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# Contrast induced nephropathy in women with infertility undergoing hysterosalpingography



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# Abstract

**Background** Contrast-induced nephropathy (CIN) defined as an acute kidney injury following the administration of iodinated contrast medium (CM). Hysterosalpingography (HSG) is a radiologic procedure used to investigate the shape and structure of the uterine cavity and the patency of the fallopian tubes in the evaluation of infertility. To date, there have been no reports evaluating the development of CIN after HSG procedure. Therefore, we investigated whether CIN development occurs in infertile women who underwent HSG and its relationship with clinical and laboratory changes in women who underwent HSG.

**Methods** This study was undertaken in 65 women who had infertility evaluation, uterine anomalies and/or tubal blockages. CIN was defined as a 25% relative increase, or a 0.5 mg/dL (44 µmol/L) absolute increase, in serum baseline creatinine (SCr) within 72 h of contrast exposure in the absence of alternative conditions. Hysterosalpingography (HSG) was performed using 5–20 ml of contrast medium. All patients performed routine laboratory tests including assessment of serum creatinine and urea and estimated glomerular filtration rates before and 2–3 day after HSG. Statistical analysis was performed with MedCalc Statistical Software Program v22.023 (Ostend, Belgium) program.

**Results** The mean ages of participants were 29.5 years and mean BMI were 26.2 kg/m2. The rate of CIN was 12.3% and the severe nephropathy was 1.5% in our study population. The baseline SCr level was  $0.59 \pm 0.06$  mg/dL in women with CIN and  $0.67 \pm 0.11$  mg/dL in women without CIN. The baseline SCr level was significantly lower in CIN group that non-CIN group (p = 0.0309). The SCr level significantly higher in CIN group than non-CIN group 48–72 h after HSG (p = 0.0005). In the multivariate logistic regression analysis, the baseline SCr was found an independent risk factor for the prediction of CIN in women who underwent HSG.

**Conclusion** The HSG procedure is generally a safe method, but the iodine-containing contrast material used in HSG may be associated with temporary adverse effects on kidney function.

Keywords Hysterosalpingography, Contrast induced nephropathy, Infertility, Creatinine

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# Background

Contrast-induced nephropathy (CIN), also known as contrast-induced acute kidney injury (CI-AKI), is a form of kidney damage that typically occurs after the injection of contrast agents during imaging tests like computed tomography (CT) scans, magnetic resonance imaging (MRI), angiography, and other radiologic procedures [1]. CIN is a significant contributor to acute tubular necrosis, with prevalence rates ranging from 3 to 50%, depending on the population studied, associated risk factors, types of contrast agents used, and the variety of medical procedures performed [2–4]. Risk factors for CIN include preexisting kidney failure, low blood pressure, heart failure, advanced age, anemia, diabetes mellitus, and the use of other nephrotoxic drugs [5, 6].

The most common presentation of CIN is asymptomatic, with changes in kidney function typically resolving within a few days. However, in approximately 5% of cases, the condition may worsen and progress to end-stage renal disease (ESRD) [4–6]. CIN is also associated with increased morbidity, extended hospital stays, a higher likelihood of requiring renal replacement therapy, and a greater risk of major cardiac events [4]. The mortality rate of CIN ranges from 3.8 to 64% [7, 8].

Hysterosalpingography (HSG) is a radiologic procedure that assesses the shape and structure of the uterine cavity and checks the openness of the fallopian tubes. It is commonly used in the evaluation of infertility and recurrent pregnancy loss [9]. HSG is generally considered a safe procedure with a low rate of complications. However, acute pelvic pain, infection, and vaginal bleeding are the most common complications that can occur during or after the procedure [9]. HSG may also rarely cause contrast medium-related complications, such as hypersensitivity reactions, venous or lymphatic intravasation, peritoneal irritation, and thyroid dysfunction [10, 11].

Although, the pathophysiology of CIN is still under investigation, it is defined as an adverse chemical reaction to iodinated contrast medium (CM), typically observed following the intravascular administration of CM. However, previous studies have shown that CIN may also develop in patients receiving CM through nonintravascular routes, such as the gastrointestinal system, urinary tract, mucosa, and hepatobiliary system [12].

