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Reducing rates of contrast-induced nephropathy in the cardiac catheterization laboratory: a program evaluation.

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Reducing Rates of Contrast-Induced Nephropathy in the Cardiac Catheterization Laboratory: A Program Evaluation

by

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Abstract

Background: Cardiac catheterizations use intra-arterial contrast media to view the coronary arteries. The use of contrast media can cause contrast-induced nephropathy (CIN). CIN is an abrupt deterioration in renal function that can occur up to 72 hours post-procedure. This diagnosis is associated with increased morbidity and mortality, increased hospital costs, and increased length of stay.

Setting: The project took place in a 432-bed urban facility located in the Midwest region of the United States.

Purpose: The purpose of this QI project was to evaluate if the implementation of an intravenous hydration protocol pre-, intra-, and post-cardiac catheterization decreases the occurrence of CIN.

Procedures: Incidence of CIN at this facility was evaluated via data collection. Rates of CIN were collected 12 months pre-fluid protocol implementation and 11-months post-implementation.

Measures: Serum creatinine levels were measured pre- and post-cardiac catheterization. An elevation in serum creatinine of 25% or more within 48 hours post-procedure constituted a CIN diagnosis.

Results: The rate of CIN for Cohort A was 12.23%. Cohort B was 9.89%. The P value is 0.48. The fluid protocol had no impact on the rates of CIN post-cardiac catheterization.

Reducing Rates of Contrast-Induced Nephropathy in the Cardiac Catheterization Laboratory: A Program Evaluation

Over 1,000,000 cardiac catheterizations are performed annually in the United States with the use of contrast media (Manda & Baradhi, 2021). While these procedures are necessary and lifesaving, latent complications can arise within the first-year post-procedure (Singh & Zughaib, 2019). Using contrast media can result in longer hospital stays, higher mortality, and higher incidences of cardiac events in patients who develop contrast-induced nephropathy (CIN) (American College of Radiology [ACR], 2020). CIN is defined as, "an elevation of serum creatinine of more than 25% or ≥ 0.5 mg/dl (44 μmol/l) from baseline within 48 hours" (Mohammed et al., 2013). This diagnosis does have risk factors which include pre-existing renal insufficiency, hypertension, tobacco use, diabetes mellitus, dehydration, age > 60, hypotension, shock, and congestive heart failure (Wichmann et al., 2015). Pre-existing renal insufficiency includes conditions such as end stage renal disease requiring dialysis, kidney transplant, single kidney, renal cancer, and renal surgery (ACR, 2020, p. 37). Medications to treat diabetes such as metformin or metformin-containing drug combinations can also worsen kidney function (ACR, 2020, p. 37). Congestive heart failure, hypotension, and shock can cause a reduction in blood flow to the kidneys related to a reduced cardiac output (Sarnak, 2014). These risk factors can damage the blood vessels of the kidneys. One of these risk factors in combination with intra-arterial contrast media can cause extensive damage to the kidneys leading to CIN.

Contrast media is mainly excreted through the kidneys, going first through the renal glomeruli (Andreucci et al., 2017). Due to the hyperosmolar nature of contrast, acute tubular necrosis can occur. According to the American College of Radiology, during cardiac catheterizations "contrast medium is injected intra-arterial and supra-renal and the contrast

medium dose to the kidneys is more abrupt and concentrated" (ACR, 2020, p. 35). The population affected by CIN are patients with suspicions known or suspected cardiovascular disease. Most of the patients affected already have some degree of kidney disease (Stage 1-IV). Since these patients already have renal insufficiency, the addition of contrast medium can create further renal injury.

CIN can increase hospital stays, increase hospital costs, and increase morbidity and mortality of patients undergoing cardiac catheterizations. Increasing hospital stays for patients increases hospital costs and increases costs for patients. Longer hospital stays can lead to increased morbidity with risk of infection, risk of falls, etc. A CIN diagnosis can increase mortality within 1 year of diagnosis (Sun et al., 2019). Interventions can be implemented to evaluate the incidence of CIN. Implementing an intravenous fluid protocol is efficient and effective in reducing rates of CIN based on the evidence and literature.

Problem Statement

A high rate of CIN was located at a chest pain accredited hospital in the midwestern United States. The rate of CIN at this facility was almost 10% higher than the national standard in the first quarter of 2020. The national standard for quarterly rates of CIN is currently 6.18% (NCDR). The rates of CIN continued to rise since the second quarter of 2019. The second quarter of 2019 saw a rate of 7.3% with a rise into the third quarter at 8.7%. The fourth quarter was significantly increased at 12.67%. The first quarter of 2020 was at 15.18%. The director of this cardiac catheterization laboratory and an interventional cardiologist noticed the rates worsening each quarter. They decided to create and implement an intravenous fluid protocol to improve the rates of CIN. A program evaluation was completed to determine if the intravenous fluid protocol implemented pre, intra-, and post-procedure with the inpatient and outpatient

population at the facility decreased the prevalence of CIN. Serum creatinine levels were evaluated pre- and post-procedure to determine if a CIN diagnosis is appropriate.

Purpose & Specific Aims

The purpose of this program evaluation was to determine the impact of an intravenous fluid protocol on rates of contrast-induced nephropathy in patients undergoing cardiac catheterization. Following an educational intervention, it was anticipated there would be 90% compliance by nursing staff and provider staff ordering and implementing the protocol. Ongoing use of the intravenous fluid protocol was expected to decrease the incidence of CIN by 2-3% every quarter. The intravenous fluid protocol was going to decrease rates of CIN over time, decrease hospital stays and costs, and decrease rates of morbidity and mortality, although monitoring of these outcomes were beyond the scope of this paper.

