The Effect of Fluorescein Angiography on Renal Function: A Meta-analysis and Systematic Review

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ABSTRACT

Background. Contrast-induced nephropathy (CIN) is a complication that occurs in patients undergoing an imaging procedure with intravenous injection of contrast media, most notably iodinated dyes. Fluorescein angiography is a diagnostic procedure performed by ophthalmologists to determine abnormalities in retinal blood vessels. It uses sodium fluorescein, an organic dye, to capture and visualize these blood vessels. There have been conflicting data and practices on how to approach the procedure especially in patients with renal insufficiency.

Objective. To determine the risk of CIN among patients undergoing fluorescein angiography.

Methods. We searched PubMed, HerdIn, Cochrane Library, and Google Scholar, for published articles on the topic. Other sources were searched for unpublished data or ongoing clinical trials. All research articles pertaining to fluorescein angiography and its effect on renal function with serum creatinine monitoring were included. Two independent authors separately screened records, assessed full texts, and extracted data. We used RevMan computer software to analyze data from the included studies. The primary outcome was the risk of CIN among patients undergoing fluorescein angiography based on the differences on serum creatinine levels and estimated glomerular filtration rates pre- and post-angiography, while the secondary outcome included risk factors for CIN.

Results. A total of 6 studies were included in the meta-analysis. Four studies had poor quality as assessed using the Newcastle-Ottawa Scale. One study was deemed to have good quality. Data analysis showed that hemoglobin ($p = 0.002$) and albumin ($p < 0.001$) levels may be associated with CIN using sodium fluorescein but were not independent risk factors for CIN (multivariable logistic regression, $p = 0.648$ and $p = 0.069$, respectively); while sex, diabetes mellitus and chronic kidney disease were not significantly associated. As a primary outcome, only 6.8% of included patients had CIN with serum creatinine levels post-exposure showed significant differences from baseline values (mean difference 0.05; 95% CI 0.02, 0.07; $I^2 = 49\%$), but translating it to eGFR yielded non-significant differences (mean difference -0.37; 95% CI -2.33, 1.59; $I^2 = 0\%$).

Conclusion. Among patients undergoing fluorescein angiography, sodium fluorescein does not pose an increased risk for CIN.

Key Words: fluorescein angiography, contrast-induced nephropathy, renal function

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INTRODUCTION

Contrast-induced nephropathy (CIN) is a complication arising from the use of contrast dye in angiographic procedures, usually using iodinated contrast. It causes a transient and reversible acute kidney injury with a highly predictable course that peaks at 48 hours and lasts for 7 days. The universally accepted definition of CIN is either an increase of more than 0.5 mg/dL or more than 25% from baseline after 48 hours post-exposure. Other factors that cause nephropathy such as nephrotoxins, hemodynamic instability, any urinary obstruction, or atheromatous emboli, need to be excluded.[1,2] Its definite mechanism is currently unknown;

however, the proposed mechanism of damage includes renal medullary hypoxia or direct toxicity via oxidative stress or free radical formation. Treatment of CIN is mainly supportive in nature with occasional need for renal replacement therapy. In the Philippine setting, data is lacking but some studies report incidence rates of CIN that range from 0 to 2.8%.[3,4]

Fluorescein angiography is a diagnostic procedure requested by ophthalmologists to record and determine blood flow in the retina. Its use is particularly important in the management of diabetic retinopathy and macular degeneration.[5] Sodium fluorescein is an organic dye with a phthalic moiety. It is used as an indicator as the dye changes color in different solutions. It may be used as an indicator for corneal perforation, trauma, or injury, as it turns bright green in an alkaline medium such as aqueous humor. It is a potent indicator that it fluoresces even at dilutions as high as 1:40,000,000.[6] In angiography, the dye is injected intravenously, and using a special camera that releases and records emitted light energy, the blood vessels of the retina can be visualized.[7]

Although sodium fluorescein is a non-iodinated contrast, there have been practices wherein caution is taken for patients with renal insufficiency undergoing the procedure. Non-nephrologists refer usually to the Nephrology service most, if not all, patients with elevated creatinine values for clearance in using any contrast, but this practice varies widely from physician to physician or institution to institution. Diabetic retinopathy is the usual indication for the procedure but most of the patients also have a certain degree of renal insufficiency.[7] There have been conflicting data regarding the incidence and risk of CIN or acute kidney injury after undergoing a fluorescein angiography, or studies have a small population limiting data analysis and applicability. This study compiled and analyzed any existing and available research on the topic. As such, this study is the first meta-analysis compiling the data on CIN on fluorescein angiography. The future implications include, but are not limited to, avoiding unnecessary referrals and costs to the patient, and therefore fast-tracking or streamlining management.

