Prediction of Contrast-induced Nephropathy in Diabetic Patients undergoing Elective Cardiac Catheterization or PCI: Role of Volume-to-Creatinine Clearance Ratio and Iodine dose-to-Creatinine Clearance Ratio

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Objective: *To assess a role of volume-to-creatinine clearance ratio (V/CrCl) and iodine dose-to-creatinine clearance ratio (I-dose/CrCl) in predicting contrast- induced nephropathy (CIN) in diabetic patients undergoing elective cardiac catheterization or percutaneous coronary intervention (PCI).*

Background: *In diabetic patients undergoing cardiac catheterization or PCI, the incidence of CIN is higher than in non-diabetic patients. High doses of contrast media also increase the likelihood of renal dysfunction. The ratio of the volume of contrast media to creatinine clearance (V/CrCl) and iodine dose-to-creatinine clearance (I-dose/CrCl) has been shown to correlate with the area under the curve of contrast media concentration over time and was used to predict the occurrence of CIN in unselected patients. No study has been conducted specifically in diabetic patients undergoing cardiac catheterization or PCI before.*

Material and Method: *We conducted a prospective, single center study. The V/CrCl and I-dose/CrCl were calculated in diabetic patients undergoing elective cardiac catheterization or PCI. An increase in serum creatinine of > 0.5 mg/dl or > 25% by 7 days from baseline was considered CIN. The incidence of CIN was determined. The predictive value of V/CrCl and I-dose/CrCl for CIN were assessed using multivariable logistic regression.*

Results: *The total number of patients that had been enrolled in the study was 248; Male 50.8%. The overall incidence of CIN was 5.2%. The mean age for the entire population was 65 $\pm$ 9 years; the mean body mass index was 25.6 $\pm$ 4.0 kg/m□; and the mean creatinine clearance was 60.6 $\pm$ 27.4 ml/min. The mean values of V/CrCl for patients with and without CIN were 3.7 $\pm$ 2.9 and 2.2 $\pm$ 1.7 (p = 0.041). The mean values of I-dose/CrCl for patients with and without CIN were 1.31 $\pm$ 0.94 and 0.82 $\pm$ 0.63 (p = 0.042). The receiver-operator characteristic curve analysis indicated that a V/CrCl ratio of 2.60 and I-dose/CrCl of 0.98 were fair predictors of CIN. After adjusting for other known predictors of CIN, a V/CrCl ratio $\geq$ 2.60 remained the only significant predictor of CIN (Odds ratio 5.8; 95% confidence interval 1.7-19.4, p = 0.005)*

Conclusions: *A V/CrCl ratio $\geq$ 2.60 was a significant predictor of CIN in diabetic patients undergoing elective cardiac catheterization or PCI.*

Keywords: *Contrast induced nephropathy, Coronary angiography, Diabetes mellitus*

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Contrast-induced nephropathy (CIN) is an acute decline in renal function after the administration of a contrast agent in the absence of an alternative cause. CIN is traditionally defined as an increase in serum creatinine of either 0.5 mg/dl or 25% from baseline within 2-7 days after contrast exposure[1-6]. CIN is responsible for approximately 11% of all iatrogenic renal insufficiency and is the third most common cause of hospital-acquired renal failure[7]. The association of CIN and short- and long-term adverse clinical outcome is well established[8-10]. Underlying renal insufficiency and diabetes mellitus are known important risk factors for the development of CIN[11,12]. The volume of contrast media also plays an important role in CIN. Previous studies found a dose-dependent risk and defined a dose below which the risk for CIN appears acceptable[12-15]. A maximum contrast medium amount formula that takes the status of renal function into ac-

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count has therefore been developed: 5 ml/kg serum creatinine (in milligrams per decilitre). In an RCT of patients with CRF (Cr $\geq$ 1.8 mg/dl), the application of this formula portended a significant lower incidence of CIN (20.7% vs. 2.3%, $p < 0.001$)[16].