Literature Review

Search Strategy

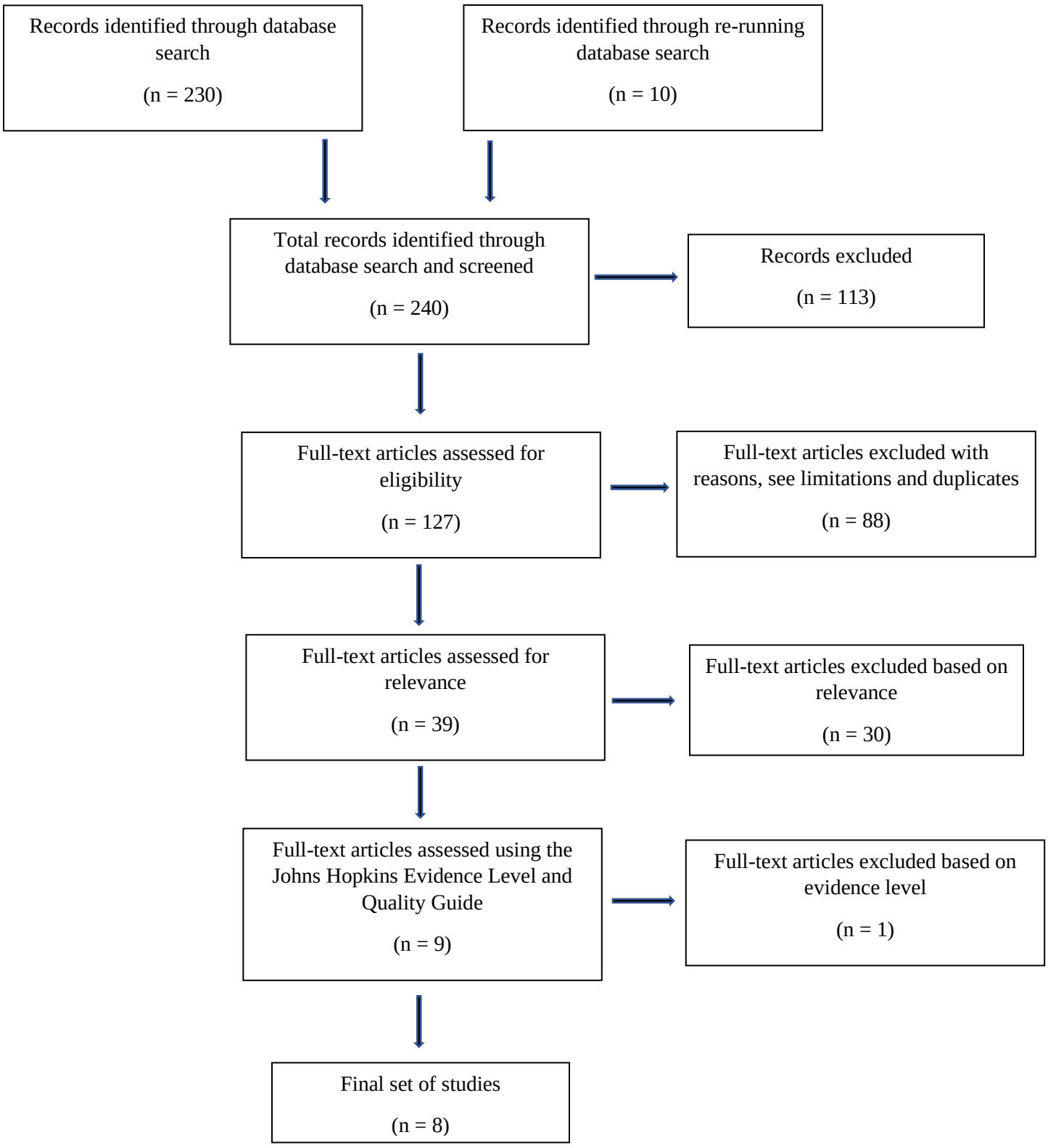
After a preliminary search, key words such as *acute kidney injury, contrast medium, cardiac catheterization, and serum creatinine* were found. Four databases including PubMed, CINAHL with Full Text, Medline (OVID), and ClinicalKey were used. The Boolean string used in each database was: (("Acute Kidney Injury"[Mesh]) AND "Contrast Media"[Mesh]) AND "Cardiac Catheterization"[Mesh] AND “Serum Creatinine”[Mesh].

The first database searched was PubMed. This initial search resulted in 108 articles. This search was limited to publication within the years 2016-2021 as well as the English language. After these limitations, 49 articles remained. This search was further limited to systematic reviews, meta-analyses, RCTs, and clinical trials. This search resulted in 27 articles. After the abstracts were reviewed, 7 articles remained. After reviewing the years with the largest

amount of research related to the search terms, the years 2014 and 2015 were included in the search for PubMed. Three additional articles were added for review from this search.

CINAHL with full text was then used with the same limitations for the search. There were 91 articles after the initial search with limitations. Of those articles, 18 were duplicates from the PubMed search. Abstracts of the remaining articles were reviewed, and 17 articles remained. This search process was repeated in Medline (OVID) and ClincalKey. Medline (OVID) resulted in 15 articles. Eleven of the 15 articles were duplicates. Two were kept after abstracts were reviewed. ClinicalKey resulted in 16 articles and 15 were duplicates from previous searches. One abstract was reviewed and the article was not kept for the review because it was deemed not relevant. A database search was re-run across the four databases initially evaluated. Ten articles were reviewed and added to the final articles. A total of 39 articles were reviewed.

The abstracts of the final 39 articles were reviewed for relevance and 9 articles remained. 30 articles were removed based on the interventions used in those studies to decrease incidence of CIN. The Johns Hopkins Evidence Level and Quality Guide was then used to grade the remaining 9 articles. One article was excluded after this review. The 8 remaining articles were at Level III or above on the Johns Hopkins guide (See Appendix A).


