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ORIGINAL ARTICLE

Severe hypersensitivity reactions to platinum compounds post-pressurized intraperitoneal aerosol chemotherapy (PIPAC): first literature report

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Abstract

Background Pressurized intraperitoneal aerosol chemotherapy (PIPAC) shows encouraging results for patients with unresectable peritoneal metastasis. Several reports demonstrated the safety of the procedure combined with systemic chemotherapy, with a low rate of complication. The aim of this study is to report severe hypersensitivity reactions to platinum compounds (SHRPC) during PIPAC procedures.

Methods All patients who underwent PIPAC for non-resectable PC in Lyon Sud University hospital were included in a prospective institutional database. All patients who presented a SHRPC after PIPAC were included in our analysis.

Results One hundred and thirty-two patients underwent 383 PIPAC procedures between December 2015 and December 2017. oxaliplatin's and cisplatin–doxorubicin's protocols were used in 71 and 312 PIPAC, respectively. Four patients (3%) developed SHRPC; two patients (2.8%) after oxaliplatin and two patients (0.6%) after cisplatin–doxorubicin protocols. SHRPC occurred during the 6th PIPAC with cisplatin–doxorubicin protocol and during 2nd and 3rd PIPAC of the oxaliplatin protocol. Three events appeared within 15 min and one event occurred 50 min following nebulization. All the SHRPC have been managed successfully without any complication.

Conclusions This is the first report of SHRPC after PIPAC. The physician must constantly keep this rare but life-threatening complication in mind, especially after repeated PIPAC administration or previous platinum-based systemic chemotherapy.

Keywords Peritoneal metastasis · Cisplatin · Doxorubicin · Oxaliplatin · HIPEC · Allergy · SHRPC

Introduction

Unresectable peritoneal metastasis (PM) remains a dramatic diagnosis despite progress of chemotherapy, targeted therapies and immunotherapies. Cytoreductive surgery (CRS) combined with hyperthermic intraperitoneal chemotherapy (HIPEC) remains the only curative option in the case of resectable and localized PM [1–5].

Recently, Pressurized Intraperitoneal Aerosol Chemotherapy (PIPAC) showed encouraging results for patients with unresectable PM [6, 7]. Several reports proved the safety of the procedure when alternated with systemic chemotherapy cycle, with a low rate of complication [8] and a good quality of life in this context of metastatic disease [9]. A recent study conducted by Teixeira-Farinha et al. showed the lack of hematological, renal or hepatic toxicities but a modest and transitory inflammatory response after repetitive PIPAC administration [10]. Despite the fact that PIPAC is

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increasingly recognized as a safe and well-tolerated procedure, the place of this innovative treatment in the cancer treatment strategy needs to be further investigated [7].

The rational of PIPAC low morbidity is due to the local drug administration, increasing the locoregional bioavailability and minimizing systemic toxicity [11]. The pioneer group from Reymond et al. provided clear recommendations with regard to operative technique, safety checklist and treatment protocols [11]. They are based on intraperitoneal administration of platinum-based chemotherapy, oxaliplatin for colorectal cancer [12], and cisplatin with doxorubicin for ovarian and gastric cancers [6, 13, 14].

Severe hypersensitivity reactions to platinum compounds (SHRPC) following platinum-based chemotherapy (PBC) administration are well known and infrequent, but a life-threatening complication [15]. For example, rates of hypersensitivity reaction to cisplatin are reported between 1 and 5% [15]. Two case reports of anaphylactic reaction post-intraperitoneal cisplatin administration [16, 17] have been described. It is important to note that this mode of administration is different from PIPAC. PIPAC procedures are based on repeated administration of the same nebulized chemotherapy agents, and the knowledge of this life-threatening complication is crucial to increase the safety of these procedures. Repetitive administration could increase the rate of anaphylactic reaction.

The aim of this study is to report SHRPC post-PIPAC procedures.

Materials and methods

The prospectively maintained, institutional PM database of Lyon Sud University Hospital was searched to identify all patients who developed SHRPC post-PIPAC, between December 2015 and December 2017. Our center followed the implantation training program for practical and safety procedures according to the defined guidelines [11] by Reymond initiating team before the 1st PIPAC. The study was performed in accordance with the precepts established by the Declaration of Helsinki.

