Table C-68. CT-related adverse events

| **Study** | **Study Design** | **Number of Patients** | **Diagnosis** | **Age, Years (Mean±SD)** | **% Male** | **NHarmed (%)** | **Adverse Events** | **Notes** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Kim et al. 2013130 | Prospective cohort | 1,048 | Renal disease: 20Cardiovascular disease: 38Other allergic disease: 91 | 55.1±14.5 | 47.8 | 61 (5.8%) | Immediate reactions:Mild: 51Moderate: 1Nonimmediate reaction:Mild: 8Moderate: 1 | Setting: Seoul National University Bundang Hospital, KoreaTiming: July to November 2010Contrast medium (CM): 721 (68.8%) Iopromide, 323 (0.8%) Iomeprol, 3 (0.3%) Iohexol, and 1 (0.1%) Iodixanol“RCM skin testing for screening is of no clinical utility in predicting hypersensitivity reactions.” |

|  Table C-68. CT-related adverse events, (continued) |
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| **Study** | **Study Design** | **Number of Patients** | **Diagnosis** | **Age, Years (Mean±SD)** | **% Male** | **NHarmed (%)** | **Adverse Events** | **Notes** |
| Kobayashi et al. 2013131 | Retro­spective cohort | 36,472 | Diabetes: 7,138 (19.5%)Hypertension: 10,461 (28.6%)Dyslipidemia: 5,972 (16.4%) | 58.3 | 52 | 779 (2.1%) | Acute adverse reactions (mild): 756Nausea/vomiting, rash, coughing/sneezingSevere reactions: 23Shock, hypotension, desaturation, and airway obstruction | Setting: A community hospital in Tokyo, JapanTiming: April 2004 to March 2011CM: non-ionic low-osmolar contrast agents such as iopamidol, iohexol, ioversol or iomeprolIn multivariate logistic regression analysis, an adverse reaction history to contrast agents, urticaria, allergic history to drugs other than contrast agents, contrast agent concentration >70%, age <50 years, and total contrast agent dose >65 grams were significant predictors of an acute adverse reaction. |
| Davenport et al. 2012132 | Retro­spective database review | 24,826 injections of IV Iopamidol12,684injections during warming period, 12,142 injections during no warming |  | 51 (Range: 1–79 years) period 152 (Range: 4–90 years), period 2 | 42% period 1,28% period 2 | 177 (0.7%)Warming: 82No warming: 95 | Iopamidol 300 (no warming): 69Extravasations: 23Allergic-like reactions: 46 (41 mild, 5 moderate)Iopamidol 300 (warming):74Extravasations: 32Allergic-like reactions: 42 (33 mild, 8 moderate, 1 severe [patient developed pulseless electric activity after injection and although use of CPR returned the patient to normal sinus rhythm, an infected sternotomy wound reopened, and became infected. The patient died 2 months later of complications related to the infected site.])Iopamidol 370 (no warming): 26Extravasations: 18Allergic-like reactions: 8 (6 mild, 2 moderate)Iopamidol 370 (warming): 8Extravasations: 5Allergic-like reactions: 3 (all mild) | Setting: Duke University Medical Center, Durham, NCTiming: March 14, 2010 to April 19, 2011 (period 1), October 1, 2010 to April 19, 2011 (period 2)CM: Iopamidol 300 for CT exams, Iopamidol 370 for CT angiographic exams“Extrinsic warming (to 37̊ C) does not appear to affect adverse event rates for intravenous injections of iopamidol 300 of less than 6 m:/sec but is associated with a significant reduction in extravasation and overall adverse event rates for the more viscous iopamidol 370.” |
| Jung et al. 2012144 | Retro­spective chart review | 47,338 | Medical history of 50 patients with cutaneous adverse reactions (CARs):17 malignant neoplasm, 13 hypertension, 6 diabetes mellitus, 5 allergic history, 5 renal disease,3 past adverse reactions to contrast medium,2 tuberculosis, 2 hepatitis | 0 to >80 years; focus on CARs occurring in 50 patients (age range: 18 to 81) | 58 | 62 (.13%)50 (80.7% of overall AEs) CARs | Severe reactions: 16 (25.8% of overall AEs)Dizziness, severe generalized urticaria, hypotension, and facial edemaImmediate CARs (46[92% of CARs])Urticaria: 39 (78%)Angioedema: 5 (10%)Erythema: 1 (2%)Pruritus without rash: 1 (2%)Delayed CARS (4 [8% of CARs])Maculopapular rash: 4 (8%) | Setting: Seoul, KoreaTiming: Aug. 2005 to Nov. 2009CM: nonionic monomers including iomeprol, iopamidol, iopromide, and ioversol |
