

GAVeCeLT* consensus statement on the correct use of totally implantable venous access devices for diagnostic radiology procedures

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ABSTRACT

The use of totally implantable venous access devices in radiology may be associated with complications such as occlusion of the system (because of the high density of some contrast), infection (if the port is not handled in aseptic conditions, using proper barrier protections), and mechanical complications due to the high-pressure administration of contrast by automatic injectors (so-called power injector), including extravasation of contrast media into the soft tissues, subintimal venous or myocardial injection, or serious damage to the device itself (breakage of the external connections, dislocation of the non-coring needle, or breakage of the catheter).

The last problem – i.e., the damage of the device from a power injection – is not an unjustified fear, but a reality. A warning by the US Food and Drug Administration of July 2004 reports around 250 complications of this kind, referring to both port and central venous catheters and peripherally inserted central catheter systems, which occurred over a period of several years; in all cases, the damage occurred during the injection of contrast material by means of power injectors for computed tomography or magnetic resonance imaging procedures.

Though the risk associated with the use of ports in radiodiagnostics is thus clear, it has been suggested that administration of the contrast material via the port may have some advantage in terms of image quality, increased comfort for the patient, and maybe more accurate reproducibility of the patient's own follow-up exams. This contention needs to be supported by evidence.

Also, since many cancer patients who need frequent computed tomography studies already have totally implantable systems, it would seem reasonable to try to define how and when such systems may safely be used.

The purpose of this consensus statement is to define recommendations based on the best available evidence, for the safe use of implantable ports in radiodiagnostics.

Key words: Implantable ports, High pressure, Extravasation, Contrast media, Power injection

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INTRODUCTION

The use of totally implantable venous access devices (ports) for contrast media infusion in both adults and children is traditionally associated with several concerns for both radiologists and referring physicians, in consideration of the potential risk of complications.

In fact, the use of totally implantable venous access devices in radiology may be associated with complications such as occlusion of the system (because of the high density of some contrast), infection (if the port is not handled in aseptic conditions, using proper barrier protections), and mechanical complications due to the high-pressure administration of contrast materials by automatic injectors (so-called power injector), including extravasation of contrast media into the soft tissues, subintimal venous or myocardial injection, or serious damage to the device itself (breakage of the external connections, dislocation of the non-coring needle, or breakage of the catheter).

The last problem – i.e., the damage of the device from a power injection – is not an unjustified fear, but a reality. A warning by the US Food and Drug Administration (FDA) of July 2004 (1) reports around 250 complications of this kind, referring to both port and central venous catheters (CVCs) and peripherally inserted central catheter (PICC) systems, which occurred over a period of several years; in all cases, the damage occurred during the injection of contrast material by means of power injectors for computed tomography (CT) or magnetic resonance imaging (MRI) procedures. In addition to the obvious loss of a vascular access and the need for repositioning a new device, in some cases the breakage of the catheter may cause an extravasation of contrast into the patient's soft tissues, and/or an embolization of catheter fragments in the central venous or pulmonary arterial circulation (which may result in the need to retrieve them by interventional radiology). Secondary contamination of health care personnel due to contact with the patients' blood (2) has also been reported. Complications of this kind may be even more frequent than reported, because in the United States, the obligation to report the event exists only in case of the

patient's death or "serious injury."

The FDA warning of 2004 thus concludes with the recommendation to use power injection only with vascular devices (3) specifically certified for such use (4). It is also important to stress that some devices, even if apparently intact, might have been irreparably damaged by the excessive pressures to which they were subjected, and damage or malfunctioning may appear some time later.

Though the risk associated with the use of ports in radiodiagnostics is thus clear, it has been suggested that administration of the contrast via the port may have some advantages in terms of image quality. This contention is not supported by the evidence, because many CT exams (the only ones to require high flow rates of viscous contrast) are routinely performed using peripheral veins with excellent qualitative results. However, the use of a power injectable device may be associated with increased comfort for the patient (i.e., avoidance of the insertion of an additional cannula into a peripheral vein) and may give results with more accurate reproducibility of the patient's own follow-up exams. Also, because many cancer patients who need frequent CT studies already have totally implantable systems, it would seem reasonable to try to define how and when such systems may safely be used.

The purpose of this consensus statement is to define recommendations based on the best available evidence, for the safe use of implantable ports in radiodiagnostics.

The first section offers a discussion on the current indications and contraindications for the administration of contrast via implantable ports. This includes both the exams focusing on the diagnosis of complications linked to these devices, as well as their use for diagnostic purposes regarding the patient's underlying condition. It also examines the potential advantages of contrast media injection through these central venous access devices versus the use of a peripheral venous access.

The second section explains the potential mechanical damage secondary to the high pressures generated by power injectors. At the same time, the advantages of high-flow high-pressure infusion and the ideal characteristics of a power injectable totally implantable system are discussed.

The last section deals with other potential complications associated with the use of ports in radiodiagnostics, such as the risk of occlusion of the system by high-viscosity contrast and the risk of infection or extravasation.

SECTION 1 – INDICATIONS FOR THE USE OF TOTALLY IMPLANTABLE VENOUS ACCESS DEVICES FOR CONTRAST MEDIA INJECTION

Question 1: What are the main indications for injection of contrast media through ports?

a. Exams performed for the diagnosis of port-related problems.

There are various clinical situations in which it may be necessary to perform a radiological study using a contrast medium specifically injected through a port (the so-called catheter-gram or line-o-gram) – e.g., to rule out the presence of an occlusion of the catheter or any mechanical damage to the reservoir and/or to the catheter itself.

The problem usually arises when there is a malfunction of the system. Typically these are clinical situations in which it is not possible to withdraw blood from the catheter to check its patency and the intravascular location of the catheter tip, before administration of intravenous infusions, especially of vesicant (chemotherapy) drugs or hyperosmolar solutions (parenteral nutrition). In accordance with the UK Royal College of Nursing (RCN) Standards for Infusion Therapy (5) and Infusion Nurses Society (INS) Infusion Nursing Standards of Practice (6), the patency of the system should in fact always be verified before each infusion: “The patency of any vascular access device (VAD) should be established prior to administration of medicines and/or solutions” (5-7).