The general objective of the study was to determine the risk of CIN among patients undergoing fluorescein angiography. The specific objectives were to determine possible risk factors for CIN from fluorescein angiography and to assess any significant changes from baseline creatinine values to post-treatment values.

MATERIALS AND METHODS

Eligibility Criteria

All retrospective or prospective cohort, cross-sectional studies, or randomized controlled trials were included in the study. Participants aged >18 years old who underwent fluorescein angiography for any indication were included in the study. All included studies had an intravenous injection of sodium fluorescein.

We collected demographic information regarding participants and serial creatinine level monitoring pre- and post-exposure to fluorescein angiography. The primary outcome of the study was the risk of CIN with serial creatinine monitoring using the following criteria: (1) an increase of more than 0.5 mg/dL or (2) more than 25% increase from baseline after 48 hours post-exposure.

Search Strategy

We searched PubMed, HerdIn, Cochrane Library, and Google Scholar to retrieve published data until September 30, 2020. The search strategy used the following terms: "acute kidney injury", "RIFLE criteria", "acute kidney network criteria", and "fluorescein angiography"; using the following format:

(((((("acute kidney injury"[MeSH Terms] OR (("acute"[All Fields] AND "kidney"[All Fields]) AND "injury"[All Fields])) OR "acute kidney injury"[All Fields]) OR (("acute"[All Fields] AND "kidney"[All Fields]) AND "failure"[All Fields])) OR "acute kidney failure"[All Fields]) OR (("acute kidney injury"[MeSH Terms] OR (("acute"[All Fields] AND "kidney"[All Fields]) AND "injury"[All Fields])) OR "acute kidney injury"[All Fields])) AND (("fluorescein angiography"[MeSH Terms] OR ("fluorescein"[All Fields] AND "angiography"[All Fields])) OR "fluorescein angiography"[All Fields])

We also searched for unpublished data or ongoing trials in ClinicalTrials.gov and corresponded with authors of published or unpublished articles.

Selection of studies

We included studies that recruited adult patients aged 18 years and older with or without any co-morbidities, undergoing fluorescein angiography for any indication. Abstracts with intervention and outcomes of interest were included.

Exclusion criteria included studies that recruited pregnant patients, patients already undergoing chronic or maintenance hemodialysis, patients undergoing other concurrent imaging studies that need another contrast dye, and non-English articles with no English translation.

Data collection, extraction, and management

Retrieved articles were scanned for inclusion in the study. Full-text articles were retrieved from various sources. Attempts to contact original authors were done as necessary. Analysis of data was done using the Review Manager 5.4 software.[8]

Two independent reviewers performed independent search strategies and selected trials. Data extraction of the studies was accomplished, encoded, and subsequently tabulated. Differences were resolved by a third independent reviewer through consensus.

Assessment of risk of bias in included studies

We assessed the risk of bias for selected articles using the Newcastle-Ottawa Scale (0-9), a tool widely used for assessing observational studies for meta-analyses. It uses a "star system" to judge a study based on three subscales: selection, comparability, and outcomes. A score of at least 6 without a zero point in any subscale is needed for a study to be assessed to have good quality. Quality assessment was conducted by two independent reviewers.

Data Analysis

All compiled data were analyzed using the RevMan 5.4 software. The mean and standard deviations of the gathered data were analyzed. Other endpoints in the included studies were noted and discussed as well. Significant outcomes were considered when the p-value was less than 0.05.

Ethical Review

The University of the Philippines Manila Research Ethics Board exempted this study from ethical review since the study involved the use and analysis of publicly available results (under provision 3.1 of the National Ethical Guidelines for Health and Health-related Research 2017).

