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Identifying strategy for *ad hoc* percutaneous coronary intervention in patients with anticipated unfavorable radial access: the Little Women study \*\*,\*\*\*

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#### ABSTRACT

*Background:* Transradial percutaneous coronary intervention (PCI) offers important advantages over transfemoral PCI, including better outcomes. However, when there is indication to *ad hoc* PCI, a 6 French workflow is a common default strategy, hence potentially influencing vascular access selection in patients with anticipated small size radial artery.

Methods: A multidimensional evaluation was performed to compare two ad hoc interventional strategies in women < 160 cm: a full 6 French workflow (namely 6 French introducer sheath, diagnostic catheters and guiding catheter) with a modified workflow consisting in the use of 5 French diagnostic catheters preceded by the placement of a 6 French sheath introducer and followed by a 6 French guiding catheter use for PCI.

Results: Overall 120 women ( $68\pm11$  years) were enrolled in the study. Coronary angiography has been performed using 5 French or 6 French diagnostic catheters in 57 (47.5%) and 63 (52.5%) cases, respectively. Radial spasm and switch to another access occurred more frequently among women who underwent coronary angiography with 6 French rather than 5 French diagnostic catheters (43% vs. 25%, p=0.03 and 2% vs. 11%, p=0.04, respectively). Total time to guidewire lesion crossing was also significantly higher when PCI has been preceded by 6 French rather than 5 French coronary angiography ( $23\pm11$  min vs  $16\pm7$  min, p=0.013).

*Conclusions:* In patients with anticipated unfavorable radial access, a workflow consisting in 6 French introducer sheath placement, 5 French coronary angiography, and 6 French coronary intervention is on multiple parameters the most straightforward and effective strategy.

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## 1. Introduction

Transradial intervention (TRI) is gaining increasing popularity among interventional cardiologists and patients with coronary artery disease [1,2]. Indeed, TRI offers important advantages over transfemoral percutaneous coronary intervention (PCI), including higher patient's comfort, early discharge, reduce bleeding and overall better outcomes, especially in patients with acute coronary syndrome (ACS) [1–5].

The radial artery is however smaller than the femoral artery, and its size is a potential limitation to TRI [6,7]. Furthermore, identified predictors of radial artery spasm or small size may influence selection of vascular access in patients in who *ad hoc* PCI is the default treatment strategy [8,9]. When coronary anatomy is not known and urgent treatment is required,

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most operators consider that 6 French is the default size of TRI guiding catheter because it allows implementing most percutaneous revascularization procedures [10], including complex bifurcation treatment [11]. Reliance on a large enough radial artery may therefore drive interventional cardiologists to exclude TRI in a sizeable proportion of ACS patients. However, as recently reported, striking 28% reduction in death with transradial access in ACS patients urges operators to identify new strategies that allow implementing TRI in a growing number of patients [3].

On this background, our study aimed at assessing optimal strategy ensuring effective and potentially complex *ad hoc* TRI in patients with anticipated unfavorable radial access.

## 2. Methods

## 2.1. Patients and procedures

The Little Women study compared the feasibility and effectiveness of PCI using a 6 French guiding catheter after transradial coronary

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angiography had been performed with either 5 French or 6 French diagnostic catheters in patients with anticipated unfavorable radial artery. More specifically, a multidimensional evaluation was performed to assess two *ad hoc* interventional strategies: a full 6 French workflow (namely 6 French introducer sheath, diagnostic catheters and guiding catheter) with a modified workflow consisting in the use of 5 French diagnostic catheters preceded by the placement of a 6 French sheath introducer and followed by a 6 French guiding catheter use for PCI (Fig. 1).

Only short stature (<160 cm) women undergoing first-time transradial coronary angiography were considered eligible for study enrolment after providing informed consent. Exclusion criteria were ST-elevation myocardial infarction, less than 18 years, previous coronary artery bypass surgery, unwilling participation to the study.

After a small wheal of 1% lidocaine, radial artery was punctured with a 21 G needle catheter and an 11 cm 6 French sheath introducer (AVANTI+, Cordis, Miami Lakes, FL) was inserted according to the over-the-wire technique. Next, intra-arterial 5000 IU heparin and 200 mcg nitroglycerine were administered.

