



Scientific Collection 04



The ACTIVE study

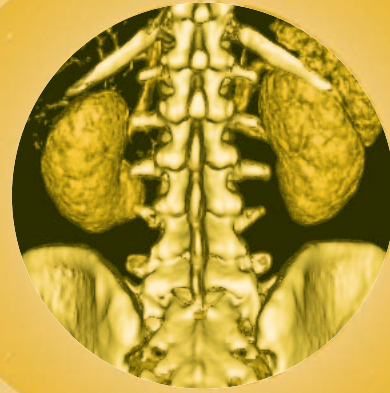
Comparison of the Effects on Renal Function of Iomeprol-400 and Iodixanol-320 in Patients with Chronic Kidney Disease Undergoing Abdominal Computed Tomography

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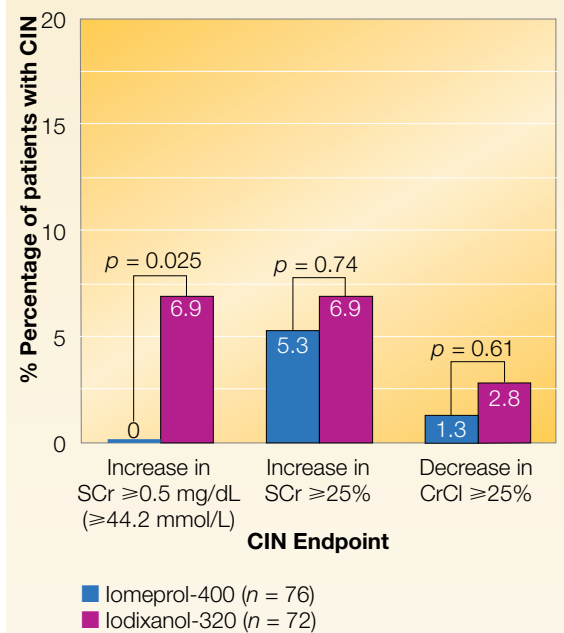
Objective

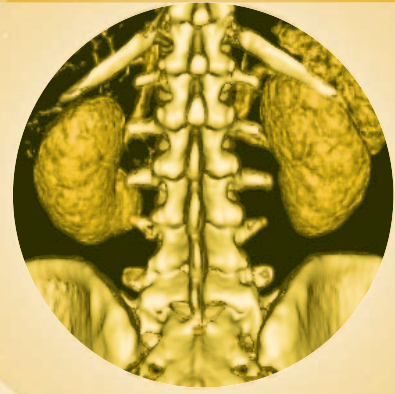
Patients with pre-existing chronic kidney disease (CKD) are at greater risk of experiencing contrast induced nephropathy (CIN) following injection of iodinated agents. This study compared the effects of iomeprol-400 (Iomeron® 400, Bracco Imaging, Milan, Italy) and Iodixanol-320 (Visipaque™ 320, GE Healthcare, Chalfont St. Giles, United Kingdom) on the renal function of patients with pre-existing moderate-to-severe CKD undergoing contrast-enhanced multidetector CT (CE-MDCT).

Study Design

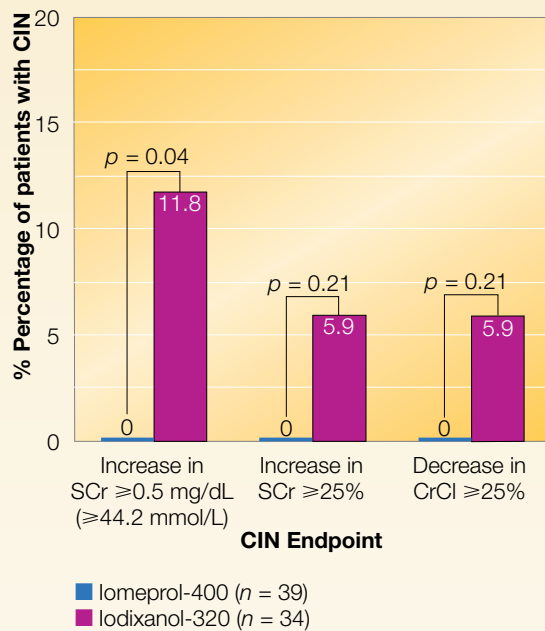
This was a prospective, multicenter, double blind, randomized, parallel group comparison of iomeprol-400 and iodixanol-320 in renally impaired patients receiving relatively high intravenous (IV) doses (40gI) of the two contrast media.