RESULTS

Results of the search

A total of 31 non-duplicate studies were collated after performing the search strategy described. There were no ongoing trials or unpublished articles retrieved. A number of articles were excluded as these articles were as a letter to the editor, or only viewed fluorescein angiography as a diagnostic procedure and not as the exposure of interest. The latter reason also included studies in which monitoring of creatinine is lacking or that an iodinated contrast procedure was also performed right before or after the fluorescein angiography. After screening, 6 articles remained for eligibility, with one article abstract excluded due to incomplete data. An additional article was retrieved thru direct correspondence and 6 studies were finally included in a meta-analysis.[4]

Only 6 articles were deemed eligible to be included in the final analysis (Figure 1).

Description of studies

Three of the six included studies were non-randomized cohort studies, while the remaining were retrospective studies. All of the articles included diabetic patients or are a subset of the study population. The studies did not specify if patients were outpatients or inpatients. All studies were conducted in a hospital-based setting using medical or procedural records as an objective basis in determining events of CIN. All studies measured serum creatinine (SCr) pre- and post-exposure to sodium fluorescein. Kameda et al. also measured SCr levels but only reported computed eGFR values. The studies used intravenous sodium fluorescein with 250–500 milligrams injected into a peripheral vein. All studies had adequate follow-up serum creatinine values post-procedure; however, it is of note that Kameda et al. extended the follow-up up to one month. The serum creatinine levels in the article were extracted between 4 to 21 days post-procedure (Table 1).

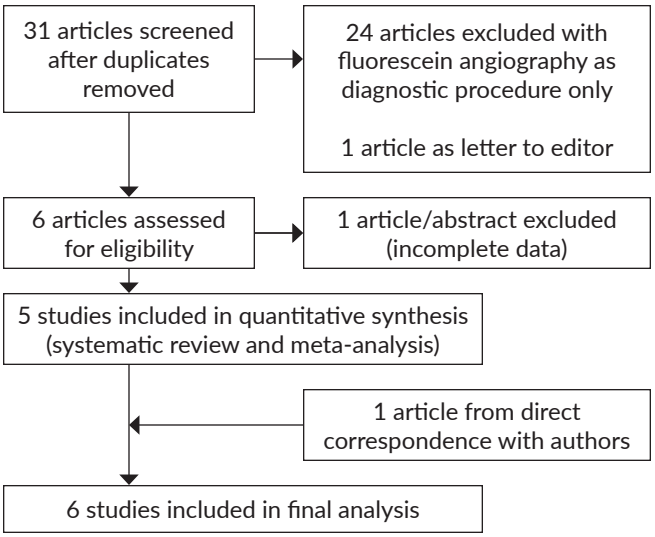

Figure 1. PRISMA flow diagram of study selection.

Only two studies were assessed to have good quality (Table 2).[4,13] The rest of the studies had 3 stars in the selection domain, no stars in the comparability domain, and 2 or 3 stars in the outcome domain, reflecting poor quality. All studies included used a single arm for the pre- and post-exposure measurement with no available non-exposed cohort. However, based on the study design, a non-exposed cohort was not necessary; instead, confounders (e.g., on maintenance HD, concurrent intravenous contrast studies) have been excluded prior to the analysis of each study. All data of the studies were based on patient medical or procedure records as objective measures of exposure.

Effects of interventions

Risk of contrast-induced nephropathy

Of the 1,555 patients included in all of the six studies, only 106 patients (or 6.8%) were assessed and reported to have CIN.

Risk Factors

Sex (OR 1.09 [0.69, 1.72], p = 0.08, I^2 = 61%), diabetes mellitus (OR 1.03 [0.63, 1.68], p = 1.00, I^2 = 0%), and chronic kidney diseases (OR 1.29 [0.81, 2.06], p = 0.28, I^2 = 20%) were not associated with having increased risk of CIN (Figure 2A-C).

