A Comparative Study in the Same Patients Treated with the 4 French Acist Power Injection System and the 5 French Manual Catheterization Technique

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Abstract

Background: The ACIST power injection system (ACIST) is used at many facilities. Some studies have reported the usefulness of ACIST which downsizes catheters and reduces the amount of contrast volume administered to the patient.

Purpose: Since only a few studies have conducted a comparative study between the ACIST and manual catheterization technique under the same conditions, this study was designed to evaluate the usefulness of the ACIST and manual technique in the same patients.

Methods: After ACIST was installed in this hospital, 40 consecutive patients, who underwent percutaneous coronary intervention (PCI) and follow-up coronary angiography (CAG), were selected for this study. Catheters were inserted from the right upper-limb artery; catheterizations by the manual technique with a 5-French (Fr.) catheter and ACIST with a 4-Fr. catheter performed 6 to 8 months later were compared. Judkins catheters were used in all patients. Any patients who underwent bypass angiography or aortography were excluded from this study.

Results: The mean total amount of contrast volume and contrast volume one per shot were 123.1 ± 23.9 ml and 12.8 ± 5.4 ml (manual) and 101.4 ± 14.3 ml and 10.5 ± 2.9 ml (ACIST), respectively, which indicated a significantly reduced amount of contrast volume in ACIST (p<0.001). No significant differences were observed in the number of shots and complications between the 2 techniques (p=n.s).

Conclusion: The results of this study result indicated that ACIST with a 4-Fr. catheter could not only minimize its influence on patients during an examination but could also significantly reduce the amount of contrast volume.

Key words

ACIST power injection system, Contrast induced nephropathy, Contrast volume, Coronary angiography

Introduction

Percutaneous coronary intervention (PCI) using newly developed stents and devices has evolved for performing revascularization in patients with coronary artery diseases. Since many of those patients are relatively old and have hypertension and diabetes mellitus, they often experience complications, such as renal disorders. Medical and PCI treatments with downsized devices have been modified to minimize the access sites and influences on patients. In 1996, a newly developed system using a
4-French (Fr.) catheter was introduced. Katahira et al. developed a new 3-Fr. diagnostic catheter in 2003³. Meanwhile, some problems have been reported, such as the maximum infusion speed of contrast media and the reliability of coronary angiograms⁴.

Currently, many medical facilities utilize the ACIST power injection system (ACIST; ACIST Medical systems, Eden Prairie, MN, USA) using downsized catheters. One study reported the efficacy of downsized catheters which provide reliable coronary angiograms and reduce the amount of contrast media administered to the patient⁵. Another study has suggested that the reduced amount of iodinated contrast media might decrease the severity of contrast induced nephropathy (CIN)⁶. Souheil Khoukaz et al. reported that coronary angiography (CAG) with a 4-Fr. catheter (ACIST) rather than a 6-Fr. catheter (manual contrast injection) significantly reduced the amount of contrast media⁶. The administration of a reduced amount of contrast media has been reported with the use of ACIST⁷; however, no study has yet compared and assessed the efficacy of ACIST and the manual catheterization technique under the same conditions. This study evaluated the outcomes of the same patients who received catheterization by the manual technique with a 5-Fr. catheter and by ACIST with a 4-Fr. catheter 6 to 12 months later.

Methods

Study patients

This study was conducted on 40 consecutive patients who underwent PCI and follow-up CAG after ACIST was installed. CAGs with 4Fr. catheter (ACIST) and with 5Fr. catheter (manual method) performed 6 to 8 months before PCI were compared. The mean amounts of contrast volume and contrast volume one per shot (contrast volume / number of shots) were obtained after CAG. Patients were excluded from this study if: ① the patients did not undergo a left ventriculography; ② they underwent bypass angiography or aortography; ③ they were treated with the Swan-Ganz catheter; ④ they received dialysis treatment; or ⑤ required large volume blood transfusions. Coronary risk factors were defined as follows: ① hypertension- a person with a history of hypertension (systolic blood pressure $\geq 140$ mmHg and/or diastolic blood pressure $\geq 90$ mmHg) and/or a person receiving antihypertension drugs, ② hyperlipide-
Blood samples were collected before and after the day of cardiac catheterization. Patients who had an elevated plasma creatine level (>0.5 mg/dl) 48 hours after blood sample collection were diagnosed as having CIN.