To date, there have been no studies evaluating the development of CIN in patients who underwent the HSG procedure. Therefore, we investigated the development of CIN and its association with clinicopathological variables in women who underwent the HSG.

# Methods

This observational study, conducted from November 2022 to November 2023 at Balikesir University Research and Training Hospital, Department of Obstetrics and

Gynecology, involved 65 consecutive women aged 19 to 43 who were undergoing infertility evaluations, dealing with recurrent pregnancy loss, or had uterine anomalies and/or tubal blockages. These participants sought their first infertility examination at the university hospital. The study received ethical approval from the Institutional Ethical Committee of Balikesir Medical School (Ethical approval no: 202-2122). All participants provided written informed consent. All participants received pretest counseling from a physician. Blood samples (5 ml) were collected from the antecubital vein both before and 2-3 days after the HSG procedure. Routine laboratory tests were performed on all samples. Serum urea and creatinine levels were measured using commercially available kits on a Cobas Integra 800 chemistry AutoAnalyzer (Roche Diagnostics GmbH, Mannheim, Germany).

The estimated glomerular filtration rate (eGFR) calculated using the Modification of Diet was in Renal Disease (MDRD) equation: eGFR(ml/ min/1.73m2)=175×[Scr]-1.154 × [Age]-0.203 X  $[0.742 \text{ if female}] \times [1.21 \text{ if black}]$ . This method is widely accepted and used in most clinical laboratories [13]. CIN was defined as either a 25% relative increase or an absolute increase of 0.5 mg/dL (44 µmol/L) in serum creatinine level (SCr) within 72 h of contrast exposure, in the absence of other underlying conditions that could explain the change [14]. For statistical analysis, patients were categorized into two groups based on the presence of CIN: Group 1 (n=57), consisting of those without CIN, and Group 2 (n=8), comprising those with CIN following the HSG procedure. Normal serum creatinine levels were considered to be between 0.5 and 1.0 mg/dL [15].

# Design

The HSG procedure was performed on days 8 or 9 of menstruation, or progesterone-induced vaginal bleeding in anovulatory cases. During the procedure, the patient lies on an X-ray table with knees bent and feet in stirrups. A speculum is placed in the vagina, and the cervix is disinfected using a povidone-iodine solution. A metal cannula (Spackmann cannula, Bridge Master Medical, UK) is then inserted into the cervical canal. Next, an iodinated water-based radiopaque contrast medium (Omnipaque 350; Nycomed Ltd., Birmingham, UK) is injected through the cannula into the uterine cavity. The flow of the contrast medium is monitored using fluoroscopy, a type of real-time X-ray imaging. Images are taken as the contrast fills the uterine cavity and flows through the fallopian tubes into the peritoneal cavity. The procedure was stopped when radiology images showed signs of lymphatic or venous intravasation, as these could potentially cause serious complications such as bleeding, or embolism.

Hysterosalpingography (HSG) was performed using 5-20 ml of contrast medium. The dosage, batch number, and expiration date of the contrast medium used were recorded for drug accountability purposes. After the HSG, analgesics and antibiotics were routinely prescribed for pain management and infection prevention. The study population included patients undergoing infertility evaluations, those with recurrent pregnancy loss, uterine anomalies, and/or tubal blockages. However, patients who were pregnant, had an active pelvic infection, or experienced heavy uterine bleeding were excluded from the study. Age, BMI, parity, tubal patency, volume of CM used were collected from electronic record of the patient's database. Pelvic pain was assessed verbally after the HSG procedure, which is routine practice at our clinic. The intensity of pelvic pain was categorized as none (0), mild (1), moderate (2), or severe (3), as previously described [16]. The study was designed prospectively but the data was collected retrospectively.