In the study by Yun et al. (2019), other reported risk factors in having CIN are hemoglobin and albumin levels. The hemoglobin level was significantly lower in patients

Table 1. Characteristics of included studies

Study (publication year)	Size	Setting (country)	Population	Exposure	Outcomes	Methods
Alemzadeh[9] (2011)	44	Department of Ophthalmology, Imam Khomeini Hospital, Ahvaz (Iran)	Adults with diabetes undergoing FA to assess retinopathy	500 mg sodium fluorescein solution injected into the antecubital vein over 5 secs	• Renal function (SCr before and on days 2 and 3 after FA)	Prospective single-arm pre- and post-exposure non-randomized cohort
Almaki[10] (2017)	100	Ophthalmology Outpatient clinic, Alexandria Main University Hospital (Egypt)	Adults with T2DM of any age, with stable kidney functions over the past three months who have signs of diabetic retinopathy referred for FA	Five milliliters of 5% fluorescein sodium injected as a bolus into a peripheral vein	• UACR before FA • Urinary NGAL before and 4 h after FA • SCr and cystatin C before and 48 h after FA	Prospective single-arm pre- and post-exposure non-randomized cohort
Kameda[11] (2009)	128	Department of Ophthalmology, Diabetic Center, Tokyo Women's Medical University Hospital (Japan)	Adult diabetic patients with an estimated glomerular filtration rate (eGFR) at baseline <60 ml/min per 1.73 m^2	2.5 ml of 10% sodium fluorescein solution was injected into the antecubital vein over 5 secs	• SCr levels at baseline (within 30 d before FA) and follow-up (within 30 d after FA)	Hospital-based retrospective cohort study
Lee[12] (2017)	160	Department of Ophthalmology, Severance Hospital, College of Medicine, Yonsei University (Korea)	All adult patients seen	500 mg of sodium fluorescein (Novartis, Basel, Switzerland) intravenously through an antecubital vein in 5–8 s	• SCr within 24 h before and within 72 h after FA	Retrospective cohort study (using medical records)
Yun[13] (2019)	979	Seoul National University Hospital and Seoul National University Boramae Medical Center (Korea)	Adult patients (≥18 years old) undergoing FA	250–500mg of sodium fluorescein was infused within 10s	• SCr within 28 d before and 3 d after FA	Retrospective cohort study (using medical records)
Naidas[4] (2020)	144	Eye Institute, St. Luke's Medical Center, Philippines	Adult patients aged 18 years old and above	500mg of sodium fluorescein (Alcon Laboratories)	• SCr up to 7 days before and 48 to 72 h after FA	Prospective observational study

SCr, Serum creatinine; FA, Fluorescein angiography; UACR, Urine albumin creatinine ratio; NGAL, Neutrophil gelatinase-associated lipocalin

Table 2. Assessment of study quality of non-randomized cohorts

	Alemzadeh 2011	Almaki 2017	Kameda 2009	Lee 2017	Yun 2019	Naidas 2020
Selection						
Representativeness of exposed cohort	1	1	1	1	1	1
Selection of non-exposed cohort	0	0	0	0	0	0
Ascertainment of exposure	1	1	1	1	1	1
Demonstration that outcome of interest was not present at the start of study	1	1	1	1	1	1
Comparability						
Comparability of cohorts on the basis of the design or analysis controlled for confounders	0	0	0	0	2	1
Outcome						
Assessment of outcome	1	1	1	1	1	1
Was follow-up long enough for outcomes to occur	0	0	1	0	1	1
Adequacy of follow-up of cohorts	1	1	1	1	1	1
Quality	Poor	Poor	Poor	Poor	Good	Good

Quality of the studies used the Newcastle-Ottawa Scale. Each criteria was assessed based on the available article and given a point for fulfilling said criteria.