Coronary angiography was then performed with either two 5 French or two 6 French diagnostic catheters (INFINITI, Cordis, Miami Lakes, FL). The standard curves Judkins Right 4.0 and Judkins Left 3.5 were used in all patients. Cases requiring a different diagnostic catheter curve shape were not considered for enrollment to avoid results confounding due to additional catheter manipulation.

Patients with an indication to *ad hoc* PCI underwent revascularization with 6 French guiding catheter(s) (VISTA BRITE TIP, Cordis, Miami Lakes, FL) and were prospectively enrolled in the study.

All procedures were performed by skilled and experienced operators performing more than 90% of coronary procedures through transradial access for at least 10 years.

#### 2.2. Outcome measures

Main outcome measures were radial artery spasm, switch to another arterial access and total and fluoroscopy time from radial access to first coronary lesion crossing. Radial artery spasm was defined as pain perceived by the patient and/or difficulty perceived by the operator during insertion, manipulation, and/or withdrawal of the catheter and was always confirmed by arteriography [12]. Switch to another access was performed in case of ungovernable radial artery spasm or unmanageable difficult arterial anatomy of the upper limb. Total and fluoroscopy time to guidewire lesion crossing were recorded in the procedure log

and mainly reflect the overall time required for advancement, manipulation, cannulation with the two diagnostic catheter and the guiding catheter. Finally, access-related pain was assessed by patient self-evaluation on a visual analogic scale at the end of the procedure.

#### 2.3. Statistics

Continuous variables were compared by Student t test. Categorical variables were compared by Pearson chi-square test. Data are reported as mean  $\pm$  standard deviation or frequency (percentage). A two-sided P value < 0.05 was required for statistical significance.

#### 3. Results

Overall, 120 patients (age  $68\pm11$  years) were enrolled in the Little Women study. Table 1 summarize their general characteristics. Height and weight were 155  $\pm$  8 cm and 55  $\pm$  6 kg, respectively and 58% of the patients had unstable presentation.

Prior to 6 French *ad hoc* PCI, coronary angiography has been performed with 5 French diagnostic catheters in 57 (47.5%) patients and with 6 French diagnostic catheters in 63 (52.5%) patients. No significant differences were found between the two groups in main general characteristics.

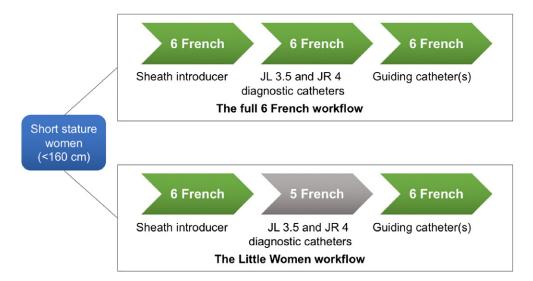
Radial spasm and switch to another access occurred more frequently among women who underwent coronary angiography with 6 French rather than 5 French diagnostic catheters (43% vs. 25%, p=0.03 and 2% vs. 11%, p=0.04, respectively, Fig. 2).

Fluoroscopy time to lesion crossing was not different between the two groups ( $14 \pm 6$  min vs.  $13 \pm 5$  min, p = 0.36, Fig. 3), however total time to lesion crossing was significantly higher when percutaneous coronary intervention has been preceded by 6 French rather than 5 French coronary angiography ( $22 \pm 11$  min vs  $17 \pm 7$  min, p = 0.013, Fig. 3).

Results of self-assessment of access-related pain by with visual analogic scale were  $4.9 \pm 2.2$  in patients who had coronary angiography with 6 French diagnostic catheters and  $3.8 \pm 2.3$  in patients had coronary angiography with 5 French diagnostic catheters (p = 0.038, Fig. 4).

#### 4. Discussion

The main finding of the Little Women study is that 5 French catheters for coronary angiography preceded by the placement of a 6 French sheath introducer significantly reduce the failure, duration and



**Fig. 1.** Flow chart of the study. The Little Women study considered for enrolment small stature (<160 cm) women undergoing first-time transradial coronary angiography. A 6 French introducer sheath was inserted in all cases. Coronary angiography was performed either with two 5 French or two 6 French Judkins diagnostic catheters. Patients were retained in the study in case of ad hoc percutaneous coronary intervention which was always performed with 6 French guiding catheter(s). Patients were then divided in two groups according to the size of the diagnostic catheters that have been used for coronary angiography.

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