

Safety and Performance of OptiVantage, a CT Contrast Media Injector, in Multi-Patient Mode

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Purpose: To evaluate the safety, performance and user's satisfaction of OptiVantage®, a dual head CT Contrast Delivery System, in multi-patient mode for patients requiring a contrast-enhanced CT examination.

Patients and Methods: A total of 100 subjects were included in this multicentre observational clinical investigation, conducted between April 20, 2023, and October 6, 2023. The primary endpoint for safety was the rate of extravasation, and the primary endpoint for performance was the success of injection assessed by the investigator. Secondary endpoints for safety were the rates of air embolism and sepsis as well as adverse events (AE) related to the injection. Other data collected included indication, set-up time, injection parameters and user's satisfaction.

Results: The study population included 59% of women. The mean age was 63.6 ± 12.7 years (range: 18 to 83 years), with the majority of patients (55%) older than 65 years. The main indications for undergoing contrast-enhanced CT were breast cancer, colon cancer and lung cancer or nodules. The mean volume injected was 119.5 ± 14.4 mL and the injection rate ranged from 2.8 to 4.5 mL/s (mean; 3.6 ± 0.3 mL/s). No extravasation or other adverse event, including air embolism and sepsis, was reported in any of the subjects (95% CI: [0.00%, 3.62%]). All the injections (100%; 95% CI: 95.39%, 100.00%) were considered as successful for the obtention of diagnostic images. The preparation of the subject, including the setting of the patient line, took between 6 and 10 seconds in most cases (68%) and 16 to 20 seconds for 30 patients (30%). The dayset was changed for 15 subjects and in all cases, it took no more than one minute.

Conclusion: In conclusion, this study confirms the safety and performance of the OptiVantage® Dual head in multi-use mode for contrast injection in adult patients, particularly elderly, undergoing contrast-enhanced CT.

Keywords: power injector, contrast medium, efficiency, usability, safety, elderly

Introduction

In the context of Computed Tomography (CT) examinations, it is generally accepted that using contrast media (CM) improves the quality, tissue characterization and diagnostic performance of imaging and provides complementary information that is often critical to establish the correct patient's treatment pathway.^{1,2} CM is administered intravenously, and power injectors are widely used in routine practice for CT-scan. Power injection of CM can be achieved safely in most patients, even at high-flow rates. Compared to manual injection, it allows medical personnel assisting the scan to operate the delivery of the contrast agent remotely, thus reducing their daily radiation exposure.^{3,4} Power injection is also recommended and routinely used to achieve consistent injection rates of CM.⁵

One of the well-known complications of CM injection is extravasation. The reported incidence of intravenous (IV) contrast media extravasation in adults and children related to power injection for CT has ranged from 0.1% to 1.2%.³ Older age is a risk factor for CM extravasation. Wienbeck et al have reported that patients older than 50 years old presented a higher rate of CM extravasation.⁶ This higher risk in this population might be explained by fragile veins as well as an inability to communicate effectively regarding pain at the injection site. Among others, female gender, use of an existing cannula instead of starting a new IV line, and a catheter site other than the antecubital fossa are also risk factors for contrast media extravasation.^{7,8}

Air embolism is another risk of CM intravenous injection and the estimated incidence of venous air embolism associated with the injection of CM for CT ranges from 7% to 23%.⁹ Although these events are mostly asymptomatic, large volume of air injected can be fatal.

The number of CT performed progresses each year and is estimated to increase annually by 3–4% worldwide.¹⁰ Multi-patient power contrast delivery systems may help reduce the setup time and by extension the workload of healthcare professional increasing the time allocated to patient's care. Their use is growing worldwide. These systems consist of a dayset used for several patients and a patient line used and changed for each patient. The main risk with this well-accepted practice is the cross-contamination due to blood backflow into the injection line. This risk was likely related to the absence of anti-reflux valves, inappropriate disconnecting procedures, and noncompliance with required aseptic procedures, potentially leading to infection.^{11–15} To limit such risk, different procedure packs and disposables with closed systems and anti-reflux valves were developed.

In this study, we evaluated the safety and performance of the Optivantage® Dual Head CT Contrast Delivery System in routine practice for contrast enhanced CT imaging, in multi-patient mode. The radiologist's satisfaction regarding the ergonomics, cleanliness, ease of use, and patient's comfort was also assessed.