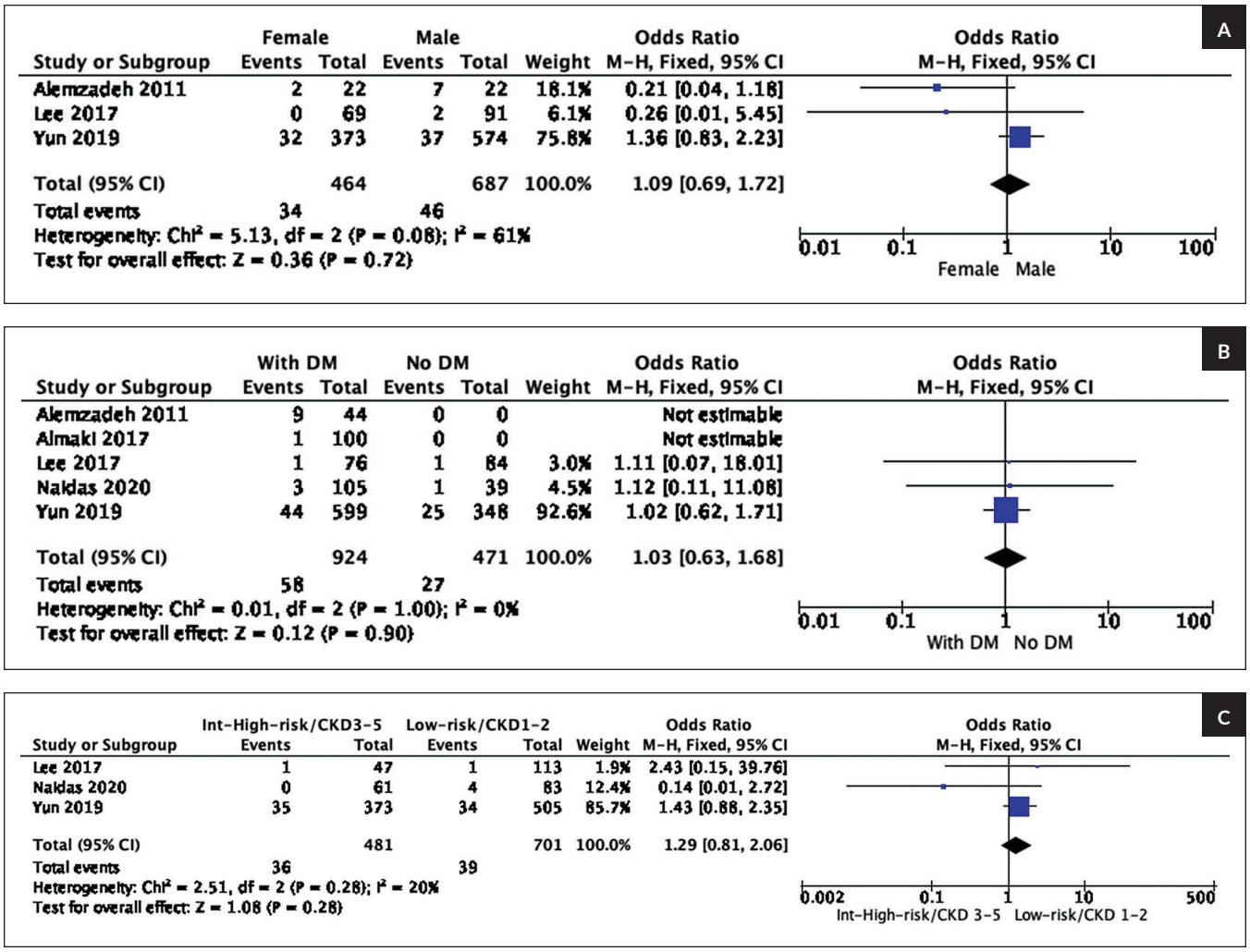

Figure 2. Forest plot of risk factors. Each of the studies presented characteristics of those with or without contrast-induced nephropathy after sodium fluorescein injections. Most of the studies based the risk factors on sex **(A)**, presence of diabetes mellitus **(B)**, and chronic kidney disease **(C)**.

with CIN (10.5 g/dL vs 11.2 g/dL, p=0.002), as well as hypoalbuminemia (3.3g/dL vs 3.6g/dL, p<0.001). However, on multivariable logistic regression for CIN, both factors showed non-significant statistical differences (hemoglobin, p=0.648; albumin, p=0.069). Other noted variables were not statistically significant between groups (hypertension, p=0.319; baseline serum creatinine, p=0.709; baseline eGFR, p=0.431; cholesterol levels, p=0.231). In addition, having CIN is associated with decreased renal survival rate in the next 10-16 years (p<0.001), with no significant increase in all-cause mortality.[13]