Incidence of Contrast-induced Nephropathy (CIN): All Patients (n = 148)



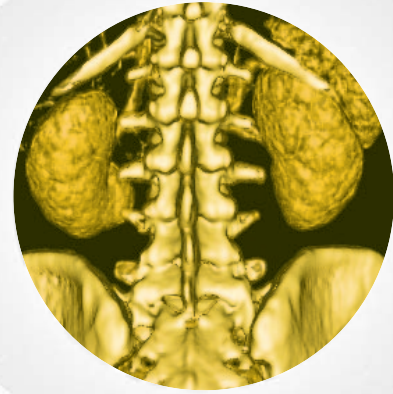


Incidence of CIN: Patients with creatinine clearance <40mL/min and/or SCr ≥2.0 mg/dL (n = 73)



Results

- The CIN analysis population consisted of 148 evaluable patients, of whom 76 received iomeprol-400 and 72 iodixanol-320.
- The two study groups were comparable at baseline with regard to age, gender, hydration status, baseline SCr and CrCl values. However, the iomeprol-400 group had a significantly higher proportion of patients with CKD and diabetes mellitus ($p = 0.02$).
- A total of 5 patients (6.9 %) receiving iodixanol-320 and none of the 76 patients (0%) receiving iomeprol-400 experienced an increase in SCr ≥0.5 mg/dL from baseline CIN ($p = 0.025$)
- Relative rises in SCr of ≥25% and relative CrCl decreases of ≥25% occurred with similar frequency in both groups ($p > 0.05$)
- In the subset of patients with CrCl <40 mL/min and SCr >2.0 mg/dL, no cases of CIN (0/39) were detected after the administration of iomeprol-400, independently of the CIN endpoint used, while the rate of CIN after iodixanol-320 was 11.8% (4/34) using the primary endpoint ($p = 0.04$), and 5.9% (2/34) using the secondary CIN endpoints
- The difference in mean change in SCr between the two groups was statistically significant ($p = 0.017$).



Patients and methods

- Patients: adult patients with moderate-to-severe CKD, i.e. serum creatinine (SCr) ≥ 1.5 mg/dL and/or creatinine clearance (CrCl) < 60 mL/min.
- Type of examination: CE-MDCT of the liver.
- Dose: equi-iodine doses (40 gI) of iomeprol-400 or iodixanol-320, both injected intravenously at a rate of 4mL/sec, followed by a 20ml bolus of saline solution.
- CIN lab parameters: SCr was measured at screening, baseline and 48–72 hours post-dose.
- Blinded review: A Renal Safety Review Board, comprised of 3 medical experts, reviewed the renal safety data of each subject in a blinded manner.
- Primary CIN endpoint: increase in SCr ≥ 0.5 mg/dL from baseline to post-dose, in the total population and in patients with baseline CrCl < 40 mL/min and SCr ≥ 2.0 mg/dL.
- Secondary CIN endpoints: increase in SCr $\geq 25\%$ from baseline; decrease in CrCl $\geq 25\%$ from baseline; mean changes in SCr from pre-dose to post-dose.



Key messages

- Contrast induced nephropathy is a recognized complication following the administration of iodinated contrast agents to patients with chronic kidney disease.
- Based on the results of this study the authors concluded:
'The incidence of CIN was significantly higher after the IV administration of iodixanol-320 than iomeprol-400 in patients with moderate-to-severe chronic kidney disease. The mean increase in SCr from baseline was also higher in patients receiving iodixanol. Characteristics of the individual contrast agents other than osmolality may be important in causing nephrotoxicity.'