McCloskey (8) proposed the following clinical classification of the most frequent types of catheter occlusion:

- complete occlusion – persistent inability to withdraw and infuse fluids;
- partial occlusion – transient difficulty in withdrawing and/or infusing;
- persistent withdrawal occlusion – persistent inability to withdraw blood, though the device retains its capacity to infuse fluids; according to the London Standing Committee (9), this complication is best defined as the possibility for fluids to be infused freely by simple gravity while blood cannot be withdrawn.

In the case of persistent withdrawal occlusion, after having taken the steps suggested by the above algorithm, it may be advisable to take a 2-view chest X-ray, which in some cases may identify the cause of the malfunction (tip malposition, pinch-off syndrome, complete breakage of the catheter, or embolization of catheter fragments). In other situations, it may be necessary to also perform

a line-o-gram, which may identify conditions that cannot be diagnosed by a plain X-ray film (venous thrombosis, sleeve, breakage and/or partial damage to the reservoir or catheter, partial intraluminal occlusion, or dislocation of the non-coring needle).

In conclusion, in the study of malfunctions of a central venous port, the use of the angiographic exam by injection of contrast media through the device plays a fundamental and well-defined role. In fact, this procedure will often allow an unequivocal diagnosis of the presence of any damage to the catheter, of extraluminal extravasation, or of kinking of the catheter lumen; it will also confirm the position of the distal tip of the catheter.

b. Use of the port for exams not focusing on the diagnosis of port-related complications.

There is a vast practical experience in the use of ports as a means for administering contrast media for diagnostic tests, especially in cancer patients.

In the case of contrast media imaging during MRI, or during traditional radiological techniques (such as, e.g., urograms), there are no particular concerns related to the performance of the venous access device.

The case of the use of ports for contrast media infusion during CT is different. CT is undoubtedly a diagnostic exam where the modality of contrast media administration plays a central role. Technological developments have led to very fast imaging techniques, so that a prevalently morphological exam has turned into a functional exam. This implies that the administration of contrast media must be carried out by well-defined protocols. In cancer patients, high-flow infusion of contrast media is useful especially in the imaging of parenchymatous organs with particular vascularization, such as liver, kidneys, pancreas, and adrenal glands. When studying other organs and systems, the technique of contrast media administration is less crucial.

Contrast media imaging parameters that may influence the quality of a CT image are flow rate, total volume of dye, and the distance of the injection site to the right atrium.

- 1) **flow:** flow rate influences the blood concentration of the contrast media (high rates = high concentrations, low rates = low concentrations).
- 2) **total volume:** this correlates with the duration of the injection of the contrast medium at a certain constant flow. Also, after the passage into the pulmonary circulation, it represents the length of the contrasted blood “column” that will reach the organ to be studied. The longer the column is, the greater the transit time, and thus the time available for studying the organ. The use of increasingly faster machines has reduced the total volume of the contrast medium needed for these exams.

3) **injection site distance:** this element may influence the time between the start of the infusion of the contrast medium and the “arrival” of the contrasted blood column into the organ to be studied. The greater the distance is from the right atrium, the greater the dilution of the contrast medium in the blood. Therefore, at equal flow rates, an injection performed at a shorter distance from the right atrium (i.e., via a central venous line) will produce a greater blood concentration.

Thus, the execution of CT for parenchymatous abdominal organs preferably requires forced injection (flow rates between 2.5 and 5 ml/s) to obtain a high blood concentration and enhance the contrast media resolution of the parenchyma in the arterial phase. A better resolution will improve the diagnostic accuracy; in particular, the contrast media imaging dynamics in the various phases (early arterial, late arterial, portal, and late phase images) will offer a better identification of the focal alterations of the liver, as well as an assessment of their nature.

Question 2: What are the potential advantages of port infusion (if feasible without complications) for exams not aiming to diagnose device complications?

In other words, to what extent may the use of the port be advantageous in terms of cost/effectiveness as compared with the use of a peripheral venous access device?

The answer to this question is a controversial one, reflecting the small amount of evidence available, and the resulting necessity to resort to data of lesser scientific impact. The key point is whether the power injection method through the port is complication-free; once this point is settled in favor of the substantial safety of the procedure (i.e., adopting devices designed and constructed to tolerate the high pressures generated by the power injection), the use of a venous port already present might be more cost effective and more comfortable than the search for a suitable peripheral vein, which may not always be easy to find.

In this regard, the scientific literature offers only indirect information.

The cost-effectiveness of the use of ports in long-term therapies in cancer patients has been addressed in several papers, but their value is biased by the fact that randomized trials comparing ports versus repeated venous accesses may be conducted exclusively in patients with an uncompromised peripheral venous system who are undergoing cycles of bolus chemotherapy (10). In patients with peripheral veins that are already compromised at the initial assessment, or in patients who require infusion chemotherapy, there is a strong recommendation for the insertion of a venous port: therefore, these patients cannot be randomized in studies of adequate statistical power, thus limiting the possibility to achieve level I scientific evidence (11). With the present state of scientific knowled-

ge, there is objective evidence that the implantation and use of a port is a safe and effective strategy for long-term venous access in cancer patients, and that this strategy is able to reduce several problems (anxiety, pain, and costs) connected with repeated searches for peripheral venous access (12-14).

Among the potential advantages of the use of ports in radiodiagnostics, worthy of note is the possibility for a better standardization of infusion techniques, both among the various patients and within the framework of the follow-up during and/or after therapy in the same patient. Moreover, the infusion of contrast media through a CVC (tip in proximity of the cavoatrial junction) would allow the use of lower flow rates and lower volumes in contrast to those needed during the infusion in a peripheral vein.

FINAL RECOMMENDATIONS

1. When is the use of a port in radiodiagnostics indicated, and when are there contraindications?

With the present state of knowledge, on the basis of what is reported in the sector's scientific literature, it is not possible to define when the infusion of contrast media via a venous port is contraindicated. On the contrary, there are some clinical situations in which infusion of contrast media via the port is strongly indicated, for the purpose of detecting device-related complications such as occlusion or damage of the reservoir and/or of the catheter (so-called catheter-gram or line-o-gram).