The study was registered on Clinicaltrials.gov under the number NCT05537779.

Materials and Methods

This observational study was conducted in two centers in Italy. All subjects (pediatrics, adults, including elderlies > 65 years old) referred to these centers for a contrast-enhanced CT examination using a power injector and having provided (or their legal representative) a written informed consent could be included. Non-inclusion criteria included a weight inferior to 10kg, known allergy or hypersensitivity to contrast media, contra-indication(s) to CT scanner and/or to contrast medium, peripherally inserted central catheter, central venous line or port-A-catheter inserted for injection. It was expected to include at least 15 children (<18 years old) and 15 elderlies (>65 years old).

Each subject underwent a screening visit, an inclusion visit (which could be on the same day as the screening visit) when the CT examination with injection of contrast medium was performed, and a phone follow-up 14 to 21 days after the CT examination.

There were two co-primary endpoints: a safety endpoint defined as the rate of extravasations occurring during the CT examination and a performance endpoint defined as the success of injection contributing to obtain diagnostic images, assessed by the Investigator with a four-point score: 1 = Poor; 2 = Fair; 3 = Good; 4 = Excellent. When the score was given as Poor or Fair, the reasons had to be provided (factors due to patient, injector, CT scanner, imaging acquisition protocol, contrast medium, or others). The injection was considered as successful if the investigator's assessment was Excellent/Good, or if the investigator's assessment was Fair/Poor and causal relationship with the injector could be excluded.

The secondary safety endpoints were the rate of symptomatic air embolism during all types of CT examinations, the rate of air embolism (symptomatic or not) in chest and/or brain CT examinations, the rate of sepsis related to the injection within 14 days after the CT examination, and adverse events (serious or not) related to the injector, or to the procedure or to the CM. Device deficiencies and user injury during the CT examination from the setup to disconnection of the patient line for each patient were also collected.

Other secondary endpoints were set-up times and user's satisfaction. The time needed to connect the patient line to the subject (from the disconnection of the last subject to the connection of the new subject) and the time needed to connect the multi-use filling/injection set (dayset) to the injector in multi-patient mode (from the opening of the first element to the purging of the patient line) were measured.

The radiographer's satisfaction on ergonomics and cleanliness of the injector, the ease of use of the injector, and the subject's comfort when the injector was used in multi-patient mode were assessed with a five-point score. For ergonomics and subject's comfort assessed by user, the scores were 1 – very bad, 2 – bad, 3 – moderate, 4 – good, 5 – very good; for cleanliness the scores were 1 – very dirty, 2 – dirty, 3 – moderate, 4 – clean, 5 – very clean and for ease of use, the score were 1 – very hard, 2 – hard, 3 – moderate, 4 – easy, 5 – very easy.

Ethical Committee

This clinical investigation received the approval from local ethics committees: Comitato Etico Interaziendale di Messina and Comitato Etico Palermo 2. It complies with the Declaration of Helsinki.

Sample Size and Statistical Analysis

For the co-primary endpoint of safety, it was assumed that the frequency of extravasation would range from 0.1% to 1.2% according to the ACR Manual on Contrast Media.³ A sample size of 100 subjects allowed to estimate, with a 95% Confidence Interval (CI), the frequency of this event with a level of accuracy maintained around 5%. For the co-primary endpoint of performance, assuming a success rate ranging from 70% to 90%, a sample size of 100 subjects allowed to estimate, with an adequate width (lower than 20%) of the 95% CI, the frequency of this rate. This study was thus planned to enroll 100 patients. Among these 100 patients, at least 15% of children and 15% of elderly patients were to be enrolled in order to assess the safety and the performance of the injector in these populations through definition and analysis of patient sub-groups.

For the rate of extravasation (co-primary endpoint of safety) and the rate of success of injection (co-primary endpoint of performance), the 95% CI has been computed using the Wilson or the Wilson interval with exact method boundary correction for extreme cases (WEMBC). If appropriate, the other 95% CI was computed using the exact confidence interval for a single proportion. Statistical analyses were conducted using SAS[®] Software version 9.4 or later. Descriptive statistics are provided as mean \pm SD for continuous variables and absolute and relative frequencies for categorical variables.

