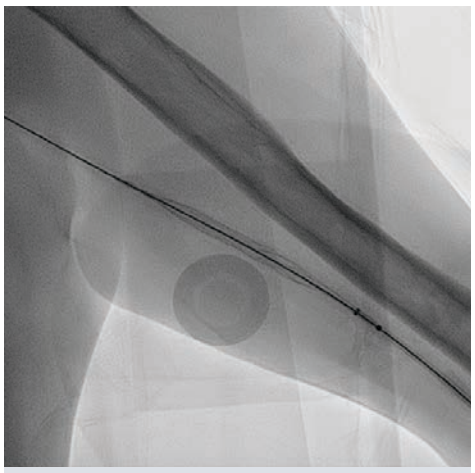
Cath Lab Digest

A product, news & clinical update for the cardiac catheterization laboratory specialist



THROMBECTOMY

Early Experience and Key Learnings of the InThrill Thrombectomy System for Treating Arteriovenous Access Thrombosis in Hemodialysis Patients

Alexander Misono, MD, MBA, RPVI

Patients with end-stage renal disease (ESRD) depend on hemodialysis treatment that often utilizes an arteriovenous fistula (AVF) or arteriovenous graft (AVG) for vascular access (Figure 1). Maintaining AV access patency remains a challenge that can require frequent interventions. AV access thrombosis is the most common cause of dialysis failure, occurring up to 2 times per year for each patient and accounting for 65%-85% of permanent access loss.[1]

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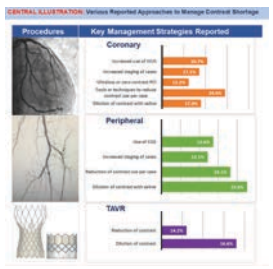
In This Issue

ORIGINAL CONTRIBUTION

Impact of the Global Iodinated Contrast Shortage on Workflow of Cardiac Cath Labs Across the U.S.

Anum Asif, MD; Yogamaya Mantha, MD; Tayo Addo, MD; Timir Paul, MD; Chadi Alraies, MD; Subhash Banerjee, MD; Emmanouil S. Brilakis, MD, PhD; Shweta Bansal, MD; Anand Prasad, MD



Iodinated contrast is a necessary pharmaceutical for imaging in the catheterization laboratory. In March of 2022, there was a surge in COVID-19 cases in Shanghai, China. This surge led to a lockdown within the cities as the Chinese government moved to prevent spread of the Omicron SARS-CoV-2 variant. This "zero-COVID" policy resulted in curfews, closure of small businesses, and halting of larger factory-based manufacturing operations. Affected by this shutdown was GE Healthcare (GE). GE is a leading worldwide producer of iodinated contrast media (CM) and the sole manufacturer of the compounds iohexol (Omnipaque) and iodixanol (Visipaque), which are widely utilized among hospitals across the United States. Nearly all CM is produced outside the United States and GE's primary operations are located in Shanghai.

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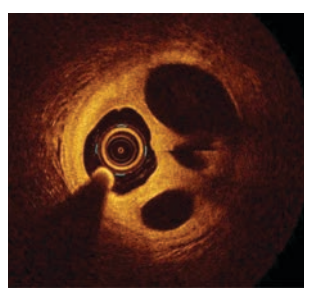
CASE REPORT

Woven Coronary Artery Presenting as High-Risk ACS

Hussain Alzayer, MD; Nasser Alhammad, MBBS; Hamed Alghamdi, MBBS



A woven coronary artery (WCA) is an unusual anomaly that has a wide range of clinical presentations. Patients can be asymptomatic, have anginal symptoms, and in extreme cases, can present with cardiac arrest. We present an interesting case of WCA presenting with high-risk features, in which optical coherence tomography (OCT) was used to establish diagnosis. A literature review is included.

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Impact of the Global Iodinated Contrast Shortage on Workflow of Cardiac Catheterization Laboratories Across the United States

Anum Asif, MD; Yogamaya Mantha, MD; Tayo Addo, MD; Timir Paul, MD; Chadi Alraies, MD; Subhash Banerjee, MD; Emmanouil S. Brilakis, MD, PhD; Shweta Bansal, MD; Anand Prasad, MD

The production shutdown significantly disrupted hospital supply chains and clinical operations throughout many U.S. hospitals. Rapid countermeasures were undertaken by GE to address these disruptions; however, the supply of CM — specifically iodixanol — has been labile in the U.S. over much of 2022.

More recently, in the last quarter of 2022, the latest Omicron variant surge has gripped China. Facing economic and societal pressures, China rescinded its "zero-COVID" policies, but the current ongoing human and economic effects of this latest surge are still being dealt with in China. Given the vulnerability of CM supply and its importance to catheterization laboratories (CCL), in the present article, we will review the timeline and underlying causes of the supply chain challenges. We will also present data from an online survey of interventional cardiologists (IC) in the U.S. on the operational impacts of the CM shortages.