# Statistical analysis

Statistical analysis was performed using MedCalc Statistical Software v22.023 (Ostend, Belgium). Continuous variables were reported as mean±standard deviation (SD) or median (range), while categorical variables were shown as counts and percentages. Normality of continuous variables was assessed using the Kolmogorov-Smirnov test, and the Levene test or F-test was used to check for equality of variances. The Student's t-test was used for comparing normally distributed measurements between independent samples, while the Mann-Whitney U test was used for comparing median values. The Chisquare test was applied for categorical data. For continuous variables, comparisons were made using either the t-test or the Wilcoxon rank-sum test, depending on their distribution. Changes in serum creatinine (SCr) and estimated glomerular filtration rate (eGFR) were analyzed with the Wilcoxon signed-rank test. Logistic regression analysis was employed to explore potential confounding factors related to CIN, with both univariate and multivariate analyses conducted to identify independent predictors. The Hosmer-Lemeshow test was used to evaluate model fit. A p-value of less than 0.05 was considered statistically significant.

## Results

In this prospective observational study, 65 infertile women who underwent the HSG procedure were evaluated for the development of CIN. The average age of the participants was 29.5 years, and the mean BMI was 26.2 kg/m<sup>2</sup>. The fundamental characteristics of women with and without CIN are summarized in Table 1.

Out of 65 patients, 56 (86.2%) experienced primary infertility, and 60 (92.3%) had at least one open tubal

passage during the HSG procedure. Approximately, 30% of patients had experienced any degree of pelvic pain during the procedure. Venous intravasation occurred in 3.1% of patients during the HSG procedure. Additionally, 1.5% developed pelvic inflammatory disease (PID) after the procedure.

The incidence of CIN was 12.3% (8 out of 65) in our study population. In particular, in one case (1.2%), a woman with a baseline serum creatinine (SCr) level of 0.68 mg/dL developed severe nephropathy following contrast administration during the HSG procedure, with her SCr level rising to 1.05 mg/dL. Recommendations for preserving kidney health, such as dietary adjustments, increased oral hydration, daily monitoring of SCr level, and urine output were given. Her SCr level normalized within seven days after the procedure.

The baseline serum creatinine (SCr) level was  $0.59\pm0.06$  mg/dL in women with CIN and  $0.67\pm0.11$  mg/dL in those without CIN, with the baseline level being significantly lower in the CIN group (p=0.0309). However, 48-72 h after the HSG procedure, the SCr level increased to  $0.85\pm0.12$  mg/dL in the CIN group compared to  $0.65\pm0.12$  mg/dL in the non-CIN group. The SCr level was significantly higher in the CIN group at this time (p=0.0005).

Additionally, the baseline eGFR was  $128.7\pm11.3 \text{ mL/}$ min/1.73 m<sup>2</sup> in the CIN group and  $121.2\pm51.4 \text{ mL/}$ min/1.73 m<sup>2</sup> in the non-CIN group, with no significant difference between the groups (p=0.6825). However, 48–72 h after the HSG procedure, the eGFR was 84.3±10.1 mL/min/1.73 m<sup>2</sup> in the CIN group compared to 118.9±25.4 mL/min/1.73 m<sup>2</sup> in the non-CIN group, and the eGFR was significantly lower in the CIN group at this time (p=0.0001).

In the CIN group, the mean serum creatinine (SCr) level was 0.59 mg/dL before the HSG procedure and increased to 0.85 mg/dL 48–72 h after the procedure, with a significant rise observed (p=0.0116) (Fig. 1). Conversely, in the non-CIN group, there were no significant changes between baseline SCr levels and those measured 48–72 h after the HSG procedure (p=0.5035) (Table 2).

To identify potential risk factors for the development of CIN, both univariate and multivariate logistic regression analyses were performed. The univariate analysis indicated that age  $\geq$  29 years, presence of venous intravasation, and baseline SCr  $\leq$  0.65 mg/dL were potential confounding factors associated with CIN.

In the multivariate logistic regression analysis, baseline SCr  $\leq$  0.65 mg/dL emerged as the sole independent risk factor for development of CIN in women undergoing the HSG procedure, with an odds ratio (OR) of 2.7687 [95% CI: 1.0178–7.5319] and a *p*-value of 0.0461 (Table 3).