Records identified through database search
(n = 230)
Records identified through re-running database search
(n = 10)
Total records identified through database search and screened
(n = 240)
Records excluded
(n = 113)
Full-text articles assessed for eligibility
(n = 127)
Full-text articles excluded with reasons, see limitations and duplicates
(n = 88)
Full-text articles assessed for relevance
(n = 39)
Full-text articles excluded based on relevance
(n = 30)
Full-text articles assessed using the Johns Hopkins Evidence Level and Quality Guide
(n = 9)
Full-text articles excluded based on evidence level
(n = 1)
Final set of studies
(n = 8)

Fluid Administration Protocol

Research has shown that using an intravenous pre-, intra-, and post-cardiac catheterization can decrease the incidence of CIN. Of the eight studies examined, all recommended the use of an intravenous fluid protocol during cardiac catheterizations to reduce rates of CIN (See Appendix B). The studies consisted of three systematic reviews, two randomized control trials, one experimental study, one retrospective cohort study, and one qualitative study. Seven studies evaluated inpatients and outpatients undergoing cardiac catheterizations with contrast media. Six of the studies also included STEMI (ST-Elevation Myocardial Infarction) patients. One study only evaluated the use of an intravenous fluid protocol with STEMI patients.

There was variation over the rate and duration of intravenous fluid administration across the studies. The most common rate was 1mL/kg/hr (Deek et al., 2014; Hong et al., 2020; Jurado-Roman et al., 2015; Lambert et al., 2017). Five of the eight studies specified that fluids should be given pre- and post-cardiac catheterization to decrease rates of CIN (Bottinor et al., 2019; Deek et al., 2014; Hong et al., 2020; Jurado-Roman et al., 2015; Lambert et al., 2017). All eight studies included a pre-procedure serum creatinine and a post-procedure serum creatinine within 48 hours to evaluate for a diagnosis of CIN (Bottinor et al., 2019; Brar et al., 2014; Deek et al., 2014; Hong et al., 2020; Jurado-Roman et al., 2015; Lambert et al., 2017; Wang et al., 2019).

There are gaps in the literature when researching this intervention. One of the primary challenges in the evaluation of CIN is the inconsistencies in the definition of CIN across studies and providers. This leads to unequal comparisons among groups. In addition, patients undergoing dialysis and patients with chronic kidney disease were often excluded from studies, despite being high risk for the development of CIN. In general, studies did not control for other

factors which may influence the development of CIN, such as amount of contrast used, pre-existing renal function, or diabetes mellitus.

Summary/Justification

After reviewing the synthesized literature, a standardized fluid protocol was created as an order set for pre-, intra-, and post-procedure cardiac catheterization patients. This intervention is easily implemented with low costs and a small amount of time allotted to educating nursing staff. Implementing an intravenous fluid protocol has shown decreases in rates of CIN leading to lower rates of morbidity and mortality.

Theoretical Framework

The quality improvement framework used for this project was the FADE model (See Appendix C). This model has four different areas: Focus, Analyze, Develop, and Execute (Spath, 2018). The focus area consists of choosing a problem and creating a statement to describe it (Spath, 2018). Analyze consists of learning about the problem through research of evidence and gathering data (Spath, 2018). The third area, develop, investigates a solution to the focus area and creating a plan for the solution (Spath, 2018). Execute starts the intervention phase and measures outcomes (Spath, 2018).

Methods

Design

This quality improvement project is a program evaluation based on a convenience sample looking at the incidence of CIN before (Cohort A) and after an intravenous fluid protocol implementation (Cohort B) for patients undergoing cardiac catheterization. The data was used to determine if the intravenous fluid protocol resulted in decreased rates of CIN at this facility. The

fluid protocol was introduced in November of 2020 by an interventional cardiologist. This was prior to the implementation phase of the DNP project for this cohort.

Setting

This facility is a chest-pain accredited urban hospital with a total of 432 beds. There are 10 interventional and diagnostic cardiologists. An average of 2,300 patients undergo cardiac catheterizations at this facility each year. The project took place in the three cardiac catheterization laboratories, cardiac catheterization prep and hold department, the ICU, cardiac step-down unit, and three telemetry floors. These areas were appropriate for this intervention because these departments care for patients pre-, intra-, and post-cardiac catheterization. The IVF protocol was implemented in these clinical areas.

This project aligns with the facility's mission to "provide quality health care to all those we serve, in a manner that responds to the needs of our communities and honors our faith heritage" (Norton Healthcare, 2021). This mission is fulfilled by the facility's employees who honor the values of the organization, which include continually improving care and service, setting the standard for quality and caring, and accepting accountability for results. This quality improvement project was committed to the values of the organization through application of evidence-based practice.

This project was discussed and implemented with assistance of a stakeholder group that consists of the director of the CCL and an interventional cardiologist. The director of the CCL had accrued data for this project and established that this was a real issue at the site that needs attention and change. The interventional cardiologist performs a high volume of cardiac catheterizations and has been evaluating the incidence of CIN. He implemented the fluid protocol standing order set for pre- and post-cardiac catheterization. The cardiology director, the

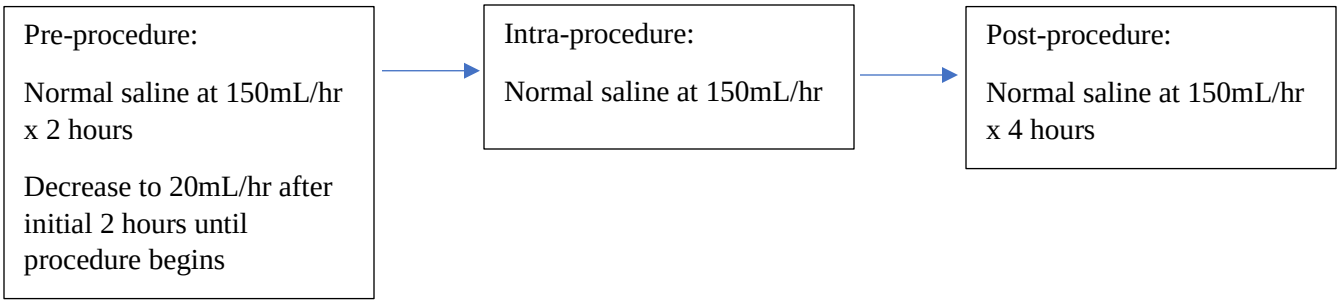
manager of the CCL, and the floor nurses and CCL nurses were involved with this intervention implementation with approvals and education.