Also, numerous clinical and experimental studies have described the use of a venous port for radiodiagnostic purposes without appreciable complications. However, considering the reports of serious damage derived from the use of power injection with central venous access devices not specifically equipped for that purpose and the fact that they have also been the subject of the already-mentioned warning from the US FDA of July 2004 (1), this panel of experts prudentially recommends that before using a port for radiodiagnostic purposes, the physician and/or the nurse should assess the specific constructive features of the device (as documented for FDA approval or for CE mark).

It is this panel's opinion that the use for radiodiagnostic purposes of a safe venous access device designed to tolerate the high flows and pressures generated by power injection may be associated with some advantage for the patient (avoidance of a new peripheral or central vein puncture).

Finally, we may identify 1 specific application for power injectable central venous access devices. There are clinical oncological studies (phase I or II) on the use of innovative experimental drugs, in which the evaluation of the response is made on the basis of response evaluation criteria in solid tumors (RECIST) criteria, which are universally recognized and documented (15). In these cases, an optimal radiological assessment is of paramount impor-

tance; for example, the RECIST Committee recommends that the lymph nodes used as parameters for the definition of the response should be measured in their short axis, rightfully considering this more significant. In such cases, for obvious ethical and cost/benefit reasons, optimal quality of radiological documentation is mandatory. The impossibility of obtaining an adequate peripheral venous access (patients with already-compromised peripheral veins, obese patients, etc.) and/or the presence of a central venous access system that cannot be used – because it is not certified for power injection – could pose a limit to the performance of this type of more refined assessment.

2. What kind of studies may be currently desirable in this field to define any aspects that may still be subject to controversy?

There are still numerous controversial aspects to this problem, and they mainly concern the cost–effectiveness ratio. In particular, there are no studies of adequate statistical power and good scientific quality (i.e., randomized clinical trials [RCTs]) comparing a “power on principle” strategy (i.e., always and in any case inserting a “power injectable” port and using it for all radiological exams) with a “peripheral venous access device on principle” strategy (the use, always and in any case, of a peripheral venous access device for the execution of CT exams, both in patients without an implanted port and in patients with non-power-injectable ports). The end points of this type of study should be the patient’s satisfaction, including issues concerning comfort and quality of life (anxiety, pain, etc.), as well as the direct costs of the 2 different strategies (in the case of the power injectable port with power injectable non-coring needles, will a higher “raw” cost be offset by possible savings on patient management?).

A second aspect that should be studied is the impact of using a power injectable port on the quality of the images. This might be of significance, for example, in oncological patients with hepatic lesions. In such cases, it is essential to have an optimal standardized sequence of the different CT phases (the so-called 3-phase). Its dual blood supply and the need to complete the scan before the balance between the intravascular and extravascular compartments occurs make the liver a unique organ; especially for RECIST assessments, the use of a power injectable technology could be more cost-effective than peripheral access.

SECTION 2 – POTENTIAL MECHANICAL DAMAGE OF TOTALLY IMPLANTABLE VENOUS ACCESS DEVICES, SECONDARY TO THE HIGH PRESSURES OF POWER INJECTION

Question 1: What are the advantages of high-flow/high-pressure contrast media infusion, and when is it indicated?

As mentioned above, the injection of contrast medium through a central line is more comfortable for the patient. Also, a central line may be better than a peripheral line, from the point of view of the quality of the exam, especially in CT scans. The use of a central line avoids the stasis of contrast medium in the venous axis of the arm and the shoulder at the end of the injector thrust, as is the case in peripheral injection. The bolus proceeds more uniformly and compactly through the heart and arrives in the pulmonary and systemic circulation less diluted. In modern injectors, the injection of the contrast medium is followed by an injection of saline solution; the latter, however, mixes together with the contrast medium and does not constitute an actual driving system that can improve its progression.

The pressure set on the injector is usually 300 pounds per square inch (PSI), which is a value used routinely for peripheral venous injection. At the same level of viscosity and temperature of the contrast media, it is preferable to speak in terms of flow rate rather than pressure values.

As already mentioned, in the case of CT assessments of parenchymatous organs (liver, kidney, adrenal gland, or pancreas), and in particular when it is desirable to obtain an arterial phase plus a balance phase and a venous phase, it is advisable to achieve a flow rate of 4-5 ml/s in an adult.

All CT equipment today provides quick scans apt to yield the required diagnostic information. A quick and compact injection, as obtained via a central catheter, may be associated with a better temporal, spatial, and contrast resolution. In cancer patients, the improvement of image quality means not only arriving at identifying smaller and smaller lesions, but also obtaining crucial information for assessing the therapeutic response.

Question 2: What are the pressures that develop in the totally implantable port during infusion by power injector? At what level may these pressures cause mechanical damage to the system?

Any infusion through a venous device is associated with the development of pressures that may potentially exceed the system’s resistance, as summarized in Table I. On the other hand, simple infusion by gravity would never permit us to achieve adequate flow rates for a good radiological visualization, as shown in Table II.

When the use of a port is desired, the necessity for an infusion pump is evident. However, several in vitro studies (16) suggest that the injection of nonionic contrast media at 2 ml/s by pump constantly entails the risk of exceeding the PSI limit recommended by the manufacturer. On the other hand, the use of low pressures (17) does not permit adequate flow rates, as shown in Table III.

From these data it follows that – when a flow rate >2 ml/s is required – the PSI limits recommended by the device manufacturer will inevitably be exceeded, with an associated risk of mechanical damage to it, and/or of extravasation.

Besides the already-mentioned warning of the US FDA of July 2004 (1), there are also a growing number of studies reporting that the administration of contrast media by power injector into a CVC can be performed safely, with the sole precaution of limiting the injection pressure (17-21); this is particularly true in pediatric patients, where a smaller volume of contrast is required. It should also be pointed out that the FDA warning refers generically to any type of device (CVCs, PICCs, and ports), whereas obviously there are significant differences among the different types of access in terms of resistance to pressure damage.