Recently, a volume-to-creatinine clearance ratio > 3.7 was shown to be a predictor of an early abnormal increase in serum creatinine after PCI in an unselected population[17]. It should be noted, however, that the iodine concentrations of commercially available contrast media range between 120 and 400 mg I/ml. The dose in grams of iodine for a certain contrast medium volume may thus vary roughly by a factor of 4. The use of the I- dose-to-creatinine clearance ratio has been suggested to correct for this problem. For coronary investigations, a linear correlation between the I-dose-to-creatinine clearance ratio and the risk for CIN and oliguria was found in a retrospective analysis[18]. At a mean I-dose-to-creatinine clearance ratio = 1, the regression line indicated a 10% risk of CIN.

We hypothesized that a volume-to-creatinine clearance ratio and I-dose-to-creatinine clearance ratio as a predictor of CIN in diabetic patients undergoing elective cardiac catheterization or PCI should be lower than in unselected patients.

Material and Method

A single center, prospective study.

Patient population

Diabetic patients undergoing elective cardiac catheterization or PCI (Percutaneous Coronary Intervention) at Siriraj Hospital between April 2008 and December 2008 were enrolled. The inclusion criteria were patients with diabetes mellitus, defined as fasting plasma glucose more than 125 mg/dl twice or random plasma glucose more than 200 mg/dl with symptoms, ages between 18-80 years, men or non pregnant women. All patients provided written informed consent. The exclusion criterion included patients who were already on regular dialysis. The study was approved by Siriraj's ethical committee, Mahidol University.

Procedures

Cardiac catheterization and PCI procedures were performed using standard techniques. Interventional devices were selected by the operator during the procedure. There were four types of contrast media in our center which included Ioxaglate (Hexabrix), Ioxitalamate (Telebrix), Iopromide (Ultravist), and Iodixanol (Visipaque). Type and brand of contrast media were determined by the operator and the amount of contrast will be collected. No formal protocol was followed regarding intravenous fluid or acetylcystein use. Aspirin, clopidogrel, glycoprotein IIb/IIIa receptor blockers, heparin, enoxaparin, beta blockers, ACEI and statins were used at the discretion of the operator. Serum creatinine was checked for 3 times (baseline serum creatinine within 14 days before procedures, 12-24 hours after procedures and at 7 days after procedures). Creatinine clearance was calculated using the Cockcroft-Gault formula: Crcl (ml/min) = 140-age (years) x weight (kgs)/72 x serum creatinine (mg/dl) {x 0.85 for female subjects}. A volume-to-creatinine clearance ratio and I dose-to-creatinine clearance ratio were calculated for each patient. CIN was diagnosed using the criteria of an increase in serum creatinine of either 0.5 mg/dl or 25% from baseline within 2-7 days after contrast exposure.

Sample Size Determination

The value of volume-to-creatinine clearance ratio and I dose-to-creatinine clearance ratio was defined as mean $\pm$ SD. Under the hypothesis that the difference between the mean value of volume-to-creatinine clearance ratio in CIN and no CIN group is 2.20 ± 3.3, it is assumed that the incidence of CIN in diabetic patients undergoing cardiac catheterization or PCI is about 10%; the initial sample size is 290.

Statistical analysis

Crude incidence rate for CIN was calculated. All quantitative data was expressed as mean $\pm$ SD. All qualitative data was expressed as frequency and percentage. Chi-square test and Fisher exact test were used for comparison of qualitative data between two groups. Unpaired t test was used for comparison of quantitative data between two groups. Odds ratios and 95% confidence intervals were calculated using logistic regression. Receiver-operator characteristics analysis was used to determine the optimal cut point for V/CrCl and I-dose/CrCl in this population using SPSS (version 10.0, SPSS Inc, Chicago, Illinois). Statistical significance for all comparisons was defined as when p-value is less than 0.05.