Sample

A convenience sample of patients undergoing a cardiac catheterization from October 2019 to October 2020 (Cohort A) pre-protocol and 11-months post-protocol (Cohort B; November 2020-September 2021) was identified. These patients were primarily patients with suspected or known coronary artery disease. The information gathered was a de-identified list of patients established by the CCL director and interventional cardiologist. Pre-protocol implementation rates from 2019 were provided. Incidences of CIN every quarter post-fluid protocol implementation were also provided. The rates pre- and post-fluid protocol implementation were compared. Patients discharged the same day of the procedure were not included in the sample as serum creatinine values were not available for this subset.

Intervention

Initially, there was no perioperative treatment for patients used at this facility for pre-, intra-, and post-cardiac catheterization to buffer the kidneys and decrease the likelihood of developing CIN. Intra-procedural fluids were infused at the discretion of the interventional or diagnostic cardiologist, using variable volumes and time frames (See Appendix D). After reviewing the synthesized literature, a standardized fluid protocol was created as an order set for pre-, intra-, and post-procedure cardiac catheterization patients. This intervention is easily implemented with low costs and a small amount of time allotted to educating nursing staff. Implementing an intravenous fluid protocol has shown decreases in rates of CIN leading to lower rates of morbidity and mortality. This DNP project evaluated a new intravenous fluid protocol and its effectiveness at lowering rates of CIN.



The fluid protocol is initiated at 6am on the day of the patient's procedure at 150 mL/hr x 2 hours, then decreased to 20 mL/hr prior to the procedure. The intra-procedural rate is set at 150mL/hr and is subject to change related to hypotension or pulmonary edema. Post catheterization fluids are infused at 150 mL/hr x 4 hours, then discontinued unless otherwise specified by a provider. The fluids are discontinued after four hours post-procedure unless otherwise specified per provider. Providers can determine if the fluid protocol is appropriate for patients who have heart failure or are volume overloaded.

Measures

Serum creatinine levels were measured pre-cardiac catheterization to establish a baseline for each patient. Post-procedure serum creatinine levels were measured after the procedure. It was hypothesized that serum creatinine levels would remain stable post-procedure following implementation of an intravenous fluid protocol.

Serum creatinine measures how well the kidneys are flushing out waste products from the body (National Kidney Foundation, 2017). The normal range for serum creatinine is 0.6-1.2 in males and females (Shahbaz & Gupta, 2020). Serum creatinine was used as a measurement to show there is an impact on CIN. Serum creatinine was used because this is the measurement used in many articles and studies over the last 20 years to support a diagnosis of CIN. It is imperative to determine serum creatinine levels when there is potential renal dysfunction

(Shahbaz & Gupta, 2020). Measuring serum creatinine levels is important when there is acute kidney injury or CIN (Shahbaz & Gupta, 2020). CIN can cause a plethora of problems, including fluid overload, sodium and potassium imbalances, and drug toxicity because of decreased renal function (Shahbaz & Gupta, 2020). Serum creatinine testing can prevent further complications of CIN and better patient outcomes (Shahbaz & Gupta, 2020).

Instruments

The reliability of serum creatinine levels is regulated by the Clinical Laboratory Improvement Amendments (CLIA) (National Archives, 2021). Serum creatinine levels are measured by routine chemistry testing (National Archives, 2021). In laboratories across the United States, the criteria of acceptable performance for serum creatinine levels is a target value of +/- 0.3mg/dL or +/- 15% (greater) (National Archives, 2021). The lab at this facility uses an Abbott Alinity machine to process serum creatinine levels.

Data Analysis

There were 55 patients at this facility diagnosed with CIN from January 2019-December 2019. All data the student reviewed was de-identified data and permission was given to view the data by the cardiac cath lab director. The patients were evaluated based on age, the amount of contrast given in milliliters, the maximum allowable contrast dose (MACD; 3.7xGFR), baseline creatinine, post-operative creatinine, if IV fluids were initiated prior to the procedure, and if the patient was diagnosed with CIN. This baseline data served as evidence that an IV hydration protocol needed to be implemented.

Initially, independent sample t-tests were planned for the mean, median, and age range between the two cohorts. The information provided by the facility for Cohort B was not as extensive as the information provided for the first cohort because a chart review was not

performed during the years of 2020 and 2021. The cath lab director would not give the principal investigator permission to access medical records to gather the same information that was collected in 2019. The ages of the patients in Cohort A were still evaluated and statistically analyzed. The mean age of the patients in Cohort A was 64.7 years old. The median age was 66 years old and the range was 47 years old. 38% (21/55) of the patients in Cohort A received an amount of contrast greater than the MACD. Only 23% (13/55) of the patients in Cohort A received IV fluids prior to the procedure. The number of patients who did receive IV fluids for Cohort B was reported to the student. 53% (16/30) of the patients in Cohort B did receive IV hydration prior to the procedure.

Independent sample t-tests were performed on the number of cases of CIN before (Cohort A) and after the intervention (Cohort B) since there were different patients in each cohort. The mean rate of CIN in Cohort A is 12.23% and the mean of Cohort B is 9.89%. The rate of CIN of the third quarter of 2020 was not included in statistical analysis of Cohort A because the percentage was low due to the Covid-19 pandemic and would skew results. Standard deviations were calculated for both means to evaluate the spread of scores across both means. The standard deviation of Cohort A is 3.76 and Cohort B is 3.68. These standard deviations are close and have almost equal variances. Since the standard deviations are comparable, the independent samples t-tests were evaluated as two samples of equal variance. The p-value of the independent sample t-test is 0.48 indicating that the fluid protocol had no impact on the rates of post-cath CIN.

