# Difference of Radial Access and Femoral Access on Patient Outcomes in Diagnostic Cardiac Catheterization: A Quasi-Experimental Study

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***Background:****Transfemoral and transradial are two common approaches for performing cardiac catheterization, while there is no consensus on which one is superior to the other.* ***Aim****: This paper aimed to compare the effect of transfemoral and transradial approaches on patient's outcomes in terms of back pain, vascular complications, and urinary discomfort in those undergoing diagnostic cardiac catheterization.* ***Methods****: A secondary data analysis method was used.* ***Results****: The results showed that transradial access could significantly reduce back pain compared to femoral access. While no significant difference was found for vascular complications and urinary discomfort between the two methods.* ***Conclusion****: The findings of this study indicate that transradial approach could reduce patients' back pain without increasing the incidence of vascular complications. Additionally, with early mobility, nursing care time could be reduced. Thus, it can be used as an alternative approach for the transfemoral approach.*

*Keywords: transradial access; transfemoral access; back pain; cardiac catheterization*

## INTRODUCTION

Coronary heart disease has become one of the leading causes of death worldwide. According to the World Health Organization (WHO, 2017), approximately 7.4 million of global death was attributed to CHD in 2012. In Hong Kong, heart disease accounted for 13.2% of all deaths in 2015, among which 66.6% of death was attributed to CHD (Department of Health, Hong Kong, 2017). Diagnosing and determining the severity of CHD are critical for implementing proper medical treatments and reduce CHD related mortality accordingly. With advanced technology, several types of investigation can be used to fulfill this purpose, such as computed tomography angiography, magnetic resonance imaging of the heart, and diagnostic cardiac catheterization (CC). Among those investigation methods, CC is considered as the most definitive procedure to diagnose and evaluate CHD and has been widely used (Goyal et al., 2010). A report from the National Cardiovascular data registry revealed that more than one million patients undergoing diagnostic CC from January 2010 to June 2011 in the United States (Dehmer et al., 2012). CC is a medical procedure to examine the heart condition

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to diagnose or treat some heart diseases (American Heart Association, 2017).

Transradial (TR) and transfemoral (TF) artery are two common approaches for performing CC (Woods et al., 2005), with TF approach as the traditional primary route of arterial access for CC. In the United States, among patients undergoing diagnostic cardiac catheterization and PCI, femoral access was the most frequently used technique, with 91.2% in diagnostic catheterization and 92.7% in PCI, while radial artery access was used in 8.3% of diagnostic and 6.9% of PCI procedures (Dehmer et al., 2012). Despite this fact, the use of TR for CC has been seen growing. A report from the National Cardiovascular Data Registry in the United States showed that the proportion of TR PCI increased dramatically in last decade, from 1.2% in 2007 to 16.1% in 2012 (Feldman et al., 2013). In the United Kingdom, TR access has become the default access site used for PCI, with the use increasing from 14% in 2005 to 58.6 % in 2012 (Mamas et al., 2016). The increasing trend of adopting TR approach for coronary angiography is also observed in Asia (Bertrand et al., 2010).

The growth of radial access use for CC is possibly attributed to TR associated benefits, such as reduced rate of access site-related bleeding complications, improved patients' comfort, and decreased length of hospital stay as well as cost-effectiveness (Hulme et al., 2017; Mamas et al., 2016). A study compared TR and TF access for PCI and found that adoption of TR access was associated with lower risk of bleeding (OR = 0.51, 95% CI: 0.49–0.54) and vascular complications (OR = 0.39, 95% CI: 0.31–0.50) compared with TF access (Feldman et al., 2013). Another randomized controlled trial (RCT) study examining the effect of radial access in women undergoing CC or PCI found that radial access could significantly reduce bleeding and vascular complications compared to femoral access (0.6 % vs. 1.7%, OR:0.32, 96% CI: 0.12–0.90) in the total randomized patients (Rao et al., 2014). A study comparing TR and TF PCI associated costs and benefits in China concluded that TR intervention was associated with