Results

The total number of patients that were included in the study was 248; males 50.8%. The mean age for the entire population was 65 ± 9 years; the mean body mass index was 25.6 ± 4.0 kg/m□; and the mean creatinine clearance (Cockcroft-Gault formula) was

60.6 ± 27.4 ml/min. The overall incidence of CIN as previously defined was 5.2%.The baseline characteristic of the population and incidence of CIN is shown in Table 1. There was no association between age, gender, BMI, concomitant diseases and CIN. The mean creatinine clearance in patients with and without CIN were 61.91 ± 27.25 ml/min and 36.43 ± 18.47 ml/min (p = 0.001), respectively. The creatinine clearance 30-60 ml/min (odds ratio 8.2; 95% confidence interval 1.01-66.9, p = 0.049) and creatinine clearance < 30 ml/min were significantly associated with CIN (odds ratio 21.8; 95% confidence interval 2.3-205.3, p = 0.007).

None of drugs given before procedures were associated with CIN. Types of contrast media used were Ioxaglate (Hexabrix) in 0.4%, Ioxitalamate (Telebrix) in 0.4%, Iopromide (Ultravist) in 95.5% and Iodixanol (Visipaque) in 3.7% respectively. There was no difference between mean of total iodine dose in patients with (34.26 ± 16.79 g) and without CIN (41.62 ± 22.19 g; p = 0.24). There was no difference between mean of total contrast volume in patients with (95.72 ± 49.72 ml) and without CIN (113.10 ± 60.27 ml; p = 0.31). There was also no association between number of significant lesions (≥ 70%), stent used, and total fluoroscopy time with CIN (Table 2).

Type of procedures consisted of coronary angiogram 42.3%, PCI 53.2% and others (Peripheral percutaneous transluminal angioplasty) 4.4%. The overall procedural success rate was 99.19%. There was unsuccessful procedure in two patients. One patient had CIN 24 hours after procedure and died due to hyperkalemia. There was only one patient who required blood transfusion after procedure. There was no stroke after procedure in our study.

The mean and median values of V/CrCl for patients with (mean 3.7 ± 2.9, median 3.09) and without (mean 2.2 ± 1.7, median 1.71) CIN were each significantly (p = 0.041) different between groups. The mean and median values of I-dose/CrCl for patients with (mean 1.31 ± 0.94, median 1.14) and without (mean 0.82 ± 0.63, median 0.63) CIN were also significantly (p = 0.042) different between groups.

Receiver-operator characteristic curve analysis showed fair discrimination between patients with and without CIN at a V/CrCl of 2.60 and an I dose/CrCl of 0.98, respectively. Univariate logistic regression indicated that a V/CrCl ≥ 2.60 (odds ratio 5.5; 95% confidence interval 1.6-18.6, p = 0.004) and an I dose/CrCl > 0.98 (odds ratio 4.1; 95% confidence interval 1.3-13.0, p = 0.02) were both highly significant predictors of CIN. Nevertheless, multivariate analysis which included all factors that associated with CIN indicated that only a V/CrCl ≥ 2.60 was significantly and independently related to CIN (odds ratio 5.8; 95% confidence interval

Table 1. Baseline characteristic and incidence of CIN

Factor	Numbers of patients n = 248	(%)	Incidence of CIN (%)
Clinical characteristics			
Age (yrs)			
< 60	77	31.1	3.9
60-69	91	36.7	2.2
≥ 70	80	32.3	10.0
Gender			
Male	126	50.8	4
Female	122	49.2	6.6
Body mass index (kg/m2)			
<25	119	48.0	5.0
25-29.9	97	39.1	4.1
≥30	32	12.9	9.4
History of smoking			
No	155	62.5	6.5
Current smoking	6	2.4	0
Quit	87	35.1	3.4
Hypertension	224	90.3	4.9
History of acute coronary syndrome	96	38.7	5.2
History of congestive heart failure	62	25.0	8.1
Chronic kidney disease	43	17.3	9.3
Peripheral vascular disease	20	8.1	5.0
Cerebrovascular disease	10	4.0	0
Chronic pulmonary disease	2	0.8	0
Creatinine clearance (ml/min)			
>60	110	44.3	0.9
30-60	114	46.0	7.0
< 30	24	9.7	16.7
Medication			
Aspirin	238	96.0	5.5
Clopidogrel	181	73.0	4.4
ACEI	93	37.5	6.3
ARB	81	32.7	3.7
Beta-blocker	185	74.6	5.4
Calcium channel blocker	66	26.6	7.6
Statins	226	91.1	4.9
N-acetylcysteine	23	9.3	4.3
Procedural characteristics			
Iodine dose (g)			
≤36	111	44.8	6.3
>36	137	55.2	4.4
Contrast volume (ml)			
≤100	130	52.4	6.5
>100	118	47.6	3.7