In a study which is extremely detailed from the technical standpoint, carried out by a pediatric radiology unit at the Children's Memorial Hospital in Chicago (21), no complication from power injection was observed in 63 children who underwent a CT body scan; care was taken to set the injector at a pressure limit of 25 PSI (172 kPa) – i.e., the minimum for this type of injector (En Vision Medrad), in accordance with previous indications from other groups (22). The authors chose 30 kg as the cutoff body weight to apply the above protocol, since the greatest impact of power injection on the quality of the exam was observed in children with weight below 30 kg. In this study, tunneled catheters offered a better performance – in terms of contrast enhancement – than ports and PICCs.

To minimize the risks of power injection, other groups have proposed the use of manual injection (23), although, when using manual injection with small-volume syringes, there is a significant risk of generating very high pressures, the magnitude of which remains unpredictable, just as the flow rate is unpredictable. In this regard, a not-too-recent in vitro study documented that manual infusion may be associated with peak pressures higher than those reached using the power injector, at equal flow rates (24). In a pediatric

study conducted in 1,440 CT scans over a 6-year period, the use of manual contrast media injection was associated with 4 episodes of damage to the catheter (all repaired without consequences), i.e., an incidence of 0.3% (23).

An in vitro study conducted in Germany a few years ago (25) evaluated 20 different types of port, using a power injector (Stellant; Medrad, Inianola, PA, USA), through which 100 ml of contrast media (Ultravist 370; Schering, Berlin, Germany) was injected, setting a pressure limit of 325 PSI. The injection speed was increased by 2 ml/s from a starting value of 2 ml/s, up to a maximum value of 10 ml/s. Maximum injection pressure and rate were measured and recorded. An injection rate of 2 ml/s was possible in all types of port, 4 ml/s was possible with 18 ports, 6 ml/s in 13 ports, and 8 ml/s in 6 ports out of 20. At a pressure limit of 325 PSI, an injection rate of 10 ml/s was never possible, regardless of the type of port. Neither breakage, or disconnection, or extravasation episodes were observed. The authors' conclusion was that the power injection of contrast media, at a pressure limit of 325 PSI, seems to be tolerated by all of the types of venous port studied, and that most of them permit flow rates suitable for multislice CT studies, which require rapid administration of the contrast media.

A nonsponsored in vitro study conducted at the European Institute of Oncology (data not yet published) substantially confirmed the reports of the German study (25). In particular, this study was conducted by administering the most viscous contrast media on the market (Iopamiro 400; Bracco, Italy) by power injectors used for angiographic exams, and with which it was possible to vary the pressure peak limit, and assess, at the end of the injection, the actual flow rate administered compared with the value set. The results showed that none of the devices suffered any damage from injections within the pressure limits commonly used in the clinical practice of CT diagnostics (325 PSI), even if used repeatedly. No damage occurred, not even at pressures close to 400 PSI (396 PSI); the only cases of damage were detected at 432 PSI, and exclusively regarding the external connection to the non-coring needle. In this in vitro study, the authors could never reach a flow rate of 5 ml/s, even varying the peak pressures, because the gauge of the non-coring needle (20G) was the "real" obstacle against the contrast media flow.

This study focuses our attention on several relevant elements:

1) at the flow rates commonly used for CT images in on-

TABLE I - SYRINGES VOLUME AND THEIR RESISTANCE IN PSI

1-ml syringe	120-300 PSI
5-ml syringe	15-40 PSI
10-ml syringe	10-20 PSI
Freehand contrast media	>90 PSI
Contrast media with power injector	300 PSI

NB: pressure usually tolerated by standard central veins: 15-25 PSI; 1 PSI = approximately 50 mm HG; PSI = pounds per square inch.

TABLE II - VENOUS ACCESS DEVICES AND GRAVITY FLOW

50-cm PICC	0.26 ml/s (20 ml/min)
20-cm CVC	0.83 ml/s
20G cannula	1 ml/s
18G cannula	1.75 ml/s
16G cannula	3.66 ml/s (220 ml/min)

CVC = central venous catheter; PICC = peripherally inserted central catheter.

TABLE III - VENOUS ACCESS DEVICES FLOW RATE AND RESISTANCE

Port	if limit is 25 PSI: 1.5 ml/s
Tunneled catheter	if limit is 25 PSI: 2.5 ml/s
Non-tunneled CVC	if limit is 15 PSI: 2 ml/s (16G) 1.5 ml/sec (18G)

CVC = central venous catheter; PSI = pounds per square inch.

- cology (2.5-3.5 ml/s), even a non-power-injectable port permits the safe administration of contrast media;
- 2) among the various components of the port system, the only one actually prone to pressure damage is the external connection (the connection with the non-coring needle);
 - 3) there is a constant significant difference between the set flow rate value and the value actually injected (in compliance with the pressure limits set for the injection device);
 - 4) the gauge of the non-coring needle represents the real bottleneck of the system. This explains the breakage upstream of the system even at pressures exceeding the limits normally present in power injectors for CT (325 PSI).

With regards to the totally implantable venous ports, the risk of pressure damage is closely related to the dynamics of the high-flow rate infusion which takes place through the whole system.

The pressure preset on the injectors is usually 300-325 PSI, a value established as appropriate for the injection of contrast media in a peripheral vein via a 18G short cannula connected to an extension tube of slightly more than 1 m in length; the extension tube is normally supplied by the manufacturer of the power injector, and both its strength and its flow capacity are compatible with the pressure required.

In the case of ports, the extension tube coming from the power injector is connected to a shorter tube of smaller caliber directly connected to the non-coring needle, which may be of variable caliber and length. When the internal caliber of one or more of these various components is smaller, in order to maintain an appropriate flow rate, the initial pressure generated by the power injector should be increased; nevertheless, in clinical practice, the power injector is programmed with a maximum pressure ceiling so that when the resistance of the system increases, the pressure applied is automatically reduced, and the injection proceeds at a slower flow rate. Since the injection cannot be interrupted, an increase in the resistance through the system may cause excessive pressure leading to detachment, damage, or bursting of some components of the system. Therefore, as a power injector is applied to a totally implanted venous port, it is necessary to take into account the high resistance created by the presence of the non-coring needle, which is the segment with the smallest caliber along the entire infusion line, and which acts as a bottleneck in the system. To infuse an adequate volume of contrast media at high flow (5-6 ml/s) through the entire system, the power injector must inevitably generate a very high pressure upstream of the non-coring needle (even more than 300 PSI). This explains why most of the mechanical damage created by high-pressure/high-speed infusion occurs on the infusion line upstream of the connection between the non-coring needle and the reservoir.