There was a statistically significant difference in serum creatinine values pre- and post-exposure (mean difference 0.05 [0.02, 0.07], p = 0.14, I^2 = 42%); although the absolute value increase seems to be clinically insignificant (0.02 to 0.07 mg/dL). There was nonuniform determinations of serum creatinine in terms of temporality before and after exposure to contrast, although heterogeneity was not statistically significant. The estimated glomerular filtration rates are not statistically significant (mean difference -0.29 [-2.15, 1.57], p = 0.97, I^2 = 0%), whether using the CKD-Epi (mean difference -0.57 [-3.20, 2.06], p = 0.88, I^2 = 0%) or the Modification of Diet in Renal Disease Study (MDRD) (Mean difference -0.01 [-2.65, 2.62], p = 0.78, I^2 = 0) equations as shown in Figure 3.

DISCUSSION

CIN is a feared complication of the use of iodinated contrast. The study presented information that fluorescein angiography did not pose significant changes in serum creatinine and renal function. In addition, sex, diabetes mellitus, CKD, anemia, and hypoalbuminemia showed non-significant association with the development of CIN. The risk is not significant in the general population, but maybe worrisome in selected patients.

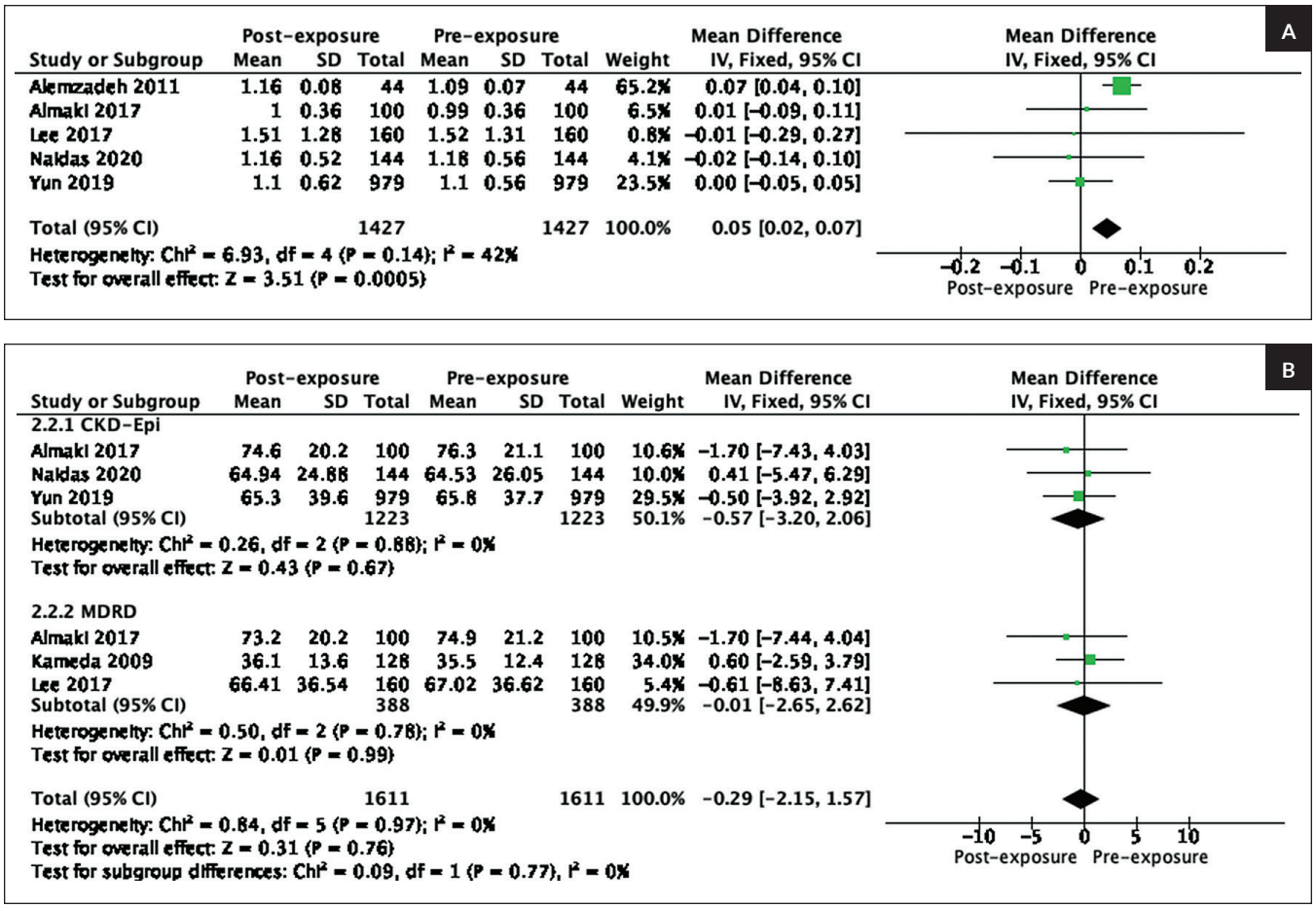

Figure 3. Forest plot of renal function. Each of the studies presented pre- and post-exposure **(A)** serum creatinine with **(B)** corresponding estimated glomerular filtration rates using CKD-Epi or MDRD formulae.

In the study of Mehran et al. (2004), eight variables (age, anemia, contrast volume, use of intraaortic balloon pump, and presence of hypotension, congestive heart failure, chronic kidney disease, and diabetes) were scored in patients undergoing percutaneous coronary intervention, and the scores were interpreted as low-or high-risk for having CIN post-procedure.[14] These variables were noted to have an impact on renal function by Mehran et al. (2004) and are often used in clinical practice to appraise patients on the risk of CIN and hemodialysis post-intraarterial contrast study. In the study of Evola et al. (2012) among Italian patients, increased risk of CIN was seen among patients who were elderly, diabetic, with kidney failure, undergoing diuretic therapy, with states of systemic inflammation, had clinical/pre-clinical extracardiac atherosclerosis, or received higher contrast amounts.[2]

