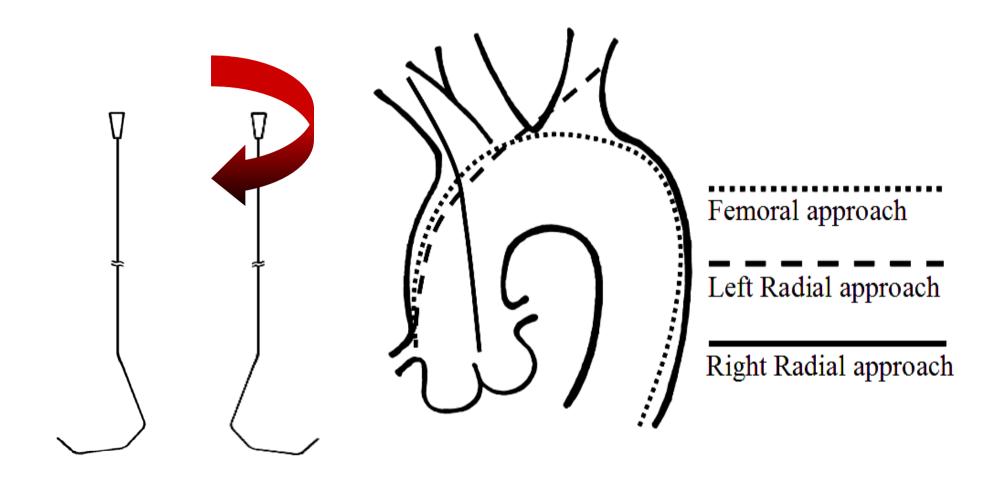


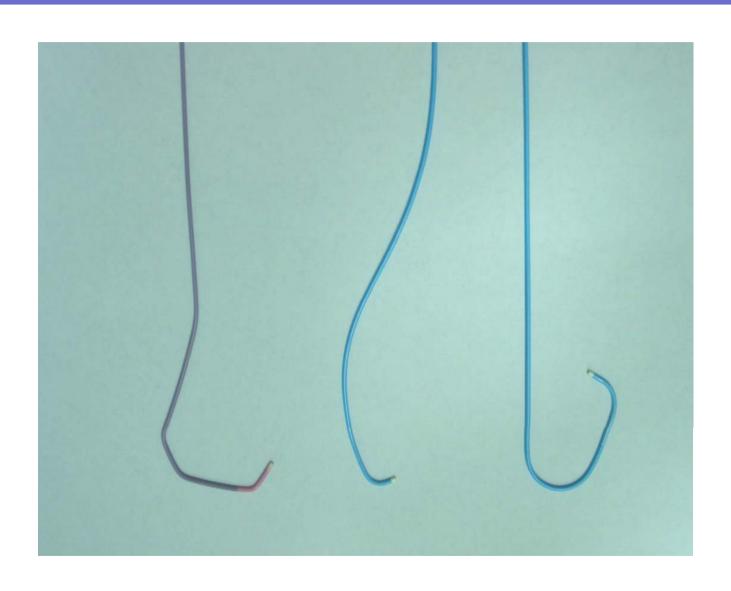
Femoral approach

Left Radial approach

Right Radial approach



New Catheter (Tiger II™)



Endpoints & Definitions

The **primary endpoints** of this study included **analysis of the various times** involved in using both catheters.

<u>Total procedure time</u>: the time spent from initial catheter insertion into radial sheath to last catheter withdrawal from sheath <u>Total fluoroscopic time</u>: the total fluoroscopic time during the procedure

LCA procedure time: the time from catheter insertion through radial sheath to catheter withdrawal from sheath in left Judkins catheter. With Tiger II, the time from catheter insertion into radial sheath to completion of left CAG.

RCA procedure time: the time from catheter insertion through radial sheath to catheter withdrawal from sheath in right Judkins catheter. With Tiger II, the time from rotating catheter from LCA ostium for RCA engagement to catheter removal from radial sheath.