Typical mechanical damages includes breakage of the extension of the non-coring needle or its detachment from the needle, sudden expulsion of the non-coring needle

from the silicone septum and thus from the port chamber, and breakage of the silicone portal septum. Other possible but rare occurrences are detachment of the catheter from the port or breakage of the catheter. The more fragile the system is, even in one of its components, the lower the injection pressure at which mechanical damage may occur.

Finally, considering the high pressures generated during power injection, it is preferable to avoid any compression/deformation of the catheter, such as may occur by the so called pinch-off of catheters inserted in the subclavian vein using the "blind" subclavian approach (i.e., without ultrasound guide). This is another reason to recommend the technique of insertion of the catheter in the internal jugular vein or – even better – any technique of ultrasound-guided insertion, either supraclavicular (internal jugular vein, innominate vein, or subclavian vein) or infraclavicular (axillary vein). This recommendation is also sometimes included in the instructions of the manufacturer for the power injectable device.

Question 3: What type of totally implantable venous access device can be used at high pressures?

For a patient, having a well-designed and functional implantable venous access device is of considerable importance for various reasons, related both to chemotherapy and to infusion of contrast media. For example, when the capacity of the silicone septum to hold the non-coring needle firmly is adequate, there will be an advantage in terms of safety, since a tight connection between the needle and the reservoir reduces the risk of extravasation of the chemotherapy drug. At the same time, a tight connection between the needle and reservoir will also allow the high pressure injection of contrast media.

Focusing on the features required by a power injectable venous access system, it must be stressed that an appropriate reservoir should be coupled with a catheter of appropriate caliber, constructed of material which must be biocompatible, but also endowed with particular physical properties in terms of strength and resistance.

Furthermore, access to the port should be achieved with a non-coring needle not only of appropriate caliber and resistance, but also connected to a pressure resistant extension tube. All of these characteristics should be certified by the manufacturer, while the physician is responsible for implanting the venous access device with the appropriate technique and for verifying the proper functioning of the system, at the pressures and flow rates indicated.

Of course, the assessment of power injectability derives from in vitro tests and not from clinical experiments.

In vitro and in vivo data are often not comparable, since the mechanical and anatomical conditions – in particular for the catheter – are quite different. For example, the catheter may be compressed or significantly bent because of its anatomical location, its trajectory inside the

vessels, the posture of the patient, and other factors.

Therefore, even using devices specifically designed for power injection, the overall clinical efficiency of the system should be verified *in vivo*, in the patient: the *in vitro* data must be implemented with the necessary adaptations for the individual patient. Each component of the system, the viscosity of the contrast media, the actual temperature during administration, the pressure value preset on the injector, the anatomical position of the catheter and its tip, etc., must be verified constantly.

In the case of ports suitable for injection at 4-5 ml/s according to the manufacturer, it is understood that the whole system (the non-coring needle with its extension and the port with its catheter) may tolerate a pressure of 300 PSI without damage. On the other hand, the use of a system not specifically indicated for power injection must be carried out under the sole and total responsibility of the operator.

Furthermore, the reservoir should not cause artifacts in the CT scans and MRI exams; the construction material should be titanium or nondeformable plastic. Of great importance is the connection between the reservoir and catheter, in terms of caliber, length, and modality of connection. Lastly, it is necessary to consider the characteristics of the catheter itself (external caliber, internal caliber, and actual length *in vivo*). With regard to the material of the catheter, the fourth-generation polyurethanes seem to have the appropriate combination of good biocompatibility, high mechanical strength, and relative resistance to bacterial colonization.

FINAL RECOMMENDATIONS

1. How to prevent mechanical damage from power injection?

Mechanical damage can be effectively prevented using devices characterized by specific features of design and construction which make them safe for power injection. The manufacturer indication that a totally implantable central venous port is safe for power injection is to be considered an essential requirement when high-flow contrast media infusion is indicated. Since the power injectability of the device is normally tested *in vitro*, the manufacturer's data should be coupled with the actual clinical data (implantation technique, type of contrast media, temperature of injection, needle used to access the system, etc.). All the components of the system should be power injectable (including the non-coring needle and its extension tube).

Before the actual pressure injection, it is also recommended to check the anatomical location of the catheter and its tip (utilizing the so-called frontal scout view), to rule out malpositions, kinking, or other abnormalities which may

affect the flow rate and hinder the power injection. The device must be checked for patency (infusion and withdrawal function) prior to connection to the power injection.

Finally, it is recommended that the venous access port and the other components (non-coring needle, etc.) suitable for power injection should be easily recognizable (with clinical and/or radiological methods: color code of the external components, structural features of the reservoir, etc.), even in absence of the paper documentation.

2. What studies may be currently desirable in this field to define any aspects that may still be subject to controversy?

At present, the clinical studies on the actual safety and cost-effectiveness of contrast media injection for CT through central lines are not satisfactory from the point of view of statistical power. For example, there are sporadic clinical reports confirming the safety of rapid injection (over 3 ml/s) into the superior vena cava or the right atrium, but no perspective controlled studies.

Furthermore, clinical studies investigating the possible correlation between power injectable port and venous thrombosis are needed. In fact, the use of power injectable ports implies the adoption of catheters made of particularly rigid material (ultra-strong polyurethane), of a caliber larger than usual (8 French), and thus introducers and dilators larger and more traumatic than usual. All of these factors may theoretically be associated with an increased risk of catheter-related venous thrombosis.