**Statistics**

The data are expressed as the mean ± SD. Unpaired Student’s t test and the χ² test were used to compare the mean values of the parameters between the 2 groups. Differences between the groups were determined by an analysis of variance (ANOVA) and the Bonferroni correction was used for multiple comparisons. Statistical significance was set at p<0.05.

**Results**

In the study subjects, the mean age was 69 years, which was relatively old and the body mass index was 22.5 ± 6.4 kg/m². Among the coronary risk factors, hypertension was the most prominent in the study subjects (55.5%); diabetes mellitus was relatively low (29.6%). Overall, 66.6% of the patients were smokers and plasma creatine at baseline was 0.98 ± 0.33 mg/dl. Follow-up CAG after PCI showed 3.7% of the patients having 3-vessel disease and 74% having less than one-vessel disease (Table 1). The mean amount of contrast volume used in ACIST with a 4-Fr. catheter (101.4 ± 14.3 ml) was significantly reduced in comparison to that used in the manual technique with a 5-Fr. catheter (123.1 ± 23.9 ml, p<0.001; Fig. 1-a). The mean amount of contrast volume one per shot used in ACIST with a 4-Fr. catheter (10.5 ± 2.9 ml) was significantly in comparison to that used in the manual technique with a 5-Fr. catheter (12.8 ± 5.4 ml, p<0.001; Fig. 1-b). No significant differences were observed in the number of patients with CIN as well as the number of fluoroscopic time and complications (Table 2).

**Discussion**

1) **CAG using downsized catheters**

The preset study successfully performed ACIST with a 4-Fr. catheter and the manual catheterization technique with a 3-valve manifold 5-Fr. catheter in the same study subjects. As Figure 1-a shows, the amount of contrast volume used in ACIST was significantly reduced. In addition, the mean
Table 2  The Frequency of CIN and Procedure Complications in Both Groups

<table>
<thead>
<tr>
<th></th>
<th>4Fr. ACIST</th>
<th>5Fr. Manual</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incidence of CIN (%)</td>
<td>22.5</td>
<td>25.0</td>
<td>0.48</td>
</tr>
<tr>
<td>Scr Change (mg/dl)</td>
<td>0.28±0.12</td>
<td>0.33±0.15</td>
<td>0.28</td>
</tr>
<tr>
<td>Fluoroscopic time (second)</td>
<td>330±120</td>
<td>294±160</td>
<td>0.18</td>
</tr>
<tr>
<td>Major hematoma (%)</td>
<td>0.03</td>
<td>0.05</td>
<td>0.33</td>
</tr>
<tr>
<td>Catheters change (%)</td>
<td>0.05</td>
<td>0.03</td>
<td>0.33</td>
</tr>
</tbody>
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CIN : Contrast induced nephropathy
Scr : Serum creatine

Figure 1 a) The mean amount of contrast volume
The mean amount of contrast media used in ACIST with a 4-Fr catheter was significantly reduced in comparison to that used in the manual catheterization techniques with 5-Fr catheter.

Figure 1 b) The mean amount of contrast volume one per shot
The amount of contrast media per shot was also significantly reduced in ACIST with a 4-Fr catheter in comparison to that used in the manual catheterization techniques with 5-Fr catheter.

Figure 2  Images of coronary angiography
No significant difference in the CAG reliability was observed between the ACIST and manual techniques.
amount of contrast volume one per shot in ACIST was significantly lower in comparison to that used in the manual technique (Fig. 1-b). ACIST allowed the use of a downsized catheter, which resulted in a reduced amount of contrast volume. Angiographic images for 4-Fr. and 5-Fr. catheters are shown in Figure 2. The accuracy of CAG with both methods was not investigated; however, no difference in the CAG reliability was observed (Fig. 2). The reduced controllability and pushability with the 4-Fr. catheter were observed in tortuous vessels and some cases showed a kink, which was not significant.

Meanwhile, 2 patients, who underwent ACIST with a 4-Fr. catheter, showed an increased amount of contrast volume and that of one per shot. We considered the increased amount of contrast volume to be attributed to the fact that different physicians performed catheterization and it depended on their skill to easily pass the catheter through tortuous vessels. Skilled individuals are required to perform CAG and PCI especially to engage the ostium of the right coronary artery. Moreover, a 4-Fr. catheter should be placed deep enough to keep its stability in CAG in comparison to 5-Fr. catheter. Otherwise, the catheters must be disconnected due to contrast media infusion.

