ABSTRACT: Objective. To compare the incidence of contrast-induced nephropathy (CIN) and vascular complications in patients undergoing cardiac catheterization using traditional manual contrast injection techniques with those in which an automated contrast injector device was used. Background. It has been suggested that use of automated contrast injectors in coronary interventions could reduce complications by reducing contrast volume usage and allowing the use of smaller sheaths. Methods. This was a retrospective cohort study with review of patient’s electronic medical charts and the Heartbase registry. Complete data were available for 13107 patients between 1999 and 2009. Of those patients, 5137 procedures were performed with traditional manual contrast injection and 7970 procedures used automated contrast injection. The CIN event rate and vascular complication rates were compared between patients who underwent catheterization using these differing techniques. Results. Overall, the incidence of CIN was comparable in traditional and automated contrast injector assisted catheterizations (9.07% vs 8.73%, P=5). However, for the subgroup of patients that had a diagnostic cardiac catheterization and went on to have an ad hoc angioplasty, incidence of CIN was much lower in the automated contrast injector group (7.04% vs 5.50%, P=0.007). The incidence of vascular complications was lower in the automated contrast injector group vs the traditional method (2.85% vs 2.17%, P=0.02), irrespective of an ad hoc angioplasty. Conclusion. Use of automated contrast injectors resulted in a significant decrease in vascular complications across all cardiac catheterizations. Additionally, there was a significant decrease in CIN when the automated contrast injector was used for catheterizations that included a percutaneous coronary intervention.

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Cardiac catheterization is an important tool used in the diagnosis and treatment of various cardiovascular diseases. It is used to evaluate hemodynamics, coronary anatomy, and ventricular function. Newer techniques have made cardiac catheterization much easier to perform. Despite recent advances, cardiac catheterization is still associated with various adverse events — ranging from minor to life-threatening. Several well-known complications of cardiac catheterization include vascular complications (bleeding, pseudoaneurysm, arteriovenous fistula, and thrombosis) arrhythmias as well as contrast-induced nephropathy (CIN). The incidence of CIN after cardiac catheterization varies greatly based on the type of procedure and the presence of various well-defined risk factors — the most significant being chronic renal insufficiency and diabetes mellitus; others include age, advanced heart failure, volume of contrast used, volume status of the patient prior to the procedure, and the use of nephrotoxic agents in the periprocedural period. Even a transient reduction in renal function due to CIN is associated with a worse in-hospital and long-term prognosis. The incidence of CIN can be minimized by various methods, including hydration of the patient prior to the procedure, avoiding nephrotoxins, and minimizing the volume of the contrast agent delivered.

The traditional method of diagnostic coronary angiography utilizes a stopcock manifold system and the manual injection of contrast with a handheld syringe. Six Fr catheters are generally used with this system. This method was used exclusively for cardiac catheterization in the Indiana University Health Methodist catheterization laboratories prior to year 2005. In the year 2005, automated contrast injector systems were introduced. This device consists of the ACIST Injection System (ACIST; ACIST Medical Systems), which provides a pre-programmable variable rate of contrast delivery controlled by hand controller. Automated contrast injectors have been available for almost 20 years and currently fourth-generation devices are being used. This device also allows for hemodynamic monitoring during the cardiac catheterization. Additionally, it has previously been shown that use of an automated contrast injection device permits the use of smaller 4 Fr catheters while still maintaining optimal opacification of the coronary tree. In our laboratories, non-ionic, low-osmolar contrast dye was used for both injection types to visualize coronary anatomy. All patients were monitored closely after the procedure for any complications.

Several studies have previously suggested that the use of these automated injectors in combination with 4 Fr catheters was associated with a lower amount of contrast dye used. In this study, we compared the incidence of both CIN and vascular complications in patients who underwent cardiac catheterization by automated contrast injectors compared to the traditional hand injection method.

Methods

Patient selection. The study was approved by the Indiana University Institutional Review Board. All adult patients who underwent cardiac catheterization at Indiana University
CIN was defined as a rise in creatinine of greater than or equal to 0.5 mg/dL from pre- to postcatheterization. Vascular complications were recorded in the Heartbase Registry; these included bleeding at the access site, retroperitoneal bleeding, access-site occlusion, distal pulse loss, access-site dissection, pseudoaneurysm formation, and development of an arteriovenous fistula. The incidence of CIN and vascular complications was calculated in each of the groups of patients. The 95% confidence interval (CI) of the difference was constructed by normal approximation of the proportions and the P-value was obtained by Chi-square test.

**Results**

**Study population.** Total cardiac catheterization subjects entered into the Heartbase Registry between 1999 and 2009 was 49,141 (31,076 from 1999-2004 and 18,065 from 2005-2009). Patients with pre-existing chronic kidney disease (creatinine >4 mg/dL) were excluded. The final study group consisted of 5137 in the traditional method group (group I) and 7970 in the automated contrast injector group (group II). Table 1 shows the characteristics of the study population. There were no significant differences between groups with respect to their baseline characteristics.