The PIPAC approach was only considered for patients with unresectable PM. Patients with extra-peritoneal disease, bowel obstruction, or presented a prior history of allergic reactions to platinum drug or doxorubicin were not considered. Surgical procedure was described previously [18, 19]. Briefly, under general anesthesia, a balloon trocar (Applied Medical, Paris, France) was placed in the midline, in accordance with the open laparoscopic technique, and a capnoperitoneum at an insufflation pressure of 12 mmHg was applied. Another balloon trocar was placed in the midline. Exploratory laparoscopy was performed and the peritoneal cancer index (PCI) [20] was determined. Parietal biopsies were performed, and ascites were collected and quantified then sent for peritoneal cytology. A nebulizer CAPNOPEN® (Reger Medizintechnik, GmbH, Villingendorf, Germany) was then connected to a high-pressure injector and inserted into the abdomen through a trocar. The safety protocol with checklist [11, 21] containing all safety aspects was systematically double checked before the administration of cytotoxics. A pressurized aerosol containing chemotherapy agents was then applied. The chemotherapies administrated were cisplatin (7.5 mg/m^2 of body surface in 150 mL of NaCl 0.9%) immediately followed by doxorubicin (1.5 mg/m^2 of body surface in 50 mL of NaCl 0.9%), or oxaliplatin alone (92 mg/m^2 of body surface in 150 mL of NaCl 0.9%). The system was then kept in a closed circuit for 30 min (application time). Remaining toxic aerosol was exhausted over a closed surgical smoke evacuation system. Trocars were removed. The goal was to repeat PIPAC every 6–8 weeks for at least three PIPAC cycles.

According to the French recommendations for management of severe hypersensitivity reactions [22] and according to the CEPO clinical recommendations [23], diagnosis of SHRPC was established by a combination of clinical parameters (brutal fall of blood pressure, brutal desaturation, generalized erythema). According to the same recommendation, allergy prick tests (APT) were conducted 6 weeks at least after resolution of the adverse event to confirm implication of the PBC. APT were conducted according to the European standards [24] by application on the forearm under the epidermis in each case of pure injectable form of cisplatin and oxaliplatin to detect crossed-reaction. Negative control was assessed by a 0.9% saline solution and positive control by a codeine phosphate 9% solution. Positive result was defined as a wheal ≥ 3 mm diameter 20 min after the injection. In case of doxorubicin–cisplatin PIPAC, doxorubicin was also tested.

Results

From December 2015 to December 2017, 132 patients underwent PIPAC for unresectable PM and 383 PIPAC procedures were performed including 71 (18.5%) with oxaliplatin and 312 (81.5%) with cisplatin and doxorubicin. Characteristics of whole population are detailed in Table 1. Among patients who had at least one PIPAC procedure, four patients (3%) developed SHRPC: two patients (2.8%) after oxaliplatin administration and two patients (0.6%) after cisplatin–doxorubicin association. SHRPC occurred during the 6th PIPAC procedure with cisplatin–doxorubicin administration for two patients and during the 2nd and 3rd PIPAC procedures with oxaliplatin protocol for the remaining two patients. Three events appeared within 15 min after nebulization and the 4th one after the extubation. All the SHRPC have been managed successfully by

Table 1 Demographics and clinical data, characteristics of the disease

	Total $N = 132$ (%)
Gender	
Male	59 (44.7)
Female	73 (55.3)
Age, median (min–max)	59.3 (25–78)
Body mass index (range)	22.1 ± 3.97 (13.2–38.6)
ASA class at 1st PIPAC	
1	30 (22.7)
2	80 (60.6)
3	22 (16.7)
Total number of PIPAC	383
Chemotherapy used during PIPAC	
Cisplatin–doxorubicin	312 (81.5)
Oxaliplatin	71 (18.5)
Median *n* of PIPAC (range)	3 (1–12)
Primary cancer (%)	
Gastric cancer	41.7)
Colorectal cancer	19.6)
Ovarian cancer	22 (16.7)
Others	29 (22.0)
Metachronous	21 (15.9)
Synchronous	111 (84.1)
PCI median (min–max)	18 (4–39)

PCI peritoneal carcinomatosis index, *ASA* American society of anesthesiology, *PIPAC* pressurized intraperitoneal aerosol chemotherapy

immediate intraperitoneal exsufflation by the surgeon and by vasopressive drugs, corticoids and intravenous volume expansion followed by intensive care unit (ICU) surveillance for one night without mortality. Characteristics of patients who developed SHRPC are detailed in Table 2 and description of all the adverse events observed per and post-operatively are detailed in Table 3. Only one patient had previous allergic history such as atopic dermatitis. Three patients had previous platinum-based systemic chemotherapy (PBC) administration. APT has been performed and confirmed hypersensitivity to platinum component for all patients. IN addition, doxorubicin was tested for two patients and was negative. In two patients out of four, APT confirmed cross-reactivity to cisplatin and oxaliplatin. Definitive contraindication of platinum-based PIPAC was advocated in all cases, and systemic chemotherapy was modified in two patients. No procedure of desensitization has been tried in our experience.

