	6	426	40.50	71.32	80.546

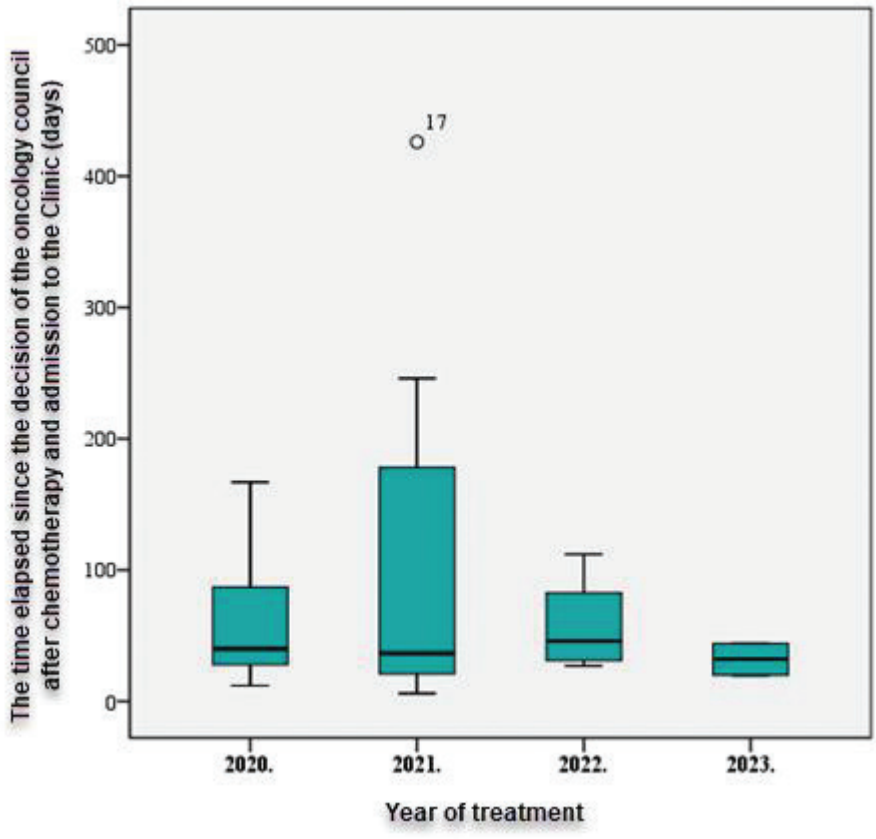

Figure 2. The time elapsed since the decision of the oncology council after chemotherapy and admission to the Clinic (days) and year of treatment

The figure 2. shows the time elapsed since the decision of the oncology council after chemotherapy, admission to the Clinic (days) and years of treatment are shown.

Applying the Kruskal-Wallis test, no statistically significant difference was obtained ($\chi 2 = .814$, $p = .846$) testing the time elapsed from the decision of the oncology council after chemotherapy and admission to the Clinic (days) depending on the year of treatment.

On average, 11.75 days have passed since admission to and discharge from the Clinic. Seven days (during 2020, 2021 and 2022) was the minimum elapsed time from admission to and discharge from the Clinic, and 36 days (2020) was the maximum elapsed time from admission to and discharge from the Clinic - table 8.

Table 8. Time elapsed since admission to and discharge from the Clinic (days) and years of treatment

Year of treatment	n	Minimum	Maximum	Median	Mean	Std. Deviation
2020.	14	7	36	10.50	12.93	7.770
2021.	11	7	14	10.00	10.18	1.991
2022.	13	7	21	11.00	12.00	3.958
2023.	2	9	12	10.50	10.50	2.121
Total	40	7	36	10.00	11.75	5.232