	Total (n = 65)	Non-CIN Group (n = 57)	CIN Group (n=8)	<i>P</i> value
Age (year)	29.5±5.4	29.2±5.2	31.5±6.5	0.1364
BMI (kg/m2)	26.2±5.1	26.0±5.2	27.2±4.3	0.5407
Gravidity ( <i>n</i> )				
0	56 (86.2%)	49 (86.0%)	7 (87.5%)	0.1639
1	7 (10.8%)	7 (12.3%)	0 (0%)	
2	2 (3.0%)	1 (1.7%)	1 (12.5%)	
Presence of Comorbidity				
No	61 (93.8%)	53 (93.0%)	8 (100%)	0.4428
Yes	4 (6.2%)	4 (7.0%)	0 (0%)	
Tubal patency (n)				
Open	60 (92.3%)	52 (91.2%)	8 (100%)	0.3869
Closed	5 (7.7%)	5 (8.8%)	0 (0%)	
Venous Intravasation (n)				
No	63 (96.9%)	56 (98.2%)	7 (87.5%)	0.1020
Yes	2 (3.1%)	1 (1.8%)	1 (12.5%)	
PID, (n)				
No	64 (98.5%)	56 (98.2%)	8 (100%)	0.7079
Yes	1 (1.5%)	1 (1.8%)	0 (0%)	
Pelvic pain ( <i>n</i> )				
0	45 (69.2%)	39 (68.4%)	6 (75.0%)	0.6462
1	11 (16.9%)	9 (15.8%)	2 (25.0%)	
2	6 (9.2%)	6 (10.5%)	0 (0%)	
3	3 (4.6%)	3 (5.3%)	0 (0%)	
Baseline SCr (mg/dL)	0.66±0.11	0.67±0.11	0.59±0.06	0.0309
SCr (mg/dL)	0.68±0.13	0.65±0.12	0.85±0.12	0.0005
Baseline Urea (mg/dL)	22.38±6.44	22.04±6.12	24.75±8.48	0.2687
Urea (mg/dL)	21.89±6.00	21.89±6.34	21.89±2.67	0.6967
Baseline eGFR (mL/min/1.73 m <sup>2</sup> )	122.1±48.3	121.2±51.4	128.7±11.3	0.6825
eGFR (mL/min/1.73 m <sup>2</sup> )	114.6±26.6	118.9±25.4	84.3±10.1	0.0001
CM volume (mL)	15.1±4.6	15.3±4.7	14.4±4.3	0.6116

Table 1	The clinical	and biochemica	I characteristics of	patients in the	CIN and non-(	CIN groups

CIN: Contrast induced nephropathy, BMI: Body mass index (kg/m2), PID: Pelvic inflammatory disease, SCr: Serum Creatinine (mg/dL), eGFR: Estimated glomerular filtration rate (mL/min/1.73 m<sup>2</sup>), CM: Contrast Media

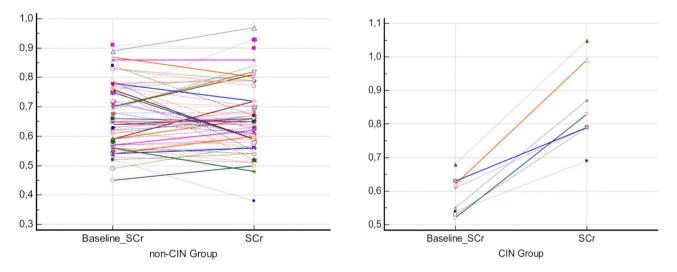


Fig. 1 The SCr values of the non-CIN and CIN groups before and 48–72 h after the HSG procedure were presented separately CIN: Contrast induced nephropathy, SCr: serum creatinine, HSG: Hysterosalpingography

 Table 2
 Comparative analysis of serum creatinine levels of the study population before and after HSG procedure