Table 1. Baseline characteristic and incidence of CIN (cont.)

Factor	Numbers of patients n = 248	(%)	Incidence of CIN (%)
Number of significant lesions (≥ 70%)			
0	38	15.3	5.3
1	33	13.3	6.1
2	22	8.9	4.5
3	33	13.3	9.1
4	29	11.7	3.4
≥ 5	93	37.5	4.3
Stent used	139	56.0	5.0
Total fluoroscopy time (minutes)			
< 10	102	41.1	6.4
10-30	112	45.2	4.3
> 30	34	13.7	4.5

Table 2. Univarate association of factors with CIN

Factor	Odds Ratio	95% confidence interval	p-value
Age ≥ 70 yrs	2.7	0.7-10.7	0.15
Female	1.7	0.5-5.3	0.37
Body mass index ≥ 30 kg/m^2	1.9	0.5-8.3	0.37
History of congestive heart failure	1.9	0.6-6.2	0.26
Chronic kidney disease	2.2	0.7-7.6	0.20
Creatinine clearance 30-60 ml/min	7.0	1.01-66.9	0.049
Creatinine clearance < 30 ml/min	16.7	2.3-205.3	0.007
Aspirin	1.3	0.1-22.6	0.99
ACEI	1.5	0.5-4.5	0.51
ARB	0.6	0.2-2.3	0.45
Beta-blocker	1.1	0.3-4.3	0.84
Calcium channel blocker	1.8	0.6-5.7	0.33
Statins	0.5	0.1-2.5	0.40
N-acetylcysteine	0.81	0.1-6.5	0.84
Iodine dose > 36 g	0.7	0.2-2.1	0.70
Contrast volume > 100 ml	0.6	0.2-1.8	0.49
Procedural failure	19.5	1.1-331.1	0.04
V/CrCl ≥ 2.60	5.5	1.6-18.6	0.004
I dose/CrCl > 0.98	4.1	1.3-13.0	0.02

1.7-19.4, p = 0.005).

Discussion

The crude incidence of CIN in diabetic patients undergoing elective cardiac catheterization or PCI in our center was 5.2%.This may be underestimated because we could not measure serum creatinine every day after the procedure.

A contrast volume limit of 5 ml/kg divided by serum creatinine has been proposed as a way to predict CIN in unselected patients receiving contrast media[16]. This formula was applied retrospectively in 16,592 patients undergoing cardiac catheterization to determine its utility in predicting the risk of postprocedural dialysis. Patients who received a volume of contrast in excess of 5 ml/kg/serum creatinine were 6-fold more likely to develop nephropathy requiring dialysis[19]. In our study we showed that the V/CrCl at ≥ 2.60 was a strong predictor of CIN in diabetic patients undergoing elective cardiac catheterization or PCI. Because V/CrCl corresponds closely to the area under the blood contrast media concentration versus time curve, this index should more closely predict the safety profile of contrast media, particularly with respect to CIN, than the absolute volume of contrast alone. Compared to the previous study by Laskey et al[17] which found that a V/CrCl > 3.7 was a significant and dependent predictor of an early abnormal increase in serum creatinine after PCI in unselected patient population, our study confirmed that a cutoff point was lower in high risk diabetic patients. Although the I dose/CrCl in our study did not show the predictive value after multivariate analysis, this may be because 95.5% of the contrast media used in our lab was Iopromide (Ultravist). Thus after calculation of iodine dose, there was a smaller difference than that of the contrast volume.