<u>LCA fluoroscopic time</u>: the total fluoroscopic time spent in LCA procedure. <u>RCA fluoroscopic time</u>: the total fluoroscopic time spent in RCA procedure.

Endpoints & Definitions

The secondary endpoint was qualitative image assessment of the CAG.

The quality of CAG was graded by the quality of each artery as follows:

- **3**: complete opacification of the entire length of the vessel throughout systole and diastole;
- 2: either complete opacification of the vessel but not throughout systole and diastole or moderate opacification of the vessel throughout systole and diastole
- 1: moderate opacification of the vessel only in systole or diastole and the picture was diagnostic
- O: picture nondiagnostic

Each artery was given a visual score for each of the standard views. The mean visual score for each artery was then calculated for each assessor.

Endpoints & Definitions

The tertiary endpoint was Catheter performance assessment

<u>Technical success</u>: the randomized catheter completed the procedure without crossover for either additional length of curve shape.

<u>Catheter success</u>: the randomized catheter size (5.0F in all patients) completed this procedure without change in F size.

<u>Procedural success</u>: completion of the procedure without clinical complications: including the need for surgical correction of vascular access site, Q-wave myocardial infarction, permanent neurological deficit, or procedural related myocardial infarction or death.

Basic Views

Four standard views for the LCA and two for the RCA.

The standard views for the LCA

LAO cranial, 30°-40° LAO, cranial 20°-30° RAO cranial, 30°-40° RAO, cranial 20°-30° RAO caudal, 30°-40° RAO, caudal 15°-25° AP caudal, caudal 15°-25°

The standard views for the RCA

RAO straight, 30°-40° RAO AP straight

When we needed additional views, we excluded the time being required for another views from calculating temporal characteristics above but took the quality of the picture into account for assessment.

Patients

| | Tiger II (n = 80) | Judkins (<i>n</i> = 80) | Total Population $(n = 160)$ | <i>P</i> value |
|-----------------|----------------------|-----------------------------|------------------------------|----------------|
| Age (years) | 56 ± 9 | 59 ± 10 | 58 ± 9 | NS |
| Male | 36 | 33 | 69 | NS |
| BSA (m²) | 1.69 ± 0.18 | 1.72 ± 0.15 | 1.70 ± 0.17 | NS |
| Diabetes | 20 | 23 | 43 | NS |
| Hypertension | 41 | 42 | 83 | NS |
| Hyperchol | 15 | 16 | 31 | NS |
| Smoking | 18 | 15 | 33 | NS |
| Vessel Diseased | | | | |
| 0-1 | 59 | 53 | 112 | NS |
| ≥ 2 | 21 | 27 | 48 | NS |
| LVEF (%) | 55 ± 10 | 57 ± 8 | 56 ± 9 | NS |

Values are absolute numbers or mean \pm SD. Abbreviations: BSA =body surface area; Hyperchol = hypercholesteremia; LVEF = left ventricular ejection fraction; NS = not significant (ρ >0.05).