| Kingston et al. 2012133 | Prospective cohort | 26,854CT and CTA (50) | Multiple clinical factors and comorbidities | NR | NR | 119 (.44%) | Extravasations: 119 (0.44%)39 (.34%) cannulations performed in the hospital, 80 performed priorExtravasation occurred at the elbow (71.4%), forearm (10.9%), wrist (6.7%) and hand (7.6%). | Setting: a hospital in AustraliaTiming: Sept. 2004 to April 2008CM: nonionic IV (Ultravist 300)“Presence of cancer, hypertension, smoking and recent surgery was associated with higher extravasation rates.” |
| Mitchell et al. 2012134 | Prospective consecutive cohort | 633174 CTPA for PE459 non-CTPA | **CTPA:**Anemia: 11%DM: 19%History of hypertension: 54%Vascular disease: 15%Congestive heart failure: 12%Baseline renal insufficiency: 10%**Non-CTPA:**Anemia: 13%DM: 17%History of hypertension: 39%Vascular disease: 8%Congestive heart failure: 5%Baseline renal insufficiency: 10% | CTPA: 50±16Non-CTPA:46±15 | CTPA: 34Non-CTPA: 46 |  | **CIN:**CTPA: 25 (14%, 95% Confidence Interval: 10% to 20%)Non-CTPA: 45 (9.8%)Severe renal failure:3 CTPADeath from renal failure: 2 CTPA**All-cause 45-day mortality rate:** 15CTPA: 6 (3%), death due to renal failure (6), patients with CIN (4)Non-CTPA: 9 (2%) | Setting: a large U.S. academic tertiary care centerTiming: June 2007 to January 2009CM: NR“Development of CIN was associated with an increased risk of death from any cause (relative risk=12, 95% Confidence Interval: 3 to 53).” |
| Vogl et al. 2012135 | Observa­tional, non-intervention­al, prospective, multicenter | 10,836 | 5,033 (46.4%) had 1 to 7 concomitant diseases (including DM (6.9%) and renal insufficiency (0.9%) that could potentially influence tolerability of ioversol | 60.9 | 48.1 | 30 (0.28%) | Mild: 26 Urticaria: 13Nausea: 11Erythema: 6Serious: 4 Anaphylactoid adverse reactions requiring hospitalization: 3Patients with ≥1 AE: 30 | Setting: 72 centers in GermanyTiming: August 2006 to April 2007CM: ioversol |
| Cadwallader et al. 2011136 | Prospective audit | 198 scans | Pancreatitis: 5.2%Biliary pathology: 11.2%Appendicitis: 12.6%Bowel obstruction: 9%Peptic ulcer disease: 3.2%Diverticular disease: 6.6%Postoperative complications: 3.6%No diagnosis: 13.2%Transferred specialty: 4.6%Other 30.8% | 50.4 (Range: 16–94) | 44.4 | 41 (20.7%) scans didn’t alter manage­ment and were deemed as un­necessarily exposing patients to CT radiation | Risk of fatal cancer induction female aged:20: 1 in 1,67530-50: 1 in 2,45260: 1 in 3,07070: 1 in 4,11380: 1 in 7,130Risk of fatal cancer induction male aged:30-50: 1 in 2,52360: 1 in 3,89780: 1 in 4,289 | Setting: Tertiary referral surgical unitTiming: March–May 2008“The potential diagnostic benefits must outweigh the risks. Figures from the U.S. from 2007 suggest 19,500 CT scans were undertaken each day – the equivalent radiation dose of up to 5,850,000 chest radiographs.” |
| Hatakeyama et al. 2011137 | Retrospective chart review | 50(64 CTAs) | Peritoneal Dialysis | 55.0±13.1 | 68 | 2 (0.04%) | Mild: 1Skin disorderSerious: 1Atrial fibrillation | Setting: A hospital and research institute in JapanTiming: 2002 to 2009CM: Iopamidol, a low osmolar nonionic |