Methods

The central survey was created using Qualtrics (Provo, UT) and is comprised of 30 multiple-choice questions. The full survey details with responses can be viewed online at cardiorenalconnections.org/contrast-dyeshortage. The American Medical Association (AMA) online database FRIEDA was used to search for academic IC programs. The survey was distributed among the cardiology community via email. To capture a broad community of academic and nonacademic physicians, the survey was also advertised via a social media platform (Twitter). The reminder emails were sent after 2 weeks of the survey and again, after 4 weeks. Responses were captured and analyzed via Qualtrics.

Results

Forty ICs from throughout the U.S. provided the survey responses. Survey responders include 64.7% IC faculty, 23.5% CCL directors, and 17.7% IC fellowship program directors. Approximately 93% were aware of the contrast shortage, with 86.1% reporting their hospital as a victim of the shortage. Almost 88% of responders depended on the use of Omnipaque and Visipaque. In terms of buying decisions, 55.6% reported having the input of the CCL director in the choice of purchased contrast, while 51.7% were dependent on the hospital group purchasing organization (GPO) for purchase. In response to the shortage, 11.1% reported having to borrow CM from other institutions. Of note, Visipaque was the most widely used dye for patients with chronic kidney disease (CKD), and in the context of peripheral vascular disease (PVD) and transcatheter aortic valve replacement (TAVR) procedures.

Impact on procedural volume and trainee education. The CM shortage affected 85.2% of the surveyed institutions. The resulting supply-demand mismatch brought hindrances in performing day-to-day CCL procedures. At the peak of the shortage, 4.3% of CCLs had CM stock remaining for 8-12 weeks, 47.8% had a 3- to 4-week supply, 26.1% had a 1- to 2-week supply. Many CCLs reported deferring outpatient elective procedures (70.4%), including stable coronary cases (63.0%), peripheral angiograms for claudication (18.5%), and TAVR (14.8%). The majority (56.0%) reported a significant reduction in the number of complex percutaneous coronary intervention (PCI) cases. Significant angina (CCS III/IV) and new-onset heart failure were noted as 2 scenarios that were less likely to be deferred in the outpatient setting. Elective pre-solid organ transplant catheterizations (especially for kidney disease) were felt to be reasonable to defer for at least 4 weeks or longer. The CM shortage not only impacted the routine workflow of CCLs, but surveyors reported a moderate-to-severe impact on cardiovascular trainee education via reduced procedural volumes, with 68.3% noting training volume disruptions.

Strategies to overcome the shortage. No uniform plans were reported to deal with this challenging situation and hospitals all handled the shortage in differing ways. CM-saving techniques varied by each institution's contrast delivery methods, with 50.0% reporting using a manifold for contrast administration,