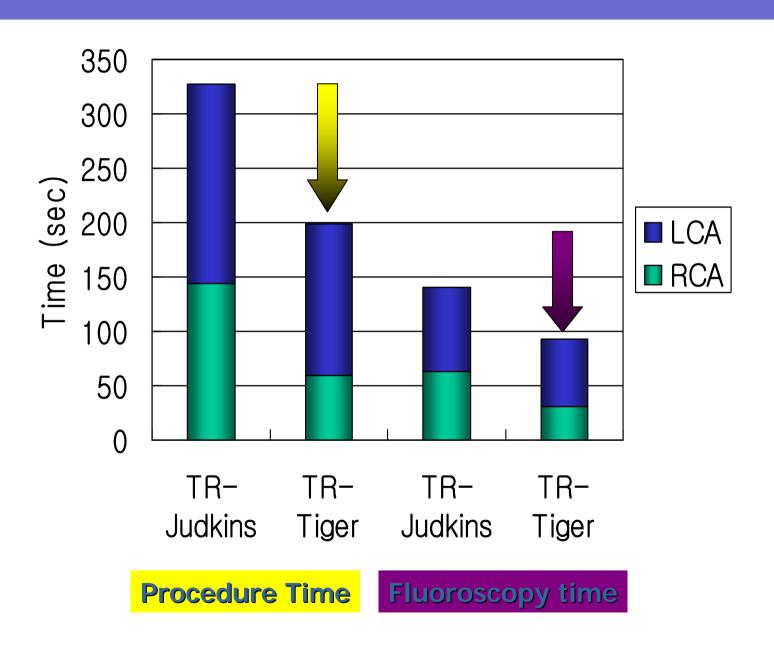
Device Chronology

Procedural Characteristics

| | Tiger II | Judkins | <i>P</i> value |
|-------------------------|-----------------------|-----------------------|--|
| Total Fluoro Time (sec) | 93.1 ± 33.8 (73) | $138.2 \pm 47.6 (74)$ | $ \rho = 0.001 $ $ \rho = 0.001 $ $ \rho = 0.001 $ |
| LCA | 61.8 ± 22.7 (73) | $77.8 \pm 26.0 (78)$ | |
| RCA | 31.0 ± 17.6 (80) | $62.8 \pm 33.2 (76)$ | |
| Total Proced Time (sec) | $199.6 \pm 50.2 (73)$ | 331.5 ± 72.9 (74) | $ \rho = 0.001 $ $ \rho = 0.001 $ $ \rho = 0.001 $ |
| LCA | $140.0 \pm 39.0 (73)$ | 181.2 ± 47.3 (78) | |
| RCA | $59.2 \pm 23.2 (80)$ | 143.2 ± 58.1 (76) | |

Values are mean \pm SD (n). Abbreviations: LCA = left coronary artery; RCA = right coronary artery; Fluoro = fluoroscopic; Proced = Procedural.