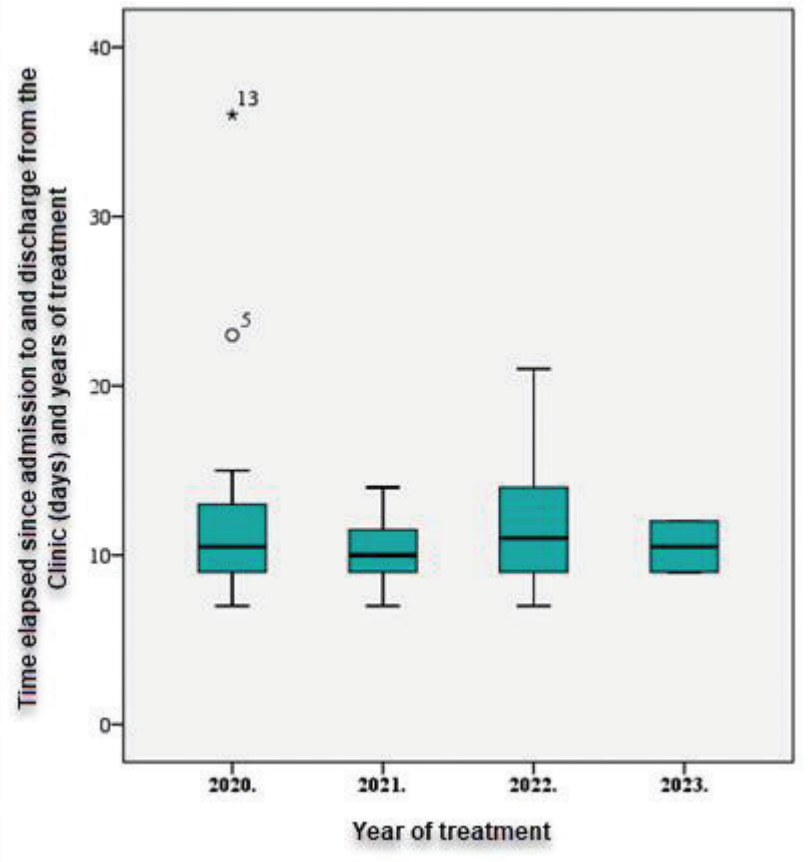

Figure 3. Time elapsed since admission to and discharge from the Clinic (days) and years of treatment

The figure 3. shows the time elapsed since admission to and discharge from the Clinic (days) and years of treatment.

Applying the Kruskal-Wallis test, no statistically significant difference was obtained ($\chi 2$ = .931. p = .818) testing the elapsed time from admission to and discharge from the Clinic (days) depending on the year of treatment.

Discussion

Cytoreductive surgery (CRS) combined with hyperthermic intraperitoneal chemotherapy (HIPEC) is a promising therapeutic approach, particularly for peritoneal carcinomatosis from ovarian cancer, gastrointestinal malignancies, and other peritoneal metastases. This

treatment strategy aims to remove visible tumor masses while delivering a concentrated, heated chemotherapy solution directly to the peritoneum to target microscopic cancer remnants. In the context of the Clinic for General and Abdominal Surgery of the University Clinical Center of Republic of Srpska, our study analyzed the outcomes of 42 patients who underwent this procedure for various malignancies [9].

The first CRS-HIPEC procedure at our institution was performed on February 26, 2020. Since then, a total of 42 patients have undergone this treatment. Among these patients, the majority (95.24%) were women, which reflects the predominance of ovarian cancer and other gynecological cancers as indications for the procedure. The age range of our patients was broad, with the youngest patient being 40 years old and the oldest being 74 years old. The average age of the patients in this cohort was 57.76 years, which is consistent with the general age distribution of patients with ovarian and peritoneal cancers. Notably, we observed a slight trend toward an older average age in patients treated in 2023, which could be related to patient demographics and the evolving nature of the indications for CRS-HIPEC as treatment protocols mature [9].

A key aspect of CRS-HIPEC is its multidisciplinary approach, which involves collaboration between surgeons, gynecologists, oncologists, anesthesiologists, and perfusionists. This team approach is vital for optimizing outcomes and minimizing complications. In our study, most patients had comorbidities (76.2%), which is a common characteristic of the population undergoing such complex procedures. Preoperative evaluation and management of these comorbidities are crucial for ensuring patient safety and improving the chances of a successful surgery and postoperative recovery [9, 10].

The decision to proceed with chemotherapy following surgery was made by the oncology team after evaluating pH diagnostics, and nearly all patients (95.2%) received postoperative chemotherapy. This highlights the importance of personalized treatment plans tailored to the individual's tumor characteristics and response to initial therapy. The use of cisplatin as the cytostatic agent in all patients is consistent with existing literature, where cisplatin has shown efficacy in the treatment of ovarian cancer and other peritoneal malignancies [10].

Our study found no intraoperative complications, which is a notable achievement considering the complexity of CRS-HIPEC. The absence of intraoperative complications can be attributed to careful surgical planning, the experience of the multidisciplinary team, and the use of advanced techniques in both surgery and chemotherapy administration. However, five patients (11.9%) did experience postoperative complications, including severe intra-abdominal hemorrhage, neurological complications, and local recurrence. The most significant complication, as expected, was hemorrhage, which could be related to the aggressive nature of the surgery and the delicate anatomical structures involved in CRS. Although postoperative complications were relatively low, the presence of even minor complications underscores the importance of meticulous postoperative care, including monitoring for signs of infection, bleeding, or organ dysfunction.