We did not intend to test the sensitivity and specificity of a V/CrCl ≥ 2.60 to predict the occurrence of CIN because we believed that at present there is lack of a gold standard in diagnosis of CIN. Nevertheless, we interpreted that a V/CrCl ≥ 2.60 was associated with a 5.5 times increase in the incidence of CIN. This cutoff value multiplied by patient's CrCl can be used to calculate the maximum volume of contrast media allowed to be used safely in diabetic patients undergoing elective cardiac catheterization or PCI.

Limitations

Limitations of our study consisted of having only a single center, non-randomized study, operator bias in the choice of contrast media and the lack of long term clinical outcome after the procedures.

Additional studies of the utility of this ratio in other populations such as in those with chronic kidney disease, LV dysfunction, emergency PCI, as well

as long term clinical outcomes studies after procedures, would be informative and useful.

Conclusion

In summary, we have shown that V/CrCl ratio is a useful and independent predictor of CIN in diabetic patient undergoing elective cardiac catheterization or PCI. This index may be applied prospectively to calculate the maximum volume of contrast media that can be given without CIN. But the cutoff value may be different in other populations depend on those populations' risk factors.

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การพยากรณ์ภาวะไตเสื่อมลงหลังจากได้รับสารทึบรังสีในผู้ป่วยเบาหวานที่เข้ารับการตรวจและรักษาหัวใจและหลอดเลือดด้วยสายสวน ด้วยการใช้อัตราส่วนของปริมาณสารทึบรังสีต่อค่าการทำงานของไต และ อัตราส่วนของปริมาณไอโอดีนต่อค่าการทำงานของไต

สุรพงษ์ วรสุวรรณรักษ์, สุวัจชัย พรรัตนรังสี

วัตถุประสงค์*: เพื่อหาค่าที่เหมาะสมของอัตราส่วนของปริมาณสารทึบรังสีต่อค่าการทำงานของไต และอัตราส่วนของปริมาณไอโอดีนต่อค่าการทำงานของไตเพื่อใช้ในการพยากรณ์โอกาสในการเกิดภาวะไตเสื่อมลงหลังจากได้รับสารทึบรังสีในผู้ป่วยที่เป็นเบาหวานที่เข้ารับการตรวจและรักษาหัวใจและหลอดเลือดด้วยสายสวน*

ภูมิหลัง*: ผู้ป่วยเบาหวานที่เข้ารับการตรวจและรักษาหัวใจและหลอดเลือดด้วยสายสวนจะพบ อุบัติการณ์ของการเกิดภาวะไตเสื่อมลงหลังจากได้รับสารทึบรังสีมากกว่าผู้ป่วยที่ไม่ได้เป็นเบาหวาน และยังพบว่าปริมาณสารทึบรังสีที่ใช้ยิ่งมากยิ่งพบอุบัติการณ์ของการเกิดภาวะไตเสื่อมลงมากขึ้น ในทางเภสัชจลศาสตร์พบว่าอัตราส่วนของปริมาณสารทึบรังสีต่อค่าการทำงานของไต และอัตราส่วนของปริมาณไอโอดีนต่อค่าการทำงานของไตจะแสดงถึงพื้นที่ใต้กราฟระหว่างความเข้มข้นของสารทึบรังสีต่อหนึ่งหน่วยเวลาและสามารถใช้พยากรณ์ภาวะไตเสื่อมลงหลังจากได้รับสารทึบรังสีได้ในผู้ป่วยได้ แต่ยังไม่เคยมีการศึกษาเฉพาะในผู้ป่วยที่เป็นเบาหวานมาก่อน*

