Table C-68. CT-related adverse events

| **Study** | **Study Design** | **Number of Patients** | **Diagnosis** | **Age, Years (Mean±SD)** | **% Male** | **N Harmed (%)** | **Adverse Events** | **Notes** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Kim et al.  2013130 | Prospective cohort | 1,048 | Renal disease: 20  Cardiovascular disease: 38  Other allergic disease: 91 | 55.1±14.5 | 47.8 | 61 (5.8%) | Immediate reactions:  Mild: 51 Moderate: 1  Nonimmediate reaction:  Mild: 8 Moderate: 1 | Setting: Seoul National University Bundang Hospital, Korea  Timing: July to November 2010  Contrast 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) | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Study** | **Study Design** | **Number of Patients** | **Diagnosis** | **Age, Years (Mean±SD)** | **% Male** | **N Harmed (%)** | **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): 756  Nausea/vomiting, rash, coughing/sneezing  Severe reactions: 23  Shock, hypotension, desaturation, and airway obstruction | Setting: A community hospital in Tokyo, Japan  Timing: April 2004 to March 2011  CM: non-ionic low-osmolar contrast agents such as iopamidol, iohexol, ioversol or iomeprol  In 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 Iopamidol  12,684  injections during warming period, 12,142 injections during no warming |  | 51 (Range: 1–79 years) period 1  52 (Range: 4–90 years), period 2 | 42% period 1,  28% period 2 | 177 (0.7%)  Warming: 82  No warming: 95 | Iopamidol 300 (no warming): 69  Extravasations: 23  Allergic-like reactions: 46 (41 mild, 5 moderate)  Iopamidol 300 (warming):74  Extravasations: 32  Allergic-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): 26  Extravasations: 18  Allergic-like reactions: 8 (6 mild, 2 moderate)  Iopamidol 370 (warming): 8  Extravasations: 5  Allergic-like reactions: 3 (all mild) | Setting: Duke University Medical Center, Durham, NC  Timing: 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 edema  Immediate 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, Korea  Timing: Aug. 2005 to Nov. 2009  CM: nonionic monomers including iomeprol, iopamidol, iopromide, and ioversol |
| Kingston et al. 2012133 | Prospective cohort | 26,854  CT 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 prior  Extravasation occurred at the elbow (71.4%), forearm (10.9%), wrist (6.7%) and hand (7.6%). | Setting: a hospital in Australia  Timing: Sept. 2004 to April 2008  CM: 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 | 633  174 CTPA for PE  459 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±16  Non-CTPA:  46±15 | CTPA: 34  Non-CTPA: 46 |  | **CIN:**  CTPA: 25 (14%, 95% Confidence Interval: 10% to 20%)  Non-CTPA: 45 (9.8%)  Severe renal failure:3 CTPA  Death from renal failure: 2 CTPA  **All-cause 45-day mortality rate:** 15  CTPA: 6 (3%), death due to renal failure (6), patients with CIN (4)  Non-CTPA: 9 (2%) | Setting: a large U.S. academic tertiary care center  Timing: June 2007 to January 2009  CM: 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: 13  Nausea: 11  Erythema: 6  Serious: 4  Anaphylactoid adverse reactions requiring hospitalization: 3  Patients with ≥1 AE: 30 | Setting: 72 centers in Germany  Timing: August 2006 to April 2007  CM: 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 1,675  30-50: 1 in 2,452  60: 1 in 3,070  70: 1 in 4,113  80: 1 in 7,130  Risk of fatal cancer induction male aged:  30-50: 1 in 2,523  60: 1 in 3,897  80: 1 in 4,289 | Setting: Tertiary referral surgical unit  Timing: 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: 1  Skin disorder  Serious: 1  Atrial fibrillation | Setting: A hospital and research institute in Japan  Timing: 2002 to 2009  CM: Iopamidol, a low osmolar nonionic |
| Loh et al.  2010138 | Prospective surveillance | 539  258 iohexol (51 CTA, 209 CT)  281 control (un­enhanced CT) | NR | 53.05±14.9 | 57.7% iohexol  46.9% control | 87 (16.1%)  76 (29.4%) Iohexol  11 (3.9%) Control | Delayed adverse reactions (DAR):  37 (14.3%) iohexol, 7 (2.5%) control; p<0.0001  Skin rashes or itching:  Iohexol: 13 (5.0%), Control: 2 (0.71%); P=0.00273  Patients with cutaneous DARs:  Iohexol: 26 (10.1%), Control: 2 (0.71%); P<0.0001  Skin 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 center  Timing: 2006 to 2008  CM: iohexol  “This study substantiates a frequent occurrence of DARs at contrast-enhanced CT compared with that in control subjects.” |
| Ozbulbul et al. 2010139 | Prospective | 52  MDCT coronary  angio­graphy | 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, Turkey  Timing: Jan. 2008 to June 2008  CM: 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 total  33,321 CT | NR | Range:  18–86 | NR | 35 (0.10%) | Mild: 17  Itching or hives, most often related to iodine-based intravenous contrast injections  Moderate: 7  Falls: 3,  Nasal congestion: 1, Nausea: 2 Dizziness: 1  Severe: 5  Shortness of breath after IV injection: 5  Others: 6  Infiltrations at IV site: 5,  Hematoma at IV site: 1 | Setting: Outpatient radiology center in New York, NY  Timing: over 4 years  CM: iopromide (Ultravist 300) |
| Shie et al.  2008141 | Prospective | 8,776  2,766 Iothala­mate  6,010 Iopromide | Hypertension,  diabetes mellitus,  asthma,  renal disease,  heart disease,  liver disease, autoimmune disease, and  history of allergy | 57.0±14.9 Iothala­mate  58.2±16.0  Iopromide | NR | 127 (1.45%) immediate ADRs  51 (1.84%) Iothalamate  76 (1.26%) Iopromide | Grade I (mild):  21 Iothalamate, 27 Iopromide; p=0.09  Grade II (moderate):  30 Iothalamate, 48 Iopromide; p=0.22  Grade III (severe):  0 Iothalamate,  1 case of Cyanosis, severe laryngeal edema occurred in Iopromide group; p=1.00 | Setting: hospital in Taiwan, Republic of China  Timing: May 2004 to Dec. 2004  CM: iothalamate meglumine vs iopromide |
| Weisbord et al. 2008142 | Prospective cohort of patients scheduled for CT with IV radiocontrast, coronary angiography, or noncoronary angiography | 660 total  421 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: 0.0  Incidence based on absolute changes in SCr levels:  ≥0.25 mg/dL: 10.9 ≥0.5 mg/dL: 3.5 ≥1.0 mg/dL: 0.3  Serious: 10  Death 30 days post-CT: 10 | Setting: Veterans Affairs Pittsburgh Health System; 25 inpatient, 70 ambulatory, 5 long-term care CT procedures  Timing: Feb. 2005 to July 31, 2006  CM: 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 severe  Chest tightness: 12 mild,  2 moderate,  1 severe  Dyspnea:  10 mild,  2 moderate,  1 severe  Torridness: 64 mild  Nausea/vomiting: 11 mild | Setting: hospital in Taiwan, Republic of China  Timing: December 2005 to June 2006  CM: 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.