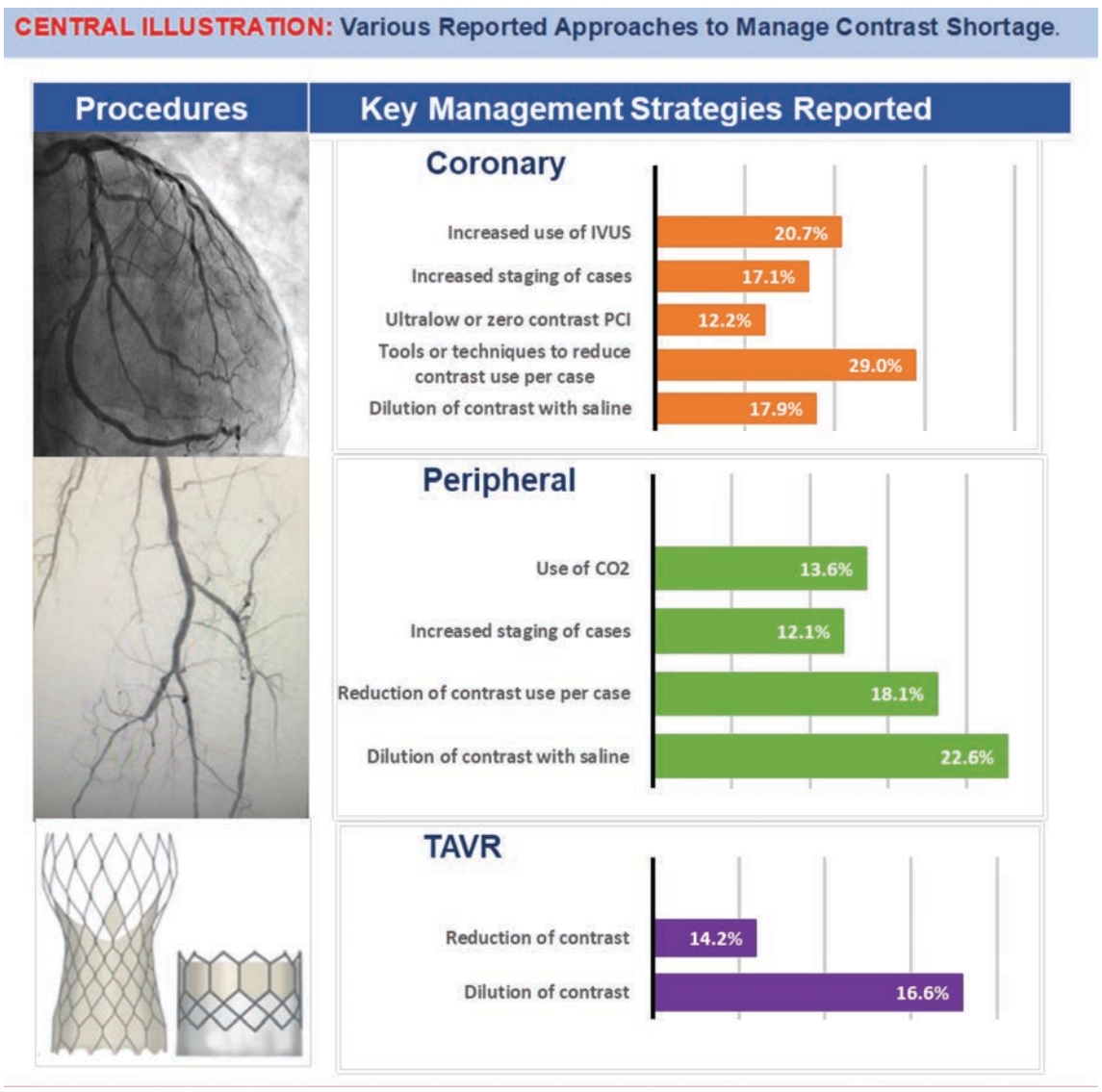

Figure. Various reported approaches to address the contrast shortage: Survey of U.S.-based interventional cardiologists. ***IVUS, intravascular ultrasound; PCI, percutaneous coronary intervention; TAVR, transcatheter aortic valve replacement***

19.2% relying on the ACIST CVi contrast delivery system (ACIST), and 30.1% using a combination of the two approaches. At 48.5% of the sites, there was use of a contrast management system such as the Miser (Merit Medical), which allows a single bottle of CM to be used on a series of patients. Approximately 41% reported diluting CM with saline and 53.9% used leftover contrast via the ACIST CVi device across multiple cases. Dilution of CM with saline was a common approach across procedure types (coronary, peripheral, TAVR). A summary of these strategies is shown in the Figure.

Preparedness for future catastrophe. Despite using various techniques to overcome the CM shortage, respondents were unsure how the CM situation would be dealt with in the future by their institutions. Specifically, 50.0% reported uncertainty as to whether their hospital would be able to acquire CM from multiple vendors or increase the total volume of purchased CM on hand.

Discussion

Our survey provides important insights into the impact of contrast shortages on the CCL workflow and various steps taken to mitigate its effects by U.S. cardiologists. The CM supply chain remains vulnerable to global interruptions and institution-specific approaches for prevention remain variable and unclear.

Pandemic-related industrial challenges have been well described in most industrialized countries. The dependence on CM production in Shanghai, China, was felt to be the primary issue involved with the recent GE Healthcare supply disruption. The U.S. lacks the domestic capacity for CM production, so is entirely dependent on international manufacturing. The CM market value in the United States is approaching 2 billion dollars each year. Commercially available contrast agents are distinguished by chemical differences in osmolarity (relative to plasma). Modern CM formulations include low-osmolar compounds such as iohexol, iopamidol, iopromide, ioversol, and the iso-osmolar agent iodixanol. There are a handful of global leaders in the manufacturing of CM, including GE Healthcare (Chicago, IL), Bracco (Milan, Italy), Bayer AG (Leverkusen, Germany), and Guerbet (Villepinte, France). GE Healthcare accounts for approximately 50% of the market share in the U.S. and 30% globally,[1] while Bracco provides 40% domestically. The GE products Visipaque (iodixanol) and Omnipaque (iohexol) are primarily produced in Shanghai, China, with a secondary smaller production volume of Omnipaque in Cork, Ireland.