	Baseline SCr	SCr	<i>P</i> value		
CIN Group (mg/dL)	0.59±0.06	0.85±0.12	0.0116		
Non-CIN Group (mg/dL)	0.67±0.11	0.65±0.12	0.5035		
CIN: Contrast induced nephropathy, SCr: Serum Creatinine (mg/dL)					

# Discussion

In this observational study, we examined the occurrence of CIN following the HSG procedure in women with infertility. Our findings indicate that contrast medium (CM) may adversely affect kidney function after HSG procedure. We also identified that low level of baseline SCr is an independent risk factor for the development of CIN in patients undergoing the HSG procedure. To the best of our knowledge, this is the first study to specifically evaluate the development of CIN in HSG procedures.

While the precise molecular and cellular mechanisms behind CIN actively under investigation, it is thought that arterial vasoconstriction leading to renal medullary hypoxia, along with the direct toxic effects of CM on renal tubular cells, play key roles in the development of CIN [6, 17]. These mechanisms are thought to involve the production of reactive oxygen species (ROS), which can cause mitochondrial dysfunction, cellular apoptosis or necrosis, and interstitial inflammation. Elevated ROS levels or diminished antioxidant enzyme activity contribute to increased oxidative stress and subsequent impairment of renal function [18]. Other contributing mechanisms include reduced vasodilation from decreased prostaglandin and nitric oxide levels, impaired endothelial function, elevated renal adenosine concentration, and an increase in oxygen free radicals due to hyperosmotic load. Additionally, contrast-induced diuresis can lead to increased intratubular pressure, heightened urinary viscosity, and obstruction of the tubules [19].

It is widely recognized that chronic kidney disease (CKD), diabetes mellitus (DM) with compromised renal function, congestive heart failure, volume depletion, advanced age, hypertension, and hyperuricemia are significant risk factors for developing CIN following the use of contrast media (CM). Previous studies have shown that the prevalence of CIN can be as high as 50% in

patients with impaired renal function and/or one or more of these risk factors [20].

On the other hand, recent studies have indicated that CIN can also occur in patients with normal kidney function who do not present with any of the commonly recognized risk factors [21]. In low-risk groups, the reported prevalence of CIN ranges from 1 to 10% [20, 22, 23]. Consistent with previous studies, we observed a CIN incidence of 12.3% following HSG in female patients with normal renal function. We also noted that one patient (1.2%) experienced severe nephropathy after the HSG procedure. However, all CIN cases were transient and asymptomatic, with renal function returning to normal within one week. This suggests that patients who develop CIN after HSG are underdiagnosed and overlooked.

According to the literature, the development of CIN is affected by various factors, such as female gender, use of iodine-containing antiseptic solutions, and nephrotoxic drugs such as nonsteroidal anti-inflammatory drugs (NSAIDs) used for pain control after hysterosalpingog-raphy (HSG) [17, 24–26]. Additionally, previous reports have shown that volume expanders, sodium bicarbonate, N-acetylcysteine (NAC), ascorbic acid, statins, and phosphodiesterase type 5 inhibitors help prevent CIN [17, 25, 26]. In this study, both the presence of predisposing risk factors and the lack of preventive measures may have contributed to the development of CIN in our study population. Therefore, we strongly recommended that future studies are needed in this topic.

In the present study, an iodinated, low-osmolar, watersoluble radiocontrast agent was used for HSG, with a typical volume between 5 and 20 ml. In the literature, many studies concluded the type of contrast agent, the volume used, and the route of administration affect the development of CIN. Moreover, some recent studies have suggested that CIN can occur even with very low doses of CM [2]. Additionally, it is known that iodine is a crucial element for life, iodine-containing substances, including antiseptics, medications, topical agents, and contrast agents, may potentially cause nephrotoxicity [27, 28]. We also observed that there was no association between the volume of CM used and the development of CIN in our study population.