Normality was assessed using a Shapiro-Wilk's test. This test assesses whether a variable's distribution is skewed and/or kurtotic (Grove & Cipher, 2017, p. 275). This test can "calculate both skewness and kurtosis by comparing the shape of the variable's frequency

distribution to that of a perfect normal curve" (Grove & Cipher, 2017, p. 275). The skewness of both cohorts is 0.07. The data is normally distributed. The kurtosis is -1.76. The data is platykurtic and has a flat distribution.

The protocol specified that the percentage of providers who complied with the protocol would be evaluated. However, this information was not provided by the hospital and therefore could not be compared. In addition, a Pearson Chi-square was planned for comparison of compliance with ordering the fluid protocol and implementing the fluid protocol. This data was not forwarded to the student and therefore, could not be analyzed. Microsoft Excel 2018 was used to analyze the data.

Financial Information

There was no funding for this project. The original intervention was implemented by the hospital. Data collection and analysis was performed at no cost as part of an educational degree requirement.

Implementation Timeline

Rates of CIN were collected from October 2019 to October 2020 for a baseline percentage pre-fluid protocol. The fluid protocol was implemented on November 9, 2020. Cohort A are the patients treated between October 2019-October 2020 and Cohort B are the patients treated between November 2020-September 2021. Data was collected by the director of the CCL after the intervention has been started (See Appendix E). The de-identified data was forwarded to the DNP student for further interpretation. This data was shared on a quarterly basis. Due to delays in data processing, data was gathered one-year post-protocol implementation which ended in November 2021. The collected data was statistically analyzed and disseminated in May of 2022.

Ethical Considerations and Permissions

This project had received approval from the director of the CCL (See Appendix E). The patient information being evaluated from the director is de-identified. Since de-identified data is being used in a protocol that has already been implemented, this DNP project was submitted to the University of Louisville Human Subjects Research and Institutional Review Board (IRB) for expedited review as a QI project. A quality improvement project is defined as a systematic approach for reducing waste or improving efficiency, reliability, and performance of a service or product (Likosky, 2014). This program evaluation received approval from both the University of Louisville IRB and Norton Healthcare IRB.

Results

Analysis of Implementation Process

The providers were introduced to the fluid protocol in November 2020. The use of the protocol was not mandated by the cath lab director. Providers were supposed to implement the protocol for every patient undergoing a cardiac catheterization unless the patient had congestive heart failure. The data provided by the hospital does not specify if the protocol was implemented or not. The facility also did not specify which providers ordered the protocol and which providers did not. Nursing staff also had the option to order the fluid protocol as a standing order.

Based on the results, it is assumed that not all providers implemented the fluid although education was provided. Therefore, this potentially affected the outcomes. There was not a way to ensure this did not happen as the fluid protocol was not a mandatory implementation. Absolute compliance could not be confirmed with the metrics that were provided.

Analysis of Project Outcome Data

There was very minimal improvement in rates of CIN post-intravenous fluid protocol implementation. The average incidence of CIN for Cohort A was 10.67% and Cohort B was 9.89%. The average rate post-protocol is still above the national standard set at 6.18%. There was improvement during the second quarter of 2021, but then the rate increased into the third quarter. The second and third quarters of 2021 are further evaluated in a table below with factors that affected rates of CIN. These factors consist of a diagnosis of heart failure and/or diabetes, GFR < 60 prior to the procedure, patients not receiving intravenous fluids post-procedure, patients receiving more contrast than their MACD, complex procedures, and subsequent procedures requiring additional contrast.

A factor that was not reported that would affect the outcome data is amount of STEMI (ST-elevation myocardial infarction) patients. It is assumed that STEMIs are skewing numbers since these patients have a reduced cardiac output which negatively impacts kidney function. STEMI patients who have underlying kidney disease are at even greater risk for developing CIN.

It should also be noted that the number of procedures during the second and third quarters of 2020 were lower due to the Covid-19 pandemic, which may have impacted CIN rates. Only emergent cardiac catheterization procedures were performed during those quarters at the facility.

Findings

Time Period	CIN Rate
2019 Q4	12.66%
2020 Q1	15.76%
2020 Q2	8.27% (covid, case load lower)
2020 Q3	5.97% (covid, case load lower)
Rate of CIN for Cohort A	12.23%
2020 Q4 – implementation phase	9.89%
2021 Q1	13.83%
2021 Q2	6.54%
2021 Q3	9.29%
Rate of CIN for Cohort B	9.89%; P value = 0.48

2021 Q2 (12/237, 6.54%) & 2021 Q3 (18/262, 9.29%) Detailed Review

Frequency	Risk Factor
17/30	56.6% diabetics
15/30	50% inpatient
14/30	46.6% GFR < 60 prior to procedure
14/30	46.6% did not receive IV hydration prior to procedure
14/30	46.6% prior heart failure
9/30	30% did not receive IV hydration after the procedure (HF, etc.)
8/30	26.6% received greater than their max contrast dose
6/30	20% complex procedures
8/30	26.6% second contrast procedure during hospitalization

The table above is further evaluating rates of CIN during the second and third quarters of 2021. It is giving a detailed review as to why some patients may have developed CIN post-cardiac catheterization.

Confounding Factors

- October 2021 – cath lab staff started calculating MACD which is GFR x 3.7. MACD was given during time out prior to procedure start and every time a new contrast bottle was hung to reiterate to physician the MACD and if/when they did reach the MACD.

- March 2022 – trialing new contrast saver system called Dyevert made by Osprey, which should limit amount of contrast. The device will add cost to procedure, but if physicians decide they want it, criteria for use will be established (STEMI, HF, DM, GFR < 60).