Discussion

To the best of our knowledge, this is the first report of SHRPC after PIPAC procedure. It is infrequent, but life threatening and it must be kept in mind by the surgeon performing the PIPAC procedure when the patient develops hypotension, especially after repeated PIPAC. In this study, SHRPC occurred at the latest 45 min after platinum salt administration and has been confirmed in all cases by a positive APT.

Severe hypersensitivity reaction must always be considered based on the patient's history. Indeed, diagnosis of severe hypersensitivity reaction is based on clinical parameters [25], and they can be caused either by allergic and non-allergic mechanisms [26], the implication of an allergen cannot always be proven. As a matter of fact, APT has demonstrated to be a reliable method to diagnose IgE-mediated allergic disease [27], but a positive APT for platinum salt is not very predictive [28, 29]. Those parameters all together have to be taken into consideration by the clinician.

In the literature, SHRPC may occur in patients who received prior treatment with PBC [15]. Clinical reports about allergic reactions to cisplatin and doxorubicin were described since early 1980s [30]. Cisplatin is more likely to be involved in allergic reaction than doxorubicin [30]. Concerning cisplatin, the incidence of anaphylactic reactions reported in the literature is between 5 and 20% [23, 31]. In our experience, two patients (0.6%) developed SHRPC after cisplatin–doxorubicin protocol at the 6th PIPAC. The risk factors of allergic reactions to cisplatin described previously were pursuit of chemotherapy after the 6th cycle [32], or combined chemotherapy which could increase the allergic reaction up to 20% [31, 33–35]. Furthermore, this allergic reactions occurred a few minutes after administration of the cytotoxic agents [31]. The same observations were found in our series. For oxaliplatin, hypersensitivity reports have an incidence estimated between 12 and 20% after systemic administration [33, 36]. No reports of anaphylactic reaction post-intraperitoneal oxaliplatin administration have been published, to the best of our knowledge. The data reported here are concordant with previous literature reports concerning IV chemotherapy. Furthermore, three SHRPC out of four occurred within 15 min after PBC nebulization. On the other hand, it is important to note that a severe event can occur with a longer onset.

Hübner et al. [21] reported that safety checklist enabled in every case the success of the PIPAC procedure, without technical or safety issues. We believe that it is important to identify patients at risk of SHRPC such as patients under systemic PBC or with combination including PBC and

Table 2 Clinicopathologic patient characteristics and chemotherapy treatment

	Patient 1	Patient 2	Patient 3	Patient 4
Patient				
Sex	Female	Male	Female	Male
Age (years)	69	78	63	62
Height (cm)	156	170	159	165
Weight (kg)	72	88	71	70
BMI (kg/m^2)	29.5	30.4	28	25.7
ASA	2	2	2	2
Past medical history	Ø	Hypertension	Ø	Type 2 Diabetes Brain stroke
Allergic history	Ø	Atopic dermatitis	Ø	Ø
Disease				
Primary cancer Previous systemic chemotherapies	CRC	CRC	OC	GC
1st line	5FU, Oxaliplatin	5 FU, Irinotecan, oxaliplatin	Paclitaxel–carboplatin–bevacizumab	Docetaxel, cisplatin, 5FU
2nd line	5FU, Irinotecan aflibercept	5FU, Oxaliplatin, Bevacizumab	Bevacizumab–carboplatin	5FU, Irinotecan
3rd line		5 FU, irinotecan bevacizumab, Paclitaxel	Carboplatin–bevacizumab	
Ongoing chemotherapy during PIPAC	5 FU, irinotecan, aflibercept	5 FU, irinotecan, bevacizumab	Bevacizumab	5FU, irinotecan
Previous administration of platinum based chemotherapy	Yes	Yes	Yes	Ø

GC gastric cancer, *CRC* colorectal cancer, *OC* ovarian cancer, *5FU* 5 Fluoro-Uracile