Results

Patient Characteristics

A total of 100 subjects were enrolled between April 20, 2023, and October 6, 2023, at two clinical centres in Italy, including 59 women. The subjects' age ranged from 18 to 83 years, and the mean age was 63.6 ± 12.7 years (Table 1). Most patients (55%) were over 65 years old. The mean weight and body mass index (BMI) were 69.9 ± 12.2 kg, and 25.7 ± 4.10 (range: 15.6 to 42.6) kg/m², respectively, and were similar in both subgroups (Table 1). The most frequent indications for undergoing contrast-

Table 1 Baseline Demographics and Characteristics

	All Subjects (N = 100)	18–65 years (n= 45)	> 65 years (n = 55)
Gender			
Male/Female (%)	41.0/59.0	44.4/55.6	38.2/61.8
Age (years)			
Mean \pm SD	63.6 \pm 12.7	52.4 \pm 9.7	72.8 \pm 5.2
Median (Min, Max)	67.0 (18.0, 83.0)	54.0 (18.0, 65.0)	72.0 (66.0, 83.0)
Weight (kg)			
Mean \pm SD	69.9 \pm 12.20	69.2 \pm 12.69	70.4 \pm 11.87
Median (Min, Max)	70.0 (40.0, 105.0)	68.0 (43.0, 96.0)	70.0 (40.0, 105.0)
BMI (kg/m²)			
Mean \pm SD	25.7 \pm 4.10	24.7 \pm 3.93	26.6 \pm 4.06
Median (Min, Max)	25.7 (15.6, 42.6)	24.1 (16.8, 32.9)	26.7 (15.6, 42.6)
Body region scanned n (%) [1]			
Head	24 (24.0)	11 (11.0)	13 (13.0)
Neck	15 (15.0)	6 (6.0)	9 (9.0)
Thorax (Lung)	62 (62.0)	25 (25.0)	37 (37.0)
Abdomen	73 (73.0)	33 (33.0)	40 (40.0)
Pelvis	23 (23.0)	6 (6.0)	17 (17.0)
Extremities	0 (0.0)	0 (0.0)	0 (0.0)
Vessels	0 (0.0)	0 (0.0)	0 (0.0)
Other	1 (1.0)	0 (0.0)	1 (1.0)

Notes: [1] More than one body region could be scanned so percentages may not total to 100%.

Abbreviations: BMI, body mass index; SD, standard deviation.

enhanced CT were breast cancer (11%), colon cancer (10%) and lung cancer or nodules (10%). The body regions scanned were most often the abdomen (73%) and the thorax (62%), and only static imaging was performed (Table 1).

Injection Characteristics

The intravenous injection was performed in the antecubital fossa in all subjects (100%) and the injected volume of contrast medium ranged from 90 to 130 mL, with a mean of 119.5 ± 14.4 mL. The injection rate ranged from 2.8 to 4.5 mL/s, with a mean of 3.6 ± 0.3 mL/s. A volume of 20 to 30 mL of saline was used for flushing (Table 2).

The contrast medium used was always iobitridol (Xenetix®, Guerbet) at a concentration of 350 mg I/mL. For all patients, Manyfill® (Medex/Guerbet) was used as dayset and Secufill® (Medex/Guerbet) was used as patient line. A patency check was performed for all patients.

Injection System Performance and Usability

The primary endpoint for performance was the success of injection. The success rate was 100% (95% CI: 95.39%, 100.00%), with a score of “excellent” for 98 subjects and “good” for 2 subjects (both in the 18–65-year age group) (Table 3).

The usability of the system was also recorded by the care provider. The preparation of the subject took between 6 and 10 seconds in most cases (68%) and 16 to 20 seconds for 30 patients (30%). The duration of the preparation was between 11 and 15 seconds for one subject and more than 20 seconds for only one subject, due to the subject’s bad walking (Table 4).

The dayset was changed for 15 subjects and in all cases, it took no more than one minute.