Limitations

There were limitations with this program evaluation related to data acquisition. The pre-protocol data review included comprehensive, detailed data that was not provided in the post-protocol data. The post-protocol data did not include which patients specifically did not receive the fluid protocol. Data on which providers implemented the protocol was not provided either. This data would be helpful to determine if the protocol itself was failing or if it was a compliance issue.

The Covid-19 pandemic did decrease the number of cases during the second and third quarters of 2020. This facility was only using the cardiac catheterization lab for emergent STEMI cases during these months. This decrease in number of cases led to an overall decrease of CIN since less patients were being seen. Some providers did not want to perform cardiac catheterizations on some Covid-19 patients due to the risk of clotting and perfusion impairment.

Practice Implications

There are numerous factors that impact CIN after contrast administration. Evaluating the variability in the amount of contrast used per provider is a practice implication that could be implemented moving forward. Another implication is analyzing each provider's compliance to the pre- and post-procedure fluid protocol.

Based on the results, many of the patients who were diagnosed with CIN were heart failure patients. This facility does have an advanced heart failure team who would be available for a discussion on how to reduce rates in this population moving forward. There could be

parameters based on ejection fraction. The results also showed that many of the CIN patients had diabetes. Patients with elevated HgbA1C prior to the procedure could be educated to self-hydrate.

Nephrology is not on each patient's treatment team whether they are inpatient or outpatient. For patients with known chronic kidney disease, a renal consult should be considered prior to implementing the fluid protocol. They could also give recommendations regarding administration of pre-contrast buffering agents (N-acetylcysteine), which nephrotoxic medications to hold post-procedure (NSAIDs, diuretics, certain antibiotics, etc.) and how long to wait after the cardiac catheterization until the patient can undergo another procedure that requires contrast. There could also be a discussion with the primary team about additional CT scans/MRIs during admission and if the additional testing can wait until outpatient. Since many of the patients who developed CIN were heart failure patients, the renal team could also be part of the discussion with the heart failure team on how to combat CIN in this specific patient population.

Future Research

Further research on how to combat CIN post-cardiac catheterization in heart failure and diabetes patients is imperative based on this program evaluation. Many heart failure patients have underlying or chronic kidney disease due to factors such as a reduced ejection fraction, the use of diuretics, and the use of guideline directed medical therapy. Dilated and restrictive heart failure can result in volume overload. These patients are typically on restricted daily fluid intake which contradicts the intravenous fluid protocol. Further research and close heart failure team collaboration when managing these patients pre- and post-cardiac catheterization is important.

Uncontrolled diabetes can lead to kidney damage/failure. Further research is indicated in these patients on how to optimize them before a cardiac catheterization. Looking into stopping, starting, and continuing diabetic medications prior to the procedure is indicated for further research.

There should be further evaluation of STEMI patients developing CIN post-procedure and ways to decrease the incidence. STEMIs caused reduced cardiac output which impairs the kidneys prior to any contrast administration. The addition of contrast media in combination with a STEMI can cause significant kidney damage. The use of an Impella device or balloon pump during a STEMI should be researched as both devices improve circulation to the kidneys. These devices would sometimes have to be inserted during times of hemodynamic instability, so the benefit would have to outweigh the risk.

Nursing and Health Policy

There should be further nursing education on kidney disease, contrast media, CIN, and cardiac catheterizations. There should also be re-education to nursing staff at this facility related to implementing the fluid protocol pre- and post-procedure. There is not information on nursing compliance with protocol implementation, but based on the results, it is assumed it was not at 100% for nurses or providers. Heart failure education for nurses and patients can also help to reduce rates of CIN. Avoiding renal congestion with fluid prior to the procedure can help decrease CIN incidence.

Conclusion

Contrast-induced nephropathy is an expensive and potentially devastating diagnosis. Patients undergoing a minimally invasive procedure can result in an additional comorbidity and even mortality. This can be prevented by using an intravenous fluid protocol before, during, and after a cardiac catheterization. Although this program evaluation does not show an improvement in CIN, this can be improved upon. Factors such as compliance, amount of contrast used per provider, heart failure team discussion, and diabetes management can be further evaluated to decrease rates of CIN in the future. Tracking provider and nursing staff compliance in the future is imperative to the success of lowering CIN rates using a fluid protocol. The same data should be collected pre- and post-implementation to evaluate where there are positive and negative outcomes. Future research reviewing the use of Impella-assisted STEMI and PCI procedures, using a MACD, and dye-reducing products should be assessed. Reducing CIN rates can decrease costs, reduce stress for patients and their family members, and increase patient care and satisfaction if successful.

References

Andreucci, M., Faga, T., Serra, R., De Sarro, G., & Michael, A. (2017). Update on the renal toxicity of iodinated contrast drugs used in clinical medicine. *Drug, Healthcare and Patient Safety, 9,* 25-37. https://doi.org/10.2147/dhps.s122207

American College of Cardiology Committee on Drugs and Contrast Media [ACR]. (2020). *American college of radiology manual on contrast media* (11th edition). American College of Radiology.

Aoun, J., Nicolas, D., Brown, J., & Jaber, B. (2018). Maximum allowable contrast dose and prevention of acute kidney injury following cardiovascular procedures. *Current Opinion in Nephrology and Hypertension, 27*(2), 121-129. https://doi.org/10.1097/MNH.0000000000000389

Bottinor, W., Chawla, R., Danyi, P., Patel, K., Turlington, J., Sangal, K., Hong, W., Perera, R., & Jovin, I. (2019). Intravenous fluid therapy is associated with a reduced incidence of contrast-induced nephropathy but not with a reduced long-term incidence of renal dysfunction after cardiac catheterization. *Cardiovascular Revascularization Medicine, 21,* 20-23. https://doi.org/10.1016/j.carrev.2019.07.020

Brar, S., Aharonian, V., Mansukhani, P., Moore, N., Shen, A., Jorgensen, M., Dua, A., Short, L., & Kane, K. (2014). Haemodynamic-guided fluid administration for the prevention of contrast-induced acute kidney injury: The POSEIDON randomized controlled trial. *Lancet, 383,* 1814-1823.