2) The prevalence of CIN

ACIST with a 4-Fr. catheter was more effective in reducing the amount of contrast media than the manual catheterization technique with a 5-Fr. catheter; however, no significant difference in the number of CIN patients was observed between the 2 techniques (Table 2). McCullough et al. investigated prospective factors and reported that creatine clearance, diabetes mellitus and the amount of contrast media were significant factors. In the present study, no correlation was observed between the number of CIN patients and the amount of contrast media. The exact mechanism of CIN remains to be elucidated; however, ischemic damage to the renal medulla and the direct influence of contrast media on the renal tubules have been considered to be causative. Renal disorder increases these patients’ fatality rates and prolongs their hospital stays, which influences their survival rates and long-term prognoses after PCI. It is necessary to use the minimum amount of contrast media to prevent renal disorders; however, the use of contrast media remains uncertain. One study reported that the prevalence of CIN in CAG ranged between 12 and 27%. Another study demonstrated that the prevalence of CIN in patients with progressive chronic diabetic nephropathy who underwent CAG was 50%. In the present study, the mean creatine level was normal at baseline, although, approximately 25% of the patients experienced CIN in both techniques due to the relatively old mean age (69 years). It has been reported that not only the amount of contrast volume but also factors, such as the age of patients, hypertension, heart failure, anemia, and plasma creatine, may affect the onset mechanism of CIN. A further study with multiple analyses is therefore called for to clarify these factors.

Conclusions

Currently, 4-Fr. catheters are often used in diagnostic catheterization. When a physician performs a non-invasive diagnostic catheterization, a downsized catheter is one of the choices; however, both reduced costs and improved accuracy are still required. The results of this study demonstrated the usefulness of ACIST with the downsized catheter. Further studies should therefore be conducted to elucidate the onset mechanism of CIN and thereby decrease the number of patients who may develop CIN.

Study Limitation

In the present study, we could compare the outcomes in the same patients who underwent catheterization by ACIST and the manual technique; however, it is necessary to conduct further studies consisting of a larger patient population.

Acknowledgements

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References

4Fr. Acist インジェーションシステムと 5Fr. manual
システムの同一症例での比較検討

抄 録

【背景】 近年、ACIST 導入によりカテーテルサイズの小径化や造影剤使用量の削減といっ
た有用性が報告されている。また、造影剤使用量の削減による造影剤腎症の軽減も期待されて
いる。

【目的】 同一条件での比較検討した報告は少なく、ACIST の有用性について同一症例、同
一条件にて比較検討すること。

【方法】 経皮的冠動脈形成術施行後に冠動脈造影 follow up を施行した連続 40 名を対象と
した。右上腕動脈穿刺にて、ACIST を用い 4Fr. カテーテルを使用した冠動脈造影と対象症例
の manual（3 連マニホールド）を用い 5Fr. カテーテルを使用した 6〜12 ヶ月前の冠動脈造影と
を比較検討した。カテーテルは全例 Judkins カテーテルを使用し、バイパス造影または大動脈
造影を施行した症例は除外とした。

【結果】 平均造影剤使用量は、manual を用い 5Fr. カテーテル使用時は 123.1±23.9 ml、
ACIST を用い 4Fr. カテーテル使用時は 101.4±43.3 ml と、ACIST を用い 4Fr. カテーテル使
用時に有意に減少していた（p<0.001）。それぞれの造影剤使用量を撮影数で割った値の平均値
は、manual を用い 5Fr. カテーテル使用時は 12.8±5.4 ml, ACIST を用い 4Fr. カテーテル使
用時は 10.5±2.9 ml と、ACIST を用い 4Fr. カテーテルを使用時に有意に減少した（p<
0.001）。造影剤腎症の出現においては、両群間において有意差は認めなかった。

【考察】 ACIST の導入により 4Fr. カテーテルを使用することで、低侵襲に検査できるだけ
でなく、造影剤の使用量を有意に減少させることができた。しかし、造影剤腎症の出現に関し
ては、今後の課題である。