Table 3 Univariate and multivariate logistic regression analysis showing the predictors for the development of CIN

	Univariate logistic regression analysis			Multivariate logistic regression analysis		
	OR	95%Cl	<i>P</i> value	OR	95%CI	<i>P</i> value
Age, ≥ 29	6.3001	0.7274-54.566	0.0463	5.1811	0.5501-48.798	0.1505
BMI, ≥ 25	1.9872	0.4332-9.1161	0.3693	-	-	-
Parity, ≥ 1	1.4705	0.3591-6.0214	0.6088	-	-	-
Intravasation, yes	8.0000	0.4486-142.66	0.1839	4.0810	0.2176-76.5325	0.3471
Pelvic pain, yes	0.5939	0.1761-2.0020	0.3426	-	-	-
Baselines SCr, ≤ 0.65	2.7637	1.0992–6.9487	0.0114	2.7687	1.0178-7.5319	0.0461

BMI: Body mass index (kg/m2), SCr: Serum creatinine (mg/dL), OR: Odds ratio, CI: Confidence interval

The literature identifies a range of modifiable and nonmodifiable risk factors for CIN. However, effective strategies for preventing or mitigating CIN remain limited and are often specific to particular procedures or patient populations [29, 30]. In our study, we investigated risk factors associated with the development of CIN and we found that age, intravasation of CM, and lower level of baseline SCr were potential risk factors, particularly in patients with open tubal passages during the HSG procedure. We also identified lower level of baseline SCr as an independent risk factor for CIN development in patients who underwent the HSG procedure.

Our present findings are noteworthy, particularly given that the study population consisted of healthy female patients. A closer analysis of the data reveals that the patient who developed contrast-induced nephropathy (CIN) exhibited a creatinine increase from 0.59 to 0.85. While this increase surpasses the 25% threshold typically required to diagnose CIN, the actual 'elevated' creatinine levels still fall within the normal range. Therefore, the statistically significant results of this study can be considered to have no clinical significance. However, based on our current results, it is clear that future long-term studies are needed to examine the potential effects of CIN after HSG on pregnancy and fetal health in this patient population.

Limitations.

It was not possible to create a control group of HSG patients who did not receive contrast material. Therefore, we limited the study to comparing creatinine values before and after HSG. The absence of a non-contrast control group prevents us from drawing definitive conclusions from our data, which is perhaps the biggest limitation of our study.

Other limitations of this study included the small number of participants and the reliance on peripheral blood samples to calculate SCr and eGFR. Additionally, the study lacked other clinical and laboratory parameters, such as genetic factors, complete blood counts, and sodium, albumin, and cholesterol levels, which could influence the development of CIN. These limitations were due to the unavailability of these records.

# Conclusion

The HSG procedure is generally a safe method, but the iodine-containing contrast material used in HSG may be associated with temporary adverse effects on kidney function.

#### Abbreviations

- CIN Contrast-induced nephropathy
- AKI Acute kidney injury
- **BMI** Body mass index
- CT Computed tomography
- CM Contrast media GFR
- Glomerular filtration rate

ESRD End-stage renal disease HSG Hysterosalpingography eGFR Estimated glomerular filtration rate PID Pelvic inflammatory disease SD Standard deviation SCr Serum creatinine CKD Chronic kidney disease DM Diabetes mellitus MDRD Modification of Diet in Renal Disease NSAIDs Non-steroidal anti-inflammatory drugs NAC N-acetylcysteine

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#### Author contributions

AU, CSU made study's conception and design. DL made material preparation, data collection, and analysis were performed. TK and EA wrote the first draft of the manuscript. All authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

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#### Data availability

No datasets were generated or analysed during the current study.

#### Declarations

#### **Conflict of interest**

The authors declare there is no conflict of interest.

#### **Financial Disclosure**

The authors have no connection to any companies or products mentioned in this article.

#### Ethics approval and consent to participate

All procedures performed in studies involving humans were in accordance with the ethical standards of the institution or practice at which studies were conducted (Institutional Ethical Committee of the Balikesir University, School of Medicine (202-2122). Informed consent was obtained from all individual participants included in the study.

#### **Consent for publication**

Not applicable

#### **Competing interests**

The authors declare no competing interests.

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