In contrast, the study showed that the anemia and hypoalbuminemia were significant associated risk factors for having CIN using sodium fluorescein (albeit the levels may still be considered within acceptable levels). Yet, in a multivariable analysis of Yun, these two factors were not robustly associated with having CIN.[13] The levels of albumin have been included in various analyses and studies of iodinated CIN. However, the results have always been conflicting. In multiple myeloma patients undergoing contrast procedures, albumin levels were not found to be statistically significant (p = 0.12).[15] Comparing the baseline characteristics of patients with renal insufficiency that had CIN, lower serum albumin levels were seen compared to patients that had not fulfilled the criteria for CIN but also not statistically significant (p = 0.4).[16] In contrast, it was seen that among patients undergoing peritoneal dialysis, hypoalbuminemia (< 3.8 g/dL) is a strong independent risk factor for contracting CIN. The main mechanism for such is still unclear; yet, it is hypothesized that the albumin increases intravascular expansion through oncotic pressure, and has anti-oxidant properties, battling the proposed concept that contrast media induces free radicals and decreases renal blood flow.[17] Other studies have correlated albumin and fibrinogen in predicting CIN post-carotid angiography or post-percutaneous coronary intervention.[18,19]

The hemoglobin level has also been implicated in predicting CIN but with varying results. In a meta-analysis by Pelliccia et al., lower hemoglobin levels were seen among

patients with CIN ($p < 0.00001$).[20] In addition, an observational study by Ugur et al. correlated a high risk of CIN with anemia combined with a low left-ventricular ejection fraction < 35% among patients with non-ST elevation myocardial infarction undergoing coronary angiography.[21] On the other hand, the observational cohort study done by Kim et al. found no significant difference in the hemoglobin levels of groups that had CIN than those who have not ($p = 0.3$).[16] A plausible mechanism of anemia contributing to CIN mainly involves the renal perfusion to the outer medullary region. Being an area of high metabolic activity and low oxygen tension, the outer medullary region is particularly susceptible to ischemic injury. It has been reported that contrast media could alter the property of hemoglobin by increasing affinity to oxygen which then leads to decreased oxygen delivery to the tissues. As such, anemia aggravates further the decreased oxygen delivery to the tissues leading to further renal hypoxia in the outer medullary region, and which in turn, increases the risk of ischemic injury and CIN.