Centers for Disease Control and Prevention (2019). *Deaths and mortality.* U.S. Department of Health and Human Services. https://www.cdc.gov/nchs/fastats/deaths.htm

Deek, H., Newton, P., Sheerin, N., Noureddine, S., & Davidson, P. (2014). Contrast media induced nephropathy: A literature review of the available evidence and recommendations for practice. *Australian Critical Care, 27,* 166-171. http://dx.doi.org/10.1016/j.aucc.2013.12.002

Grove, S., & Cipher, D. (2017). *Statistics for nursing research: A workbook for evidence-based practice* (2nd edition). Elsevier.

Hong, W., Kabach, M., Feldman, G., & Jovin, I. (2020). Intravenous fluids for the prevention of contrast-induced nephropathy in patients undergoing coronary angiography and cardiac catheterization. *Expert Review of Cardiovascular Therapy, 18*(1), 33-39. https://doi.org/10.1080/14779072.2020.1724537

Jurado-Roman, A., Hernandez-Hernandez, F., Garcia-Tejada, J., Granda-Nistal, C., Molina, J., Velazquez, M., Albarran, A., & Tascon, J. (2015). Role of hydration in contrast-induced nephropathy in patients who underwent primary percutaneous coronary intervention. *The American Journal of Cardiology, 115,* 1174-1178. http://dx.doi.org/10.1016/j.amjcard.2015.02.004

Lambert, P., Chaisson, K., Horton, S., Petrin, C., Marshall, E., Bowden, S., Scott, L., Conley, S., Stender, J., Kent, G., Hopkins, E., Smith, B., Kelloway, A., Roy, N., Homsted, B., Downs, C., Ross, C., Brown, J., & the members of the Northern New England Cardiovascular Disease Study Group. (2017). Reducing contrast-induced acute kidney injury: How nurses can improve patient safety, a qualitative investigation. *Critical Care Nurse, 37*(1), 1-21. https://doi.org/10.4037/ccn2017178

Likosky, D. (2014). Developing and executing quality improvement projects (concept, methods, and evaluation). *The Journal of ExtraCorporeal Technology, 46,* 38-44.

Liu, S., Shan, X., & Zhang, X. (2020). The place of hydration using intravenous fluid in patients at risk of developing contrast-associated nephropathy. *British Journal of Hospital Medicine,* 1-7. https://doi.org/10.12968/hmed.2020.0394

Manda, Y., & Baradhi, K. (2021). Cardiac catherization risks and complications. *StatPearls.* https://www.ncbi.nlm.nih.gov/books/NBK531461

Mehran, R., & Nikolsky, E. (2006). Contrast-induced nephropathy: Definition, epidemiology, and patients at risk. *Kidney International, 69,* S11-S15.

Mohammed, N., Mahfouz, A., Achkar, K., Rafie, I., & Hajar, R. (2013). Contrast-induced nephropathy. *HeartViews, 14*(3), 106-116. https://www.doi.org/10.4103/1995-705X.125926

National Archives. (2021). *Electronic codes of federal regulations.* https://www.ecfr.gov/cgi-bin/text-idx?node=pt42.5.493&rgn=div5

National Kidney Foundation. (2017). *Creatinine.* https://www.kidney.org/atoz/content/what-creatinine

Norton Healthcare. (2021). *About us.* https://nortonhealthcare.com/about-us/

Sarnak, M. (2014). A patient with heart failure and worsening kidney function. *American Society of Nephrology, 9,* 1790-1798. https://doi.org/10.2215/cjn.11601113

Shahbaz, H., & Gupta, M. (2020). Creatinine clearance. National Center for Biotechnology Information. https://www.ncbi.nlm.gov/books/NBK544228/

Singh, B., & Zughaib, M. (2019). Timeout for contrast: Using physician behavior modification to reduce contrast in the catheterization laboratory. *Cardiology Research and Practice, 2019,* 1-6. https://doi.org/10.1155/2019/9238124

Spath, P. (2018). *Introduction to healthcare quality management* (3rd edition). Health Administration Press.

Sun, G., Chen, P., Wang, K., Li, H., Chen, S., Liu, J., He, Y., Song, F., Liu, Y., & Chen, J. (2019). Contrast-induced nephropathy and long-term mortality after percutaneous coronary intervention in patients with acute myocardial infarction. *Angiology, 70*(7), 621-626. https://www.doi.org/10.1177/0003319718803677

Wang, Z., Song, Y., A, G., & Li, Y. (2019). Role of hydration in contrast-induced nephropathy in patients who underwent primary percutaneous coronary intervention. *International Heart Journal Association, 60*(5), 1077-1082. https://doi.org/10.1536/ihj.18-725

Wichmann, J. L., Katzberg, R. W., Litwin, S. E., Zwerner, P. L., De Cecco, C. N., Vogl, T. J., Costello, P., & Schoepf, J. (2015). Contrast-induced nephropathy. *Circulation, 132*, 1931-1936. https://doi.org/10.1161/circulationaha.115.014672

Appendices

A. Johns Hopkins Evidence Level and Quality Guide

Johns Hopkins Nursing Evidence-Based Practice
Appendix C: Evidence Level and Quality Guide