Hospital mortality was recorded in one patient (2.4%), which, although low, reflected the inherent risks associated with complex surgeries like CRS-HIPEC. The cause of death, "infarctus cerebri" (cerebral infarction), is not uncommon in elderly patients with comorbidities, and it is unlikely to be directly attributable to the surgery itself. This mortality rate is within the expected range for such high-risk procedures, though continuous improvements in perioperative care are essential to further reduce these risks.

The recovery time in our cohort was relatively short, with patients spending an average of 11.75 days in the hospital. This is a promising result, as shorter hospitalization times are indicative of successful surgical recovery and

the effective management of postoperative complications. The short time between admission and discharge, along with the fact that seven days was the shortest hospitalization period, further supports the notion that CRS-HIPEC is an efficient procedure when carefully managed.

Overall, our findings are consistent with those of previous studies, which suggest that CRS-HIPEC is an effective treatment for peritoneal metastases, offering improved survival outcomes, reduced complications, and shorter hospital stays. The lower complication rate and hospital mortality in our cohort support the safety of the procedure, although ongoing monitoring and protocol optimization are necessary to maintain these favorable outcomes [9–11].

However, there are several areas for further research. The choice of cytostatic agents and the optimal HIPEC regimen remain under investigation, as does the identification of the ideal patient population. While cisplatin remains the most commonly used agent, its toxicity profile, particularly nephrotoxicity, needs careful consideration, and alternative chemotherapeutic agents may be explored in future studies. Moreover, larger, prospective studies with long-term follow-up data are needed to confirm the impact of CRS-HIPEC on survival and quality of life [9–11].

Conclusion

The combination of cytoreductive surgery and hyperthermic intraperitoneal chemotherapy represents a significant advancement in the treatment of peritoneal malignancies. Our experience reflects the growing success of this treatment modality, and we anticipate that ongoing clinical research will help refine and standardize protocols for its use, ultimately improving patient outcomes and further solidifying CRS-HIPEC as a cornerstone of cancer treatment. Local intraoperative chemotherapy represents a novelty in our country and a global standard, thus improving both surgery and oncology therapy.

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Ethical approval. The Ethics Committee of the University Clinical Centar of Republic of Srpska, Republic of Srpska, Bosnia and Herzegovina, approved the study and informed consent was obtained from all individual respondents. The research was conducted according to the Declaration of Helsinki.

Conflicts of interest. The authors declare no conflict of interest.

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Primjena hipertermične intraperitonealne hemoterapije u Univerzitetskom kliničkom centru Republike Srpske

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Uvod. Citoreduktivna hirurgija (CRS) u kombinaciji sa hipertermijskom intraperitonealnom hemoterapijom (HIPEC) predstavlja napredni terapijski modalitet za peritonealne maligne bolesti, uključujući rak jajnika, adenokarcinom slijepog crijeva, kolorektalni karcinom i peritonealne metastaze. Ovaj pristup nudi potencijalne koristi u liječenju ovih složenih stanja.

Metode. Efikasnost CRS sa HIPEC zavisi od izbora citostatika, njihove farmakokinetike i farmakodinamike. Iako su ovi složeni hirurški postupci povezani sa određenim rizicima, obično rezultiraju manjim brojem komplikacija i kraćim vremenom hospitalizacije.

Rezultati. Prva CRS-HIPEC procedura u Univerzitetskom kliničkom centru Republike Srpske izvedena je 26. februara 2020. godine. Od februara 2020. do februara 2023. godine, izvedene su 42 CRS-HIPEC procedure sa povoljnim postoperativnim ishodima. Terapija je dovela do niže incidencije intraoperativnih (0%) i postoperativnih komplikacija (11,9% kod 5 pacijenata), smanjenih nuspojava lokalne hemoterapije u poređenju sa sistemskom hemoterapijom i smanjenja stope mortaliteta (2,4% kod 1 pacijenta). Pacijenti su bili starosti između 40 i 70 godina. Multidisciplinarni tim hirurga, ginekologa, anesteziologa, onkologa i perfuzionista je izvodio procedure.

Zaključak. Lokalna intraoperativna hemoterapija kroz HIPEC predstavlja moderan i efikasan terapijski pristup koji poboljšava kako hirurške, tako i onkološke ishode. Naša institucija i Klinika za opštu i abdominalnu hirurgiju treba da nastave sa usvajanjem inovativnih procedura kako bi unaprijedili liječenje i brigu o pacijentima.

Ključne riječi: hipertermijska intraperitonealna hemoterapija (HIPEC), citoreduktivna hirurgija (CRS), rak jajnika, peritonealne metastaze (PC)