Safety

The primary safety endpoint was the rate of extravasation during the injection process. No event of extravasation was observed in any of the patients during the study period (Table 5). The 95% CI for extravasation was calculated as [0.00%,

Table 2 Characteristics of the Injection

	All Subjects (N = 100)
Location of Injection, n (%)	
Left antecubital vein	40 (40.0)
Right antecubital vein	60 (60.0)
Concentration of contrast medium (mg/mL)	
Mean \pm SD	350.0 \pm 0.00
Median (Min, Max)	350.0 (350.0, 350.0)
Volume of injected contrast medium (mL)	
Mean \pm SD	119.5 \pm 14.44
Median (Min, Max)	130.0 (90.0, 130.0)
Injection rate (mL/sec)	
Mean \pm SD	3.6 \pm 0.29
Median (Min, Max)	3.5 (2.8, 4.5)
Volume of saline injected (mL)	
Mean \pm SD	29.8 \pm 1.41
Median (Min, Max)	30.0 (20.0, 30.0)
Dynamic or static imaging n, (%)	
Static	100 (100.0)
Patency check performed	
Yes	100 (100.0)

Table 3 Injection System Performance per Investigator

	All Subjects (N= 100)	18–65 years (n = 45)	> 65 years (n= 55)
Injection performance, n (%)			
Excellent	98 (98.0)	43 (95.6)	55 (100.0)
Good	2 (2.0)	2 (4.4)	0 (0.0)
Fair	0 (0.0)	0 (0.0)	0 (0.)
Poor	0 (0.0)	0 (0.0)	0 (0.)
Injection Success [1], n (%)	100 (100.0)	45 (100.0)	55 (100.0)
95% CI for Injection Success [2]	95.39%, 100.00%	90.20%, 100.00%	91.87%, 100.00%

Notes: [1] Injection success is defined as an Excellent or Good Rating or a Fair and Poor Rating not due to the Injector.
[2] 95% CI was calculated using the Wilson corrected method.

Table 4 Injection Usability per Investigator

	All Subjects (n = 100)
Duration of preparation of subject, n (%)	
≤5 seconds	0 (0.0)
6–10 seconds	68 (68.0)
11–15 seconds	1 (1.0)
16–20 seconds	30 (30.0)
>20 seconds	1 (1.0)
Duration of setup of injection line, n (%)	n = 15*
≤ 1 minute	15 (100.0)

Note: *number of patients for whom the whole injection line has been changed.

Table 5 Adverse Events

	n (%)	95% CI [1]
Extravasation rate	0 (0.0)	0.00%, 3.62%
Symptomatic Air Embolism	0 (0.0)	0.00%, 3.62%
Air Embolism [2]	0 (0.0)	0.00%, 3.62%
Sepsis Related to CM Injection	0 (0.0)	0.00%, 3.62%

Notes: [1] 95% CI was calculated using the WEMBC methodology.
[2] Air Embolism was only measured on Chest and/or Brain CT scans.

3.62%], showing a nil to low risk of extravasation with OptiVantage[®]. No adverse event was observed in the study, including air embolism and sepsis. No device deficiency was reported either.

User's Satisfaction

The user's satisfaction was recorded for all injections (n=100). The radiographer's satisfaction with the injector was high in all cases, with an assessment of very satisfying in 96% of the cases for ergonomics, ease of use and subject's comfort in multi-patient mode and satisfying for the 4% remaining cases. Regarding cleanliness, the injector was assessed as “very clean” in 97% of the injections and clean in the remaining 3%.

Discussion

The aim of the study was to evaluate the safety and performance of the power injector OptiVantage[®] Dual Head CT Contrast Delivery System for contrast medium (CM) injection with a focus on specific populations such as elderly, which are considered at higher risk of extravasation.

Among the 100 subjects included in this study, most were aged over 65-years old (55%), and none were under 18-years old. Our data showed that there was no increased rate of extravasation in the >65 years old sub-population compared to the 18–65-year age group. Indeed, no extravasation was observed in any participant during the study. In addition, no other complications such as symptomatic or asymptomatic air embolism or sepsis related to CM injection were reported. A higher extravasation rate was previously reported in older subjects undergoing high-rate power injection of CM as compared to younger patients (≥ 50 vs < 50 years, 0.6% vs 1.4%; $p = 0.019$; ⁶). Our results confirm that the use of the OptiVantage[®] in the multi-use mode is safe, including in this higher risk population.