**Comparison of complications.** We defined CIN as a creatinine rise of ≥0.5 mg/dL from pre to postcatheterization values. When including all study patients undergoing coronary angiography (both diagnostic and staged PCIs), there was no significant difference in the incidence of CIN between the two groups (9.07% vs 8.73%, respectively; P=.5). However, when the groups were further subdivided into catheterizations that were diagnostic only and those in which an ad hoc PCI was performed at the same time as the diagnostic procedure, there was a significant drop in the incidence of CIN in the ad hoc PCI group when the automated system was used (7.04% vs 5.50%; P=.007), as seen in Table 2.

The Heartbase Registry was designed to track vascular complications including bleeding at the entry site, retroperitoneal bleeding, access-site occlusion, distal pulse loss, dissection at access site, pseudoaneurysm formation, and arteriovenous fistula formation. Data concerning the incidence of these vascular complications were available for 4869 of the 1999-2004 group and 7160 of the 2005-2009 group. We found a significant drop in the incidence of vascular complications across all catheterizations (diagnostic and PCI) when the automated contrast injector device with the 4 Fr catheter was utilized (2.85% vs 2.17%, respectively; P=.02; Table 3).

**Discussion**

One of the more frequent and serious complications of cardiac catheterization is CIN and because of this, multiple techniques for reducing its incidence have previously been explored. Pretreatment with N-acetylcysteine and/or sodium bicarbonate at first appeared promising but neither has consistently proven
to provide a real benefit. Similarly, neither diuretics nor the use of the dopamine-1 receptor agonist, fenoldopam, has reliably been shown to prevent CIN. Our practice was to hydrate all patients with abnormal kidney function as determined by serum creatinine; outpatients received hydration 3-6 hours prior to the procedure and inpatients were hydrated overnight prior to procedure. Intuitively, one might reason that by reducing exposure to the offending agent (ie, the amount of contrast agent used during a catheterization procedure), one might reduce the incidence of CIN. The topic of reduced contrast usage has been studied before; those studies have shown that the use of automated contrast injectors resulted in a 49% reduction in the total volume of contrast delivered in patients undergoing diagnostic coronary angiography and a 53% reduction in patients undergoing coronary angiography with PCI. This was the incentive to look at our own single-center experience both before and after the introduction of automated contrast injectors and smaller, 4 Fr catheters. A previous study showed a 31% reduction in the rate of CIN when using an automated contrast injection system compared with traditional manual injection. Additionally, previous studies, as well as our own experience, have shown that the use of automated contrast injectors results in equal quality images despite the use of less contrast and smaller catheters. Our study site noted a 32% lower overall use of contrast when comparing the two time frames of the study. In contrast to other previous smaller studies, we saw no significant decrease in CIN when using the ACIST device in patients who underwent diagnostic catheterization alone. However, when ad hoc angioplasty was performed (which accounts for most of the percutaneous revascularization performed at our institution), there was a 22% reduction in CIN. While we cannot say for certain that these results are directly related to use of the ACIST device, we believe our data suggest that its use may well have contributed to decreased contrast volume and thus decreased CIN. It is possible that some threshold volume of contrast might need to be infused before definite CIN becomes manifest, thus explaining the difference we saw between the purely diagnostic procedures and the group of ad hoc PCI procedures.

Another major group of adverse events associated with cardiac catheterization is vascular complications. These complications can be related to multiple factors, including access site and access technique; the common practice in our laboratory is for all practitioners to use fluoroscopic guidance when performing catheterization via the femoral approach (radial access was used less than 3% of the time) and use of a Doppler needle or ultrasound site finder was left to the discretion of the individual practitioner. Once again, it would seem very intuitive that a “smaller hole” (ie, the use of smaller French catheters) would be associated with fewer access-site/vascular complications. As implied previously, the ACIST device facilitates the use of smaller catheters (4 Fr vs 6 Fr) and thus when both of these changes were made in our laboratories, we in fact saw a 24% reduction in the incidence of all vascular complications.

Study limitations. This is a retrospective review and thus has all the inherent disadvantages of such a study. While our hypotheses seem reasonable and appear to be supported by our data, we can only presume that the advantages gained are directly related to the automated contrast injector system (namely, reduced contrast volume usage and ability to use smaller catheters). While we would certainly support a prospective trial to examine these issues further, the reality of the logistics and costs for such an endeavor might be prohibitive in today’s environment.

Conclusion

The idea that the use of an automated contrast injector system is associated with definite quality improvement benefits is not new and has also been suggested by previous groups. To our knowledge, this confirmatory data in our own single-center study represents the largest such study to date. Automated contrast injector systems appear to have consistently shown a reduction in the use of contrast volume, the incidence CIN and in vascular complications — all without disrupting the quality of images. Furthermore, no group, ourselves included, has seen a drawback or disadvantage to using the automated contrast injector systems. Our results, in combination with the results from previous investigators, are beginning to mount a convincing argument that the use of automated contrast injector systems should be standard practice in all cardiac catheterization labs. Further modification of these automated techniques in the future may further help to improve quality in the cardiac catheterization laboratory.

References