Procedural Characteristics

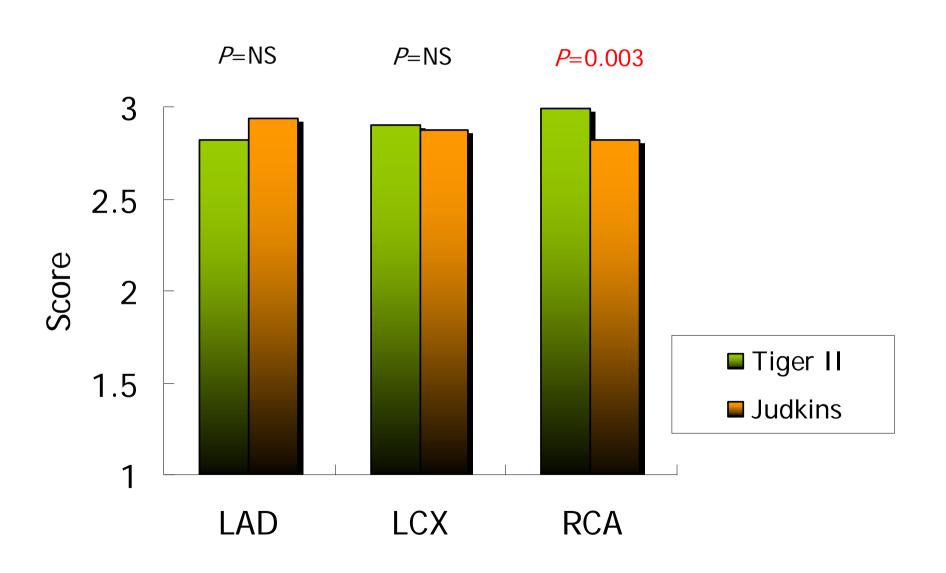


Catheter Performance & Procedural difficulties

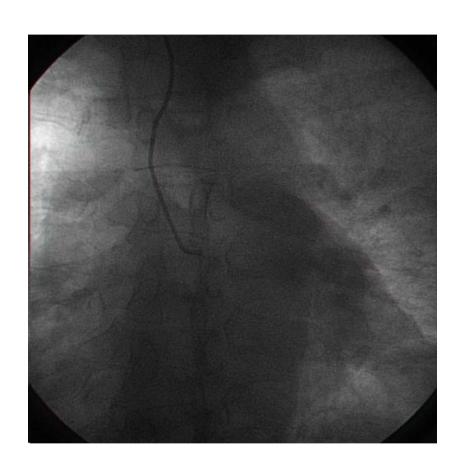
| | Tiger II | Judkins | <i>P</i> value |
|-----------------------------|--------------|--------------|----------------|
| Technical success | | | |
| LCA | 73/80 (91%) | 78/80 (98%) | NS |
| RCA | 80/80 (100%) | 76/80 (95%) | 0.043 |
| Catheter success | | | |
| LCA | 73/73 (100%) | 78/78 (100%) | NS |
| RCA | 80/80 (100%) | 76/76 (100%) | NS |
| Procedural success | | | |
| LCA | 73/73 (100%) | 78/78 (100%) | NS |
| RCA | 80/80 (100%) | 76/76 (100%) | NS |
| Selecting conal branch | 6/80 (8%) | 2/76 (3%) | NS |
| Catheter backing out of LCA | 10/73 (14%) | 4/78 (5%) | NS |
| Catheter backing out of RCA | 0/80 (0%) | 8/76 (11%) | 0.003 |
| Excessive engagement of LCA | 0/73 (0%) | 5/78 (7%) | NS |
| Excessive engagement of RCA | 11/80 (14%) | 4/76 (5%) | NS |

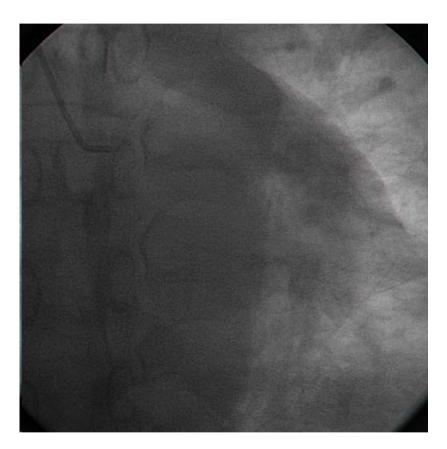
Abbreviations: LCA = left coronary artery; RCA = right coronary artery; NS = not significant (ρ >0.05).

Angiographic Scores



CAG quality





Conclusions

- Tiger II catheter is associated with decreased total procedure and fluoroscopic time as compared to Judkins catheters and has same results in each coronary artery.
- 40% of time saving implies less contrast media, less fluoroscopy time, and less chance of spasm.
- Significant reduction of procedure and fluoroscopic time is owed to needless of catheter exchange.
- This catheter may be of interest to high volume operators who are concerned about speed of procedure and exposure to fluoroscopy.

Conclusion

- Our transradial approach using Tiger II catheter provides a safe and useful alternative for coronary imaging in situations where patients had suffered from radial artery spasm in previous transradial coronary interventions, much contrast agent would be harmful to patients, or patients could not endure supine position longer due to back pain.
- However, detailed knowledge of angiographic characteristics associated with increased technical success awaits additional studies.

Limitations

This study is limited by its small size.

We compared Tiger II catheters with only Judkins catheters but other shaped catheters are widely used in transradial procedure in practical. Clinical and angiographic characteristics associated with success of engagement of the Tiger II and other styled catheters including Judkins styled catheters await confirmation by prospective analysis.

Additionally, we could not measure the quantitative angiography because all the coronary angiography was recorded in cine roll film which could not be digitalized.

Just rotate it !!!