| Loh et al. 2010138 | Prospective surveillance | 539258 iohexol (51 CTA, 209 CT)281 control (un­enhanced CT) | NR | 53.05±14.9 | 57.7% iohexol46.9% control | 87 (16.1%)76 (29.4%)Iohexol11 (3.9%)Control | Delayed adverse reactions (DAR):37 (14.3%) iohexol, 7 (2.5%) control; p<0.0001Skin rashes or itching:Iohexol: 13 (5.0%), Control: 2 (0.71%); P=0.00273Patients with cutaneous DARs:Iohexol: 26 (10.1%), Control: 2 (0.71%); P<0.0001Skin redness (p=0.0055), skin swelling (p=0.0117) and headache (p=0.0246) also occurred statistically more frequently in the iohexol group. | Setting: Tertiary academic medical centerTiming: 2006 to 2008CM: iohexol“This study substantiates a frequent occurrence of DARs at contrast-enhanced CT compared with that in control subjects.” |
| Ozbulbul et al. 2010139 | Prospective | 52MDCT coronaryangio­graphy | Suspected coronary artery disease | 56.4±13.6 iodixanol (N=28)54.1±17.1 iopamidol(N=24) | 38 | 32 (61.5%) | Moderate: 32 (61.5%)Intense injection-related heat:Iodixanol: 11 (39.3%)Iopamidol: 20 (83.3%)Nausea:Iodixanol: 1 (3.5%), Iopamidol: 6 (25%)Dizziness:Iodixanol: 0, Iopamidol: 3 (12.5%) | Setting: radiology department, TurkeyTiming: Jan. 2008 to June 2008CM: iopamidol 370 (a low-osmolar) vs. iodixanol 320 (an iso-osmolar)“Iodixanol 320 causes less frequent sensation of heat on intravenous injection. This means more comfort and success in following the breath-hold commands of patients during scanning.” |
| Shah-Patel et al. 2009140 | Retro­spective chart review | 106,800 total33,321 CT | NR | Range: 18–86 | NR | 35 (0.10%) | Mild: 17Itching or hives, most often related to iodine-based intravenous contrast injectionsModerate: 7Falls: 3, Nasal congestion: 1, Nausea: 2Dizziness: 1Severe: 5Shortness of breath after IV injection: 5Others: 6Infiltrations at IV site: 5, Hematoma at IV site: 1 | Setting: Outpatient radiology center in New York, NYTiming: over 4 yearsCM: iopromide (Ultravist 300) |
| Shie et al. 2008141 | Prospective | 8,7762,766 Iothala­mate6,010 Iopromide | Hypertension,diabetes mellitus,asthma, renal disease,heart disease,liver disease, autoimmune disease, and history of allergy | 57.0±14.9Iothala­mate58.2±16.0Iopromide | NR | 127 (1.45%) immediate ADRs51 (1.84%)Iothalamate76 (1.26%)Iopromide | Grade I (mild):21 Iothalamate, 27 Iopromide; p=0.09Grade II (moderate):30 Iothalamate, 48 Iopromide; p=0.22Grade III (severe):0 Iothalamate, 1 case of Cyanosis, severe laryngeal edema occurred in Iopromide group; p=1.00 | Setting: hospital in Taiwan, Republic of ChinaTiming: May 2004 to Dec. 2004CM: iothalamate meglumine vs iopromide |
| Weisbord et al. 2008142 | Prospective cohort of patients scheduled for CT with IV radiocontrast, coronary angiography, or noncoronary angiography | 660 total421 CT | At increased risk for contrast-induced acute kidney injury (CIAKI)Comorbidities:41 diabetes mellitus, 14 liver disease,16 congestive heart failure, 13 peripheral vascular disease, and 11 cerebrovascular disease | 69±10 | 96 | See incidence  | CIAKI:Incidence of CIAKI based on relative increases in SCr levels:≥25: 6.5≥50: 0.5≥100: 0.0Incidence based on absolute changes in SCr levels:≥0.25 mg/dL: 10.9≥0.5 mg/dL: 3.5≥1.0 mg/dL: 0.3Serious: 10Death 30 days post-CT: 10 | Setting: Veterans Affairs Pittsburgh Health System; 25 inpatient, 70 ambulatory, 5 long-term care CT proceduresTiming: Feb. 2005 to July 31, 2006CM: 14% low-osmolar contrast (Iohexol), 86% iso-osmolar contrast (Iodixanol)Of the 3 modalities, the incidence of CIAKI was lowest with CT.“CIAKI was not independently associated with hospital admission or death.” |
| Yang et al. 2008143 | Prospective | 67 | NR | 48±13 | 56.7 | 125 reports | Palpitation: 17 mild, 4 moderate, 1 severeChest tightness:12 mild, 2 moderate, 1 severeDyspnea: 10 mild, 2 moderate, 1 severeTorridness: 64 mildNausea/vomiting: 11 mild | Setting: hospital in Taiwan, Republic of ChinaTiming: December 2005 to June 2006CM: ionic iothalamate meglumine |

CECT=Contrast-enhanced computed tomography; CIN=contrast-induced neuropathy; CPR=cardiopulmonary resuscitation; CTA=CT angiography; CTPA=CECT of the pulmonary arteries; NR=not reported; PE=pulmonary embolism; SCr=serum creatinine.