The main limitation of this investigation is the absence of pediatric subjects. This was, however, expected as the enrollment in this study reflected the real-life private practice, where a small number of children undergo contrast-enhanced CT procedures, compared to the adult population. Patient enrollment was unfortunately limited to two sites that rarely perform pediatric contrast-enhanced CT procedures and the short timeline to enrolment completion (5.5 months) did not enable to add another site with better potential. In children, CM injection is complicated by patient's factors such as small volumes of CM, small gauge angio-catheters and unusual vascular access sites (hand, forearm, elbow, foot).³ However, recent studies on large pediatric populations have confirmed the safety of the power injection of contrast media for CT examination, in this more sensitive population. Extravasation rates in children appear to be similar to those in the adult population. An extravasation rate of 0.3% was documented in a study of 554 children in which a power injector was used to administer iodinated CM.¹⁶ A more recent study, including 2429 contrast-enhanced CT examinations with power injectors performed in children, identified 18 cases (0.7%) of extravasation.¹⁷ In addition, in the retrospective study by Shaqdan et al of the incidence of CM extravasation for CT and MRI among 502,391 injections performed in a large academic medical centre, the incidence of extravasation was 0.13% (451/352,125) for CT overall, with no significant difference according to the age: 0.12% (4/3309) for pediatric patients (<18 years old), 0.12% (201/169,702) for adults 18–60 years and 0.14% (246/179,114) for patients >60 years old.¹⁸ Considering the evidence found in the literature, and despite the lack of data for children in this investigation, one can expect the safety profile of OptiVantage[®] to be as good in the pediatric population as it was in adults.

The device was evaluated as successful to obtain diagnostic images in 100% of cases. Radiographers were very satisfied with OptiVantage[®] Dual Head CT Contrast Delivery System regarding ergonomics, cleanliness, ease of use, and subject's comfort in multi-patient mode. Regarding the time of preparation in the context of a multi-patient use, this investigation showed a quick preparation of the subject, taking less than 20 seconds for all patients except one (due to the patient's bad walking). It took even less than 10 seconds for 68% of the patients. The change of the patient line took no more than 1 minute in all cases. These set up and patients changeover times are comparable to that reported for another multi-use piston-based system.¹⁹ Altogether, this demonstrates the performance of OptiVantage[®] when used as intended in routine practice in multi-patient mode. The advantage of using multi-use systems in terms of time saving has been reported previously. In a multicenter study with 42 radiology nurses across 6 regions of China, evaluating the CT-contrast operational workflow and hospital imaging efficiency when using a multi-dose bulk IV contrast delivery system compared with a single-dose packaging contrast, the total operating times were 68.47 ± 8.11 s and 84.64 ± 11.67 s, respectively (when both used with dual-syringe system) ($p < 0.01$).²⁰ In another study carried out on 15 technologists, time using single-use vs multi-use systems showed that CT technologists spent 40.5 seconds less per exam with multi-use system compared to single-use system ($p < 0.001$).²¹ Another advantage of the multi-patient set-up is the reduction of contrast agent, saline and plastic waste. Routhier et al reported that the change from a single use IV system to a multi-dose IV system resulted in average used contrast agent volume reductions of 15.9mL, 35.1mL and 11.4mL ($p < 0.0001$) for pulmonary embolism CT angiography, head and neck and abdomen/pelvis CT examinations, respectively.²²

Although, a breach of sterility is possible as for any other multi-dose system, the multi-user dayset combined with a patient line changed for each patient used in this study is designed to eliminate the possibility of patient-to-patient contamination. Indeed, this set includes anti-reflux valves and dual filter connectors. Accordingly, this investigation did not highlight any problems with the multi-use setting in terms of safety or efficiency. Altogether, this multi-patient power injector system demonstrated efficiency and potentially timesaving and cost-effectiveness compared to mono-patient systems, without impacting the safety. Its use may thus impact positively on the care professional's workload, allowing them to spend more time with the patient which is particularly important in the fast-growing number of CT examination performed each year globally.

Conclusion

This study confirms the safety and performance of the use of the OptiVantage[®] power injector in routine multi-patient mode, for adults, including elderly, undergoing contrast-enhanced CT.

Abbreviations

BMI, body mass index; CI, confidence interval; CM, contrast media; CT, computed tomography; SD, standard deviation.

Data Sharing Statement

No data are intended to be shared.

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Disclosure

A.T. and F.S. report no conflicts of interest in this work. A.S. is a former employee of Guerbet. F.H. is employed by Guerbet.

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