วัสดุและวิธีการ*: เป็นการศึกษาแบบไปข้างหน้าในผู้ป่วยเบาหวานที่เข้ารับการตรวจและรักษาหัวใจและหลอดเลือดด้วยสายสวนในโรงพยาบาลศิริราชโดยคำนวณอัตราส่วนของปริมาณสารทึบรังสีต่อค่าการทำงานของไต และอัตราส่วนของปริมาณไอโอดีนต่อค่าการทำงานของไตในผู้ป่วยแต่ละราย โดยใช้เกณฑ์การวินิจฉัยภาวะไตเสื่อมลงหลังจากได้รับสารทึบรังสีคือ มีการเพิ่มขึ้นของค่าครีตินีนจากเดิมมากกว่าหรือเท่ากับ 0.5 มิลลิกรัมต่อเดซิลิตร หรือเพิ่มขึ้นจากเดิมมากกว่าหรือเท่ากับ 25 เปอร์เซนต์ นอกจากนี้ยังศึกษาถึงอุบัติการณ์ของการเกิดภาวะไตเสื่อมลงหลังจากได้รับสารทึบรังสีในผู้ป่วยที่เป็นเบาหวานที่เข้ารับการตรวจและรักษาหัวใจและหลอดเลือดด้วยสายสวน*

ผลการศึกษา*: มีผู้ป่วยที่เข้าร่วมในการศึกษาทั้งหมด 248 คน เป็นชาย 50.85 เปอร์เซนต์ พบอุบัติการณ์ของการเกิดภาวะไตเสื่อมลงหลังจากได้รับสารทึบรังสี 5.2 เปอร์เซนต์ อายุเฉลี่ยของผู้ป่วยคือ 65 $\pm$ 9 ปี, ค่าดัชนีมวลกายเฉลี่ยเท่ากับ 25.6 $\pm$ 4.0 กก/เมตร^2, ค่าการทำงานของไตเฉลี่ยเท่ากับ 60.6 $\pm$ 27.4 มิลลิลิตรต่อนาที ค่าเฉลี่ยของอัตราส่วนของปริมาณสารทึบรังสีต่อค่าการทำงานของไตในผู้ป่วยที่เกิดและไม่เกิดภาวะไตเสื่อม ลงหลังจากได้รับสารทึบรังสีเท่ากับ 3.7 $\pm$ 2.9 และ 2.2 $\pm$ 1.7 (p = 0.041) ค่าเฉลี่ยของอัตราส่วนของปริมาณไอโอดีน ต่อค่าการทำงานของไตในผู้ป่วยที่เกิดและไม่เกิดภาวะไตเสื่อมลงหลังจากได้รับสารทึบรังสีเท่ากับ 1.31 $\pm$ 0.94 และ 0.82 $\pm$ 0.63 (p = 0.042) จากการวิเคราะห์ทางสถิติพบว่าค่าอัตราส่วนของปริมาณสารทึบรังสีต่อค่าการทำงานของไตที่ 2.60 และ ค่าอัตราส่วนของปริมาณไอโอดีนต่อค่าการทำงานของไตที่ 0.98 สามารถใช้เป็นจุดตัดในการพยากรณ์ภาวะไตเสื่อมลงหลังจากได้รับสารทึบรังสีในผู้ป่วยเบาหวานที่เข้ารับการตรวจและรักษาหัวใจและหลอดเลือดด้วยสายสวนได้ ภายหลังจากการวิเคราะห์ตัวแปรร่วมทั้งหมดพบว่ามีเพียงค่าอัตราส่วนของปริมาณสารทึบรังสีต่อค่าการทำงานของไตที่มากกว่าหรือเท่ากับ 2.60 เพียงตัวเดียวเท่านั้นที่สามารถใช้ในการพยากรณ์ภาวะไตเสื่อมลงหลังจากได้รับสารทึบรังสีได้ (odds ratio 5.8; 95% confidence interval 1.7-19.4, p = 0.005).*

สรุป*: ค่าอัตราส่วนของปริมาณสารทึบรังสีต่อค่าการทำงานของไตที่มากกว่าหรือเท่ากับ 2.60 สามารถใช้ในการพยากรณ์ภาวะไตเสื่อมลงหลังจากได้รับสารทึบรังสีในผู้ป่วยเบาหวานที่เข้ารับการตรวจและรักษาหัวใจและหลอดเลือดด้วยสายสวน*