SECTION 3 – OTHER POTENTIAL COMPLICATIONS DERIVED FROM THE USE OF TOTALLY IMPLANTABLE SYSTEMS IN RADIODIAGNOSTICS

Apart from the pressure-related mechanical complications we have discussed above, there are other complications potentially associated with the use of ports in radiodiagnostics: occlusion of the system, infection, and extravasation.

These iatrogenic complications are secondary to an inappropriate handling of the device by the radiologist or by the radiology nurse, because in many countries the radiology technician is NOT authorized to position or use a venous access device.

Question 1: What is the risk of obstruction of the system after the use of a contrast media, and what does it depend on?

The obstruction of the totally implantable system – whether partial or complete – may be due to factors extrinsic to the device or, in contrast, to intraluminal

factors. Examples of obstructions secondary to extrinsic factors are kinking of the catheter, the pinch-off syndrome (i.e., pinching of the catheter in its extravascular passage between the clavicle and the first rib), malposition of the catheter tip (e.g., tip erroneously positioned into a small vessel), or catheter tip trapped in a fibrin sleeve or in a venous thrombus caused by the catheter itself. Many of these causes are due to errors during the implantation of the device. The most common errors are (a) "blind" puncture of the subclavian vein using a subclavian approach (a practice that is now widely discouraged by international guidelines), resulting in pinch-off syndrome, and (b) the lack of intraoperative and/or postoperative control of the precise location of the catheter tip, whose ideal position is in the area between the lower third of the superior vena cava and the upper third of the right atrium (catheters whose tip have not been situated in that area are characterized by a higher risk of malfunction) (26, 27).

Nevertheless, even if positioned according to the recommendations of the international guidelines, proper functioning of a totally implantable system requires proper catheter maintenance.

The washing ("flush") of the system is to be carried out exclusively with saline solution, using a handheld 10-ml syringe ("active" flush), if possible using the "push-pause" (also called "start and stop") technique. The "standard" flush (10 ml of saline solution) is used in the following situations: at the start of use, before each infusion through the system, between the infusion of different products, and at the end of the use of the system. A special flush (20 ml of saline solution) is carried out after drawing blood and after the infusion of blood or blood products, or particularly viscous solutions (the infusion of a contrast medium falls into this category).

The lock of the system is carried out – depending on the type of port and type of protocol adopted – with saline solution or heparin solution (or any other solution with an anticoagulant and/or antibacterial property – e.g., citrate and/or taurididine): the lock solution is injected into the system, in a volume equal to the double of the dead space of the device, at the end of the use of the system, immediately after a final saline flush. The lock of the system is preferably done using the "positive pressure" method (i.e., if the non-coring needle is left in place, "clamp as you infuse"; if the non-coring needle has to be removed, "remove as you infuse") (5, 28, 29).

Each access to a totally implantable system should be performed by medical nursing personnel who possess the basic knowledge needed for proper maintenance of the system. Use by personnel who have not received specific training will inevitably increase the risk of complications. In particular, the risk of obstruction of the implantable system after administration of contrast media may be particularly high, considering

the viscosity of the infusate. It is recommended that the level of skill in the use of implanted venous ports in radiology departments should be as high as in oncology departments.

The risk of obstruction from contrast is due to various factors:

- 1) the viscosity of the contrast media itself;
- 2) the diameter and length of the catheter;
- 3) the patency of the whole implantable system which, if impaired, causes a further slowdown of the flow;
- 4) the effectiveness of the flushing of the device before and after its use for administration of contrast media.

Viscosity is a measurement of the flow resistance of a liquid and is expressed in centipoises (cps). The viscosity of iodinated contrast media depends on the iodine concentration, the size of the molecules, and the temperature, and normally lies between 1.4 and 26.6 cps. Low-osmolality contrast media are more viscous than high-osmolality ones. The viscosity of the iodinated contrast medium is partially responsible for the discomfort felt during its injection.

Some iodinated contrast are liposoluble, with the iodine bonded to vegetable oil unsaturated fatty.

The great majority of iodine-based contrast media are hydrosoluble and can be injected into the bloodstream and into natural cavities. Their range of use is vast: from the morphological and functional study of the biliary and urinary tracts, to opacification of heart, vessels and cavities, arthrography, myelography, etc. (Tab. IV). The contrast media used for MRI are particularly viscous and hyperosmolar (Tab. V).

Thus, the risk of catheter obstruction from contrast media is particularly relevant for high-osmolality and high-viscosity media.

Question 2: What is the risk of infection of the system after use of contrast media, and what does it depend on?

The use of ports is generally associated with a minimal infection risk (0.1 infections/1,000 days), especially if used by skilled staff (e.g., in the oncology units); the risk, however, may increase proportionally to the lack of specific expertise among the staff (e.g., use in the operating room, emergency department, or radiology facility).

Infection is triggered by contamination, which may occur extraluminally (e.g., due to errors in non-coring needle insertion, failure to use sterile gloves in a sterile way, absent or poor skin antisepsis prior to puncture) or intraluminally (contamination of the infusate while using the non-coring needle, failure in the use of sterile gloves in a sterile way, failure to disinfect the needle-free connector enough, lack of asepsis in handling the syringes and infusion ports).

There is no evidence of increased incidence of catheter-related blood stream infections when the port is used

for power injection, and it is not known whether the infection risk may be increased in the radiology suite.

In practice, a central role is played by the training of the radiology department nursing and/or medical staff in charge of using totally implantable systems. In this sense, an important element to be considered is the turnover of the staff involved in accessing ports, as well as the size of the hospital. In small hospitals this problem is less obvious, but in larger ones where the turnover rate is much higher, the need to train new personnel may pose difficult challenges.

Question 3: What is the risk of extravasation of contrast media, and what does it depend on?

It is not easy to estimate the incidence of contrast media extravasation. Many events often remain undiagnosed and unreported: therefore the overall incidence is underestimated. In some cases, only local pain may lead to a late diagnosis of extravasation (30).