Evidence Levels	Quality Guides
Level I Experimental study, randomized controlled trial (RCT) Systematic review of RCTs, with or without meta-analysis	**A High quality:** Consistent, generalizable results; sufficient sample size for the study design; adequate control; definitive conclusions; consistent recommendations based on comprehensive literature review that includes thorough reference to scientific evidence
Level II Quasi-experimental study Systematic review of a combination of RCTs and quasi-experimental, or quasi-experimental studies only, with or without meta-analysis	**B Good quality:** Reasonably consistent results; sufficient sample size for the study design; some control, fairly definitive conclusions; reasonably consistent recommendations based on fairly comprehensive literature review that includes some reference to scientific evidence
Level III Non-experimental study Systematic review of a combination of RCTs, quasi-experimental and non-experimental studies, or non-experimental studies only, with or without meta-analysis Qualitative study or systematic review with or without a meta-synthesis	**C Low quality or major flaws:** Little evidence with inconsistent results; insufficient sample size for the study design; conclusions cannot be drawn

Johns Hopkins University. (2022). *Johns Hopkins nursing evidence-based practice appendix c: Evidence level and quality guide.* https://www.hopkinsmedicine.org/evidence-based-practice/_docs/appendix_c_evidence_level_quality_guide.pdf

B. Evidence Table

Intervention: Intravenous Fluid Protocol								
	Lambert 2017	Deek 2014	Liu 2020	Bottinor 2019	Brar 2014	Jurado 2015	Wang 2019	Hong 2020
Rate and duration	500mL/hr for one hour or 200mL/hr for two hours, then 100mL/hr until start of procedure; 1 mL/kg/hr after procedure for 6 hours	1 mL/kg/hr for 12 hr prior to procedure and for 6 hrs after procedure	This was a systematic review and did not conclude on what the rate and duration of fluids should be.	100mL/hr for 5-10 hours before procedure and for 5-10 hours after the procedure	The rate and volume should be individualized based on the pt's left ventricular end-diastolic pressure.	1 mL/kg/hr from beginning of procedure and the following 24 hrs; rate was reduced to 0.5 mL/kg/hr in patients with EF < 40%.	This was a systematic review. There were multiple different rates and duration of fluid protocol; there was no conclusion or recommendation for rate and duration.	Recommended fluid rate after systematic review is: 1 mL/kg/hr for one hour pre-procedure and six hours post-procedure.
Outpatient	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes
Inpatient	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes
STEMI	No	Yes	Yes	Yes	No	Yes	Yes	Yes
Intervention: Intravenous Fluid Protocol								
Outcomes	Lambert 2017	Deek 2014	Liu 2020	Bottinor 2019	Brar 2014	Jurado 2015	Wang 2019	Hong 2020
	CI-AKI was	Fluid administration can	Pre-hydration before	The main finding of this	Intravenous administra	In patients with	The use of intravenous volume	This review researched the most

	decreased by more than 20%.	reduce rates of CIN in cardiac catheterization patients.	administering contrast media seems to be crucial.	study is that the administration of IVF to patients undergoing coronary or peripheral angiography and intervention is associated with a decrease in incidence of CIN at 72 hours.	tion of normal saline, guiding by the left ventricular end-diastolic pressure, is well tolerated and could substantially reduce the incidence of contrast-induced acute kidney injury and major adverse clinical events in patients undergoing cardiac catheterization.	STEMI who undergo PPCI, intravenous hydration is a simple and effective preventative measure against CIN.	expansion with saline decreased rates of CIN.	recent clinical trials, RCTs, and systematic reviews and made recommendations based off the research found. This review should be applied to practice based on relevancy and articles reviewed.

C. Theoretical Model: FADE Diagram

Focus	This program evaluation is focusing on improving rates of contrast-induced nephropathy post-cardiac catheterization. This cardiac catheterization laboratory is almost 10% over the national standard of quarterly rates of CIN and the rate is rising every quarter.
Analyze	Over 10% of patients who underwent a cardiac catheterization during the first quarter of 2020 were diagnosed with CIN post-procedure related to a 0.5mg/dL rise in serum creatinine. The national standard for quarterly rates of CIN is currently set at 6%. Statistics will be gathered from this site 6 months before project implementation. CIN is resulting in longer hospital admission, increased hospital costs, and increased risk of morbidity and mortality for patients with this diagnosis.
Develop	An intravenous fluid protocol has been developed. The fluid protocol will be used pre-, intra-, and post-cardiac catheterization.

	This fluid protocol will be initiated at 6am on the day of the patient's procedure at 150mL/hr x 2 hours, then decreased to 20mL/hr prior to the procedure. During the procedure, the fluids will be set at 150mL/hr unless otherwise indicated. Post catheterization fluids will infuse at 150mL/hr x 4 hours, then discontinued unless otherwise specified by a provider.
Execute	This program was started in November 2020. Serum creatinine levels are being measured 24-48 hours post-cardiac catheterization. All cardiac catheterization patients have a baseline creatinine level drawn before the procedure. These creatinine levels are compared to the baseline level drawn prior to the procedure. CIN rates are going to be evaluated every 3-4 months post protocol implementation. These rates will be compared to the rates of CIN 12 months prior to protocol implementation.

D. Data Collection Sheet

Pre-Protocol Group (Cohort A): January 2019-December 2019

Patient	Age	CC Contrast	MACD (3.7xGFR)	Baseline Cr	Post-op Cr	IVF started pre-proc	CIN Dx
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							

E. Approval from Director of the CCL:

From: McDonogh, Lesli L. <Lesli.McDonogh@nortonhealthcare.org>
Sent: Monday, February 15, 2021 9:01 AM
To: Schaefer, Sarah <Sarah.Schaefer@nortonhealthcare.org>; El-Refai, Mostafa <Mostafa.El-Refai@nortonhealthcare.org>
Cc: Meyer,Kimberly S <kimberly.meyer.2@louisville.edu>
Subject: RE: CIN project

Hi Sarah,
Yes, you are welcome to use the pre-intervention data that was collected for all of 2019. The only post intervention data we will have will be the quarterly CathPCI executive summary which runs approximately 6 months behind. The interventions were started in Nov 2020 so we should get quarter 1 2021 sometime around June. I am happy to share this data with you as it rolls out.