The initial COVID-19-related disruption was in early 2020, when Wuhan and other Chinese cities were first affected by the pandemic. The resulting reduction in CM production was not felt globally due to the marked reduction in demand for contrast-based imaging. Rationing of care, fear on the part of patients, and halting of elective procedures during the first few months of the pandemic have been well described. Subsequent months led to aggressive testing, quarantines, and eventually mandated immunizations in China. Reported rates of new COVID-19 cases in China have been comparatively low since the initial outbreak. The Chinese government's "zero-COVID" policy involved widespread testing and rapid lockdowns with forced quarantines. The measures appeared to blunt the impact of the 2021 Delta variant in China, which devastated hospital systems around the globe, including the U.S., Europe, and India.

The Omicron variant of SARS-CoV-2 represented another challenge for the "zero-COVID" China policy. Shanghai has a population of over 26 million people and is widely recognized as the technological and manufacturing hub of the country. The Omicron variant was associated with an outbreak of COVID-19 in late February 2022 in Shanghai. Within days, lockdowns began, accelerating in scope and severity over the subsequent weeks. The broadest lockdown was issued on March 31, 2022. The easing of restrictions began to occur in early June 2022. Although the number of individuals who tested positive exceeded 100,000, the actual number of severe cases and deaths appears to have been modest. The social, economic, and healthcare system disruptions have been extensively described in the press.

The March 31, 2022 lockdown was immediately felt by GE Healthcare. Their largest production facility was reduced to 25% capacity and one-third of the workforce were actually quarantined within the factory.[2] The ability to move products from the facility to distribution hubs and onwards for export was also severely curtailed. As noted earlier, shifting of full production to Cork, Ireland, was not an option due to lack of immediate capacity.

The total CM stock in most hospitals is fixed at any given moment in time. U.S. hospitals seldom directly purchase CM directly. Rather, GPOs act as intermediaries and the hospital relationships with GPOs provide cost savings. These contractual agreements result in reduced expenses, but also limit choice as the financial benefits are on volume purchases of a particular product. Some hospitals are, therefore, "GE only/majority" or "Bracco only/majority". Few hospitals have the physical or financial capacity to store months of CM in their facilities. Rather, CM is seen as a continuous-need item that is shipped in on a regular weekly or monthly basis. Its high utilization rate and limited stockpile makes CM vulnerable to supply chain interruptions.

In this light, the Shanghai lockdown was very quickly felt by U.S. hospitals. There was an immediate demand for product from other companies; however, using this pathway is problematic for many hospitals. Competitors are often limited in their ability to help for 3 primary reasons. First, these companies may also be dealing with intrinsic or extrinsic production limitations. Second, they usually first respond to their own existing customers who may also be experiencing an increased demand for product ("hoarding"). Lastly, the contractual agreements with suppliers and hospitals represent a hurdle to overcome for all parties involved and may take time to negotiate. Although the initial estimate from GE was a severe disruption for 2 weeks, the prolonged nature of the lockdown led to tangible impact on U.S. hospitals for approximately 2 months and intermittently beyond.

Conclusion

The contrast shortage has impacted many hospitals, resulting in reduced procedural volume and impacting trainee education. While various steps were taken to mitigate its effects, those surveyed expressed uncertainty around the ability to prepare for any similar situations in the future. Economic disruptions from lockdowns in China have currently been replaced by the devastating impact of the recent, ongoing Omicron variant surge in the country. The U.S. remains dependent on international production of CM and thus vulnerable to future supply chain issues. Potential opportunities to secure domestic production of this valuable pharmaceutical should be considered by the U.S. healthcare system. ■

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Anum Asif, MD[1]; Yogamaya Mantha, MD[1]; Tayo Addo, MD[2]; Timir Paul, MD[3]; Chadi Alraies, MD[4]; Subhash Banerjee, MD[2]; Emmanouil S. Brilakis MD, PhD[5]; Shweta Bansal, MD[6]; Anand Prasad, MD[1]

[1]Department of Medicine, Division of Cardiology, UT Health San Antonio, San Antonio, Texas
[2]Department of Medicine, Division of Cardiology, University of Southwestern, Dallas, Texas
[3]Department of Medicine, Division of Cardiology, University of Tennessee, Nashville, Tennessee
[4]Department of Medicine, Division of Cardiology, Detroit Medical Center, Detroit, Michigan
[5]Minneapolis Heart Institute, Minneapolis, Minnesota
[6]Department of Medicine, Division of Nephrology, UT Health San Antonio, San Antonio, Texas

The authors can be contacted via Anand Prasad, MD, FACC, FSCAI, RPVI, Director of Interventional Cardiology at UT Health San Antonio; Director Heart and Vascular Institute Catheterization Laboratories at University Health; Department of Medicine, Division of Cardiology, UT Health San Antonio, San Antonio, Texas, at prasada@uthscsa.edu

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