Extravasation of injected contrast media is fortunately a rare event, considering the large number of venous lines in use and the wide use of contrast imaging. Nevertheless this small number is anything but negligible. The incidence of contrast media extravasation varies depending on type of radiological investigation, but its incidence during CT scans has increased considerably since the late 1990s, probably because of the increase in both the number of scans done and the use of automatic injectors. Miles et al observed an incidence of 0.2% in a series of 5,280 injections with an automatic injector; even at low

flow rates (1-2 ml/s), an incidence of 0.14% was reported (31). This means that there are somewhere between 9,000 and 235,000 extravasation events occurring each year in United States as a complication of contrast media injections during CT scans.

Extravasation, also, must be interpreted as a complication that is always and exclusively iatrogenic. It is often secondary to a primary malposition of the non-coring needle (false perception of the positioning of the tip of the non-coring needle in the port chamber while it is still in the subcutaneous tissue) or even to a secondary malposition (i.e., dislocation of the non-coring needle from the reservoir due to inappropriate stabilization or movement of the needle during administration of the contrast medium).

Among the possible mechanisms of extravasation are

- Difficulty in puncturing the reservoir, secondary to an erroneous site of implantation (too deep) and/or to a lack of specific know-how of the radiologist or radiology nurse who is inserting the non-coring needle;
- Use of an inappropriate non-coring needle (e.g., too short or too long);
- Lack of stabilization of the non-coring needle with a transparent dressing (as recommended by the RCN guidelines).

The effects of contrast media extravasation are sometimes dramatic and may lead to serious local chemical inflammation, leading to skin and subcutaneous tissue necrosis of varying degree. Tissue necrosis may cause long-lasting lesions that are difficult to treat, associated with high costs, have a huge negative impact on the patient's quality of life, and involve significant risk of medicolegal suits (32).

Also according to Cohan, the following factors can increase the extravasation risk and their consequences:

- Noncommunicative patients
 - Elderly
 - Babies and children
 - State of unconsciousness
- Patients who are severely debilitated or chronically ill
 - Those with marked weight loss or diffuse metastatic disease
- Preexisting vascular damage
 - Diabetic disease with vascular lesions
 - Connective tissue diseases (e.g., Raynaud phenomena, etc.)
 - Thrombosis or venous insufficiency
 - Tourniquets
 - Previous radiotherapy to the limb to be cannulated
 - Ipsilateral regional lymph node dissection
- Multiple punctures in the same vein
- Injections on the back of the hand, foot, or ankle
- Use of indwelling peripheral catheters (Midline)
- Injections through metal needles instead of plastic catheters (33).

TABLE IV - CHARACTERISTICS OF CONTRAST MEDIA

Characteristics of contrast medium	
Ionic activity	Ionic contrast
	Non-ionic contrast
Osmolarity	High-osmolarity contrast: 1,200-2,400 mOsm/L
	Low-osmolarity contrast: 290-890 mOsm/L
Viscosity	Between 5 and 25 cps (max for gadolinium) (water = 1; blood = 3-4; mineral oils 20-70)

TABLE V - CONTRAST MEDIA AND THEIR OSMOLARITY

All hyperosmolar	Magnevist – 1,960 mOsm/L
	Omniscan – 789 mOsm/L
	Optimark – 1,110 mOsm/L
	Prohance – 630 mOsm/L
	Multihance – 1,970 mOsm/L
All viscous (between 2 and 5 cps at room temperature)	

FINAL RECOMMENDATIONS

1. *How to prevent complications?*

With regard to the *prevention of infectious complications*, there are numerous international guidelines:

- RCN 2010 (Royal College of Nurses, UK) (5);
- INS 2006 (Infusion Nursing Society, USA) (6);
- EPIC 2007 (Evidence-based Practice in Infection Control, UK) (28);
- ESPEN 2009 (29);
- BCSH 2006 (British Committee for Standards in Hematology, UK) (34);
- SHEA/IDSA 2008 (35);
- CDC Atlanta 2002 (Centers for Disease Control, USA) (36).

All of these guidelines suggest the following essential elements for the prevention of infections of ports used in radiodiagnostics:

- Operator education (medical, nursing, and technical staff) (cf. EPIC 2007: “Healthcare workers caring for a patient with a central venous access device should be trained and assessed as competent in using and consistently adhering to the infection prevention practices described in this guideline.” (28));
- Washing of hands + sterile gloves;
- Appropriate skin asepsis, if possible with chlorhexidine 2% in isopropyl alcohol 70% solution (waiting time for effectiveness: 30 seconds);
- Correct insertion technique for non-coring needle
 - Sterile gloves!!!
- Correct running of the infusion line
 - Sterile gloves; disinfection of the needle-free connectors before their use;
- Drafting of local recommendations for the prevention of infections associated with the use of CVCs/ports in radiodiagnostics (37).

Before proceeding with the power injection, it is always necessary to verify the *patency of the line*, controlling the blood return (also recommended by the INS 2006 and RCN 2005 standards), flushing the port with 10 ml of saline solution, and making sure the intravenous fluid can infuse freely. In the event the patency is not certain, it is necessary to follow the local protocol for the diagnosis and treatment of the obstructed system (38). In any case, it is advisable to never proceed with the power injection if the patency and correct positioning of the system have not been confirmed.

As for obstructions caused by pinch-off, these can be prevented by implanting the catheter under ultrasound guidance, or by avoiding the infraclavicular subclavian puncture as is now recommended by all international guidelines. The user's instructions provided by port manufacturers also usually give instructions on how to flush the implantable system in situ.

With regard to the *extravasation of contrast media*, prevention is based on a single important rule: it is advisable to entrust the positioning and stabilization of the non-coring needle exclusively to medical or nursing personnel specifically trained in the procedure. Adequately trained staff will know how to adopt the following precautions:

- Use a sufficiently long non-coring needle to sufficiently access the reservoir;
- Make sure the reservoir is positioned correctly (adequately stable and sufficiently superficial to be easily palpable);
- Once the reservoir is punctured, make sure there is a blood return through the non-coring needle and that the flush solution can be infused freely;
- Secure the non-coring needle in the appropriate way (the RCN 2005 standards recommend stabilizing with transparent semipermeable polyurethane dressings);
- Monitor for any effects of the power injection on the stability of the non-coring needle inside the reservoir septum.