Table 3 Description of adverse event characteristics, management and evolution

	Patient 1	Patient 2	Patient 3	Patient 4
PIPAC number when SHRPC	2	3	6	6
PIPAC's cytotoxic agent	Oxaliplatin 92 mg/m^2	Oxaliplatin 92 mg/m^2	Cisplatin/7.5 mg/m^2; doxorubicin 1.5 mg/m^2	Cisplatin/7.5 mg/m^2; doxorubicin 1.5 mg/m^2
Anaphylactic reaction	Anaphylactic collapse, generalized erythema	Anaphylactic collapse, generalized erythema	Anaphylactic collapse, generalized erythema, Bilateral parotidosis	Anaphylactic collapse, Desaturation
NCI-CTCAE	IV	IV	IV	IV
Time of PIAC after administration (min)	50	15	5	15
Management	Exsufflation, IV noradrenalin, IV corticoïds, IV volume expansion, reintubation	Exsufflation, IV adrenalin, IV corticoïds, IV volume expansion	Exsuflation,IV adrenalin, IV corticoïds, IV volume expansion	Exsufflation, IV adrenalin, IV corticoïds, IV volume expansion
Favorable evolution	Yes	Yes	Yes	Yes
Allergic explorations	APT	APT	APT	APT
Responsible molecule	Oxaliplatin	Oxaliplatin	Cisplatin	Cisplatin
Allergy to other Platinum agents	Yes, cisplatin	Yes, cisplatin	Ø	Ø

SHRPC severe hypersensitivity reactions to platinum compounds, *IV* intravenous, *APT* Allergy Prick Test

patients who underwent several PIPAC, to avoid this life-threatening complication with a mortality rate evaluated at 5% [15]. Fortunately, no mortality was reported in our experience, but we recommend that surgeons and anesthesiologists to be constantly vigilant. They should be ready to exsufflate the pneumoperitoneum and manage patient's hypotension.

Anaphylactic shocks are immediate hypersensitivity reactions that can occur during the postoperative time of PIPAC procedure. All the drugs used during anesthesia induction can be responsible of allergic reaction [37]. As it has been mentioned previously, anaphylactic shocks are rare events. Their incidence during a general anesthesia is about 0.01% [38] in general population. Usually the three main culprits are the neuro-muscular blocking agents, latex and antibiotics [38]. Clinical evidences are still scarce but repeated administration of nebulized chemotherapy seems to increase the risk of allergic reaction compared to "standard" procedures. Furthermore, several studies described perioperative anaphylactic reactions as predominant in female patients, with a sex ratio from 2.7 to 8.1 [39]. Because of this, it is possible to identify some patients at risk for anaphylactic reactions post-PIPAC such as female sex, previous systemic administration of PBC, oxaliplatin-based PIPAC or allergic background in addition to repeated administration of platin-based PIPAC especially after the 6th procedure which has been already highlighted for systemic injection [32] which appears to be quite similar for PIPAC. Currently, there is no primary prevention for sensibilization to any allergen except avoidance of the incriminated agents. The only efficient secondary prevention of anaphylaxis is identification of the allergen and its definitive avoidance [37]. Furthermore, no premedication is efficient to prevent an anaphylactic reaction. Despite this, antihistaminic use could tend to reduce incidence and intensity of those reactions [40, 41]. There is no report of corticoid premedication efficacy [37]. Finally, premedication with antihistaminic might be considered for these procedures, especially for high-risk patients and desensitization as described by some author might be established options for platinum-based hypersensitivity reactions [42].

This study has limitations. First, patient population is heterogeneous regarding the origin of PM, number of previous chemotherapy lines and initial status regarding chemo-sensitivity. Second, the small number of SHRPC described and the fact that we included SHRPC post-cisplatin and oxaliplatin in our analysis. Third, allergic explorations have not been conducted in patients without hypersensitivity symptoms; thus this study does not provide any sensitivity/specificity of APT in a context of SHRPC after PIPAC. Last, no attempt of desensitization has been conducted in this study, and this could be an option as it has been described as common and established options for platinum-based hypersensitivity reactions [42].

Conclusion

This is the first report of SHRPC after PIPAC. The physician must be vigilant for this infrequent but life-threatening complication, especially after repeated PIPAC procedure.

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Compliance with ethical standards

Conflict of interest Matthieu Siebert, Mohammad Alyami, Frederic Mercier, Colin Gallice, Laurent Villeneuve, Frédéric Bérard, Olivier Glehen, Naoual Bakrin, and Vahan Kepenekian have no conflicts of interest or financial ties to disclose.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee, and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study.

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