It is also interesting to note that lower serum albumin and hemoglobin levels were also associated with CIN in patients with hepatocellular carcinoma undergoing transarterial chemoembolization ($p = 0.05$ and $p = 0.03$, respectively).[22] Yet, another study found that a periprocedural drop in hemoglobin (> 1 g/dL), rather than baseline hemoglobin level, correlates with a higher incidence of CIN in patients undergoing percutaneous coronary intervention, and even using the least nephrotoxic contrast agent. [23] However, it is worth mentioning that the study of Wang et al. observed a delayed-type of CIN or delayed kidney injury after 1–6 months after a coronary angiography procedure and that anemia (hemoglobin < 110 g/L) was associated with this delayed type of CIN ($p = 0.003$).[24] For the studies above, the risk factors of sex, diabetes mellitus, anemia, CKD, and hypoalbuminemia were selected as risk factors for this study as these variables have a certain degree of effect on renal function in using iodinated contrast.[25]

In addition, there was a significant difference in serum creatinine levels pre- and post-exposure. However, the difference did not meet the criteria of AKI from CIN, which is an increase of serum creatinine of at least 0.3 mg/dL. This difference in serum creatinine was not reflected in the corresponding changes in eGFR; however, the equations used (CKD-Epi and MDRD formulae) in determining eGFR may not be suitable in an acute setting. It is of note that the late addition of the study of Naidas et al. did not significantly alter the results and conclusion of the meta-analysis.

One factor to consider that may contribute to the results may be the route of administration. Fluorescein angiography is given through the intravenous route. Studies have been done comparing the effect of intravenous versus intra-arterial contrasts on patients with renal impairment. Both routes have been associated with CIN and AKI post-procedure in patients with CKD; however, there were slightly lower rates using intravenous contrast. The exact mechanism of decreased rates for intravenous contrast is poorly elucidated. Stronger evidence for association is lacking in the absence of randomized controlled trials.[26,27]

Sodium fluorescein is a widely-used contrast dye in the field of ophthalmology as it helps visualize the retinal blood vessels. It has often been debated whether non-iodinated contrast may cause CIN or not. However, our study shows that using sodium fluorescein as contrast, the increase in serum creatinine levels may be statistically significant but not necessarily clinically significant.

Our study did a thorough search online and for unpublished data available in the current situation. The population mostly studied were patients with diabetes except for one study that expanded its study population to the general population then subsequently did a subgroup analysis on special populations. The scope of the study did not cover pregnant patients and children. Most of the studies showed the fair-to-good quality of evidence and one study showed excellent quality based on the Newcastle-Ottawa scale. The absence of a non-exposed cohort is deemed acceptable for a pre- and post-exposure design.

The use of steady-state eGFR equations (CKD-Epi, MDRD) may undermine the relative acute changes in the serum creatinine levels and may limit the analysis and generalizability of the results. Kinetic GFR may be a more accurate option in translating data in terms of renal function. Another limitation of the study is whether patients were seen as outpatients or in-patients. Confounders may affect the results as admitted patients may have more severe illnesses or other interventions (diagnostic or therapeutics) that may alter renal function more acutely or severely than fluorescein angiography.

Although there was a change of creatinine values ranging from 0.02 to 0.07 mg/dL from baseline, sodium fluorescein does not significantly pose an increased risk for CIN among patients undergoing angiography. It has been shown that while statistically significant differences were seen in pre- and post-exposure creatinine determinations, renal function is not severely affected.

CONCLUSION

Hemoglobin and albumin levels were notable risk factors associated with CIN using sodium fluorescein, while sex, diabetes mellitus, and chronic kidney disease were not significantly associated. Serum creatinine levels post-exposure showed significant differences from baseline values, but translating it to eGFR yielded non-significant differences.

Using sodium fluorescein in angiographic procedures may be a viable alternative contrast dye compared to the usual iodinated contrast dyes. Further studies are needed to conclusive associate hemoglobin and albumin levels as risk factors to CIN using sodium fluorescein.

Statement of Authorship

All authors contributed in the conceptualization of work, acquisition and analysis of data, drafting and revising and approved the final version submitted.

Author Disclosure

All authors declared no conflicts of interest.

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