In conclusion, the prevention of any complication secondary to the use of a port in radiology includes the adoption of systematic protocols for interventions: specific evidence-based recommendations are already available in the literature, both for infection and occlusion, as well as for extravasation. Treatment protocols are well defined for infection and occlusion and somehow less empiric evidence exists for extravasation.

It is highly recommended that all radiological units using contrast infusion through venous ports should adopt specific prevention protocols (or “bundles”), and should implement an educational strategy including training courses for the health care personnel working with venous access devices.

2. *What studies may be currently desirable in this field to define any aspects that may still be subject to controversy?*

At present, there are no studies on the actual possibility of obtaining a good nursing level for handling of these devices during their use in radiodiagnostics. Although strongly suggested by common sense, it would in any case be advisable to document, with specific clinical studies, the association between the level of training of the health care workers in charge of the use of ports in radiodiagnostics and the rate of complications caused by faulty handling. Furthermore, it is advisable to assess this problem in terms of cost-effectiveness, weighing on the one hand the advantages of the use of the port over other venous access devices suitable for high-pressure contrast media infusion (peripheral venous cannula) and, on the other hand, the economic and logistic costs of the specific training of radiologists and radiology nurses in the use of the ports.

In other words:

- a) the positioning of a peripheral venous cannula is feasible in 99% of cases (specially when ultrasound guidance is available: it is a low-cost maneuver, which – in the most difficult cases – could be performed by a PICC/CVC team already active in the hospital);
- b) the complications secondary to faulty use of the port (infection, obstruction, and extravasation) are expensive and potentially associated with the need to remove the device; to minimize such complications, specific training of all radiology personnel is necessary, something that is inexpensive and feasible in small centers, but costly and difficult in large hospitals.

Therefore the solution does not appear simple, nor automatically applicable to all hospital situations. Hopefully, future studies should consider these practical aspects, and should define local strategies based on 6 cornerstones:

- Patient safety;
- Minimization/elimination of complications;
- Cost-effectiveness;
- Best clinical outcome with minimum risk;
- Structure efficiency;
- Maximum economic yield with minimum use of resources.

SUMMARY OF THE RECOMMENDATIONS

Recommendations about the choice of a power injectable port vs. a standard port

- 1) Mechanical damage secondary to high pressure injection of contrast media into venous access ports can be effectively prevented using devices characterized by specific features of design and construction which make them safe for power injection (so-called power injectable ports).
- 2) The use for radiodiagnostic purposes of the same port previously inserted for chemotherapy (if the port is power injectable) may be associated with some advantages for the patient, since it avoids the insertion of an additional peripheral line.
- 3) In clinical oncological studies in which the evaluation of the response is made on the basis of RECIST criteria, an optimal radiological assessment is of paramount importance: in these cases, a CT scan performed via a central venous line (such as a power injectable port) may yield a specific advantage in terms of image quality versus a scan performed via a peripheral line.

Future studies suggested in this area

- Studies of adequate statistical power and good scientific quality comparing a “power on principle” strategy (i.e., always and in any case inserting a power inject-

able port and using it for all radiological exams) vs. a “peripheral venous access device on principle” strategy (the use, always and in any case, of a peripheral venous access device for the execution of CT exams, both in patients without an implanted port and in patients with non-power-injectable ports). The end points of this type of study should be patient’s satisfaction, including issues concerning comfort and quality of life (anxiety, pain, etc.), as well as the direct costs of the two different strategies (in the case of the power injectable port with power injectable non-coring needles, will a higher “raw” cost be offset by possible savings on patient management?).

- Radiological studies investigating the impact of using a power injectable port on the quality of the images, particularly when studying the abdominal parenchymal organs by CT scan.

Recommendations for the safe and appropriate use of a power injectable port in radiodiagnostics

1) Identification of the power injectable device:

- Before using a port for radiodiagnostic purposes, the physician and/or the nurse should assess the specific constructive features of the device (as documented for FDA approval or for CE mark), so as to be certain that the port is power injectable;
- Not only the port, but all of the components of the central venous system (including external connectors, non-coring needles, etc.) should be power injectable;
- The power injectable port as well as the other power injectable components (connectors, non-coring needle, etc.) should be easily recognizable.

2) Prevention of complications:

- Before using the system, a scout view is mandatory, so as to rule out malpositions, kinking, or other abnormalities in the central line;
- If the catheter of the port has been inserted via an infraclavicular approach, the health operators should check that the catheter has been inserted by ultrasound venipuncture, so as to exclude any potential risk of pinch-off;
- The patency of the system should be checked prior to connection to the power injector;
- Positioning and stabilization of the non-coring needle should be performed exclusively by medical or nursing personnel specifically trained in this procedure;
- When flushing the venous line, the user’s instructions provided by port manufacturers should be followed.

3) Education and training:

- To minimize the risk of infection, needle dislocation, catheter occlusion, etc., the average level of skills in the

- use of implanted venous ports in radiology departments should be as high as that in oncology departments;
- When using a port for contrast medium injection, systematic protocols of interventions for early detection and early management of potential complications should be adopted in the radiological suite;
- All radiological units using contrast infusion through venous ports should adopt specific protocols (or “bundles”) for prevention of infective and mechanical complications, and should implement an educational strategy including training courses for the health care personnel working with venous access devices.

FUTURE STUDIES SUGGESTED IN THIS AREA

Clinical studies investigating the possible association between power injectable port and risk of catheter-related venous thrombosis (considering that the catheter connected to power injectable ports is of large caliber and made of rigid polyurethane).

Studies of the cost-effectiveness of using a venous port for high-pressure contrast media infusion versus other venous access devices (peripheral venous cannula), considering also the economic and logistic costs of the specific training of radiologists and radiology nurses.

Specific clinical studies apt to document the association between the level of training of the health care workers in charge of the use of ports in radiodiagnostics and the rate of complications caused by faulty handling.

FINAL COMMENT

It is recommended that all future studies defining local strategies for optimal use of ports in radiodiagnostics should focus on the following end points: patient safety (minimization/elimination of complications), cost-effectiveness (best clinical outcome with minimal risk and minimal costs), and efficiency (maximal economic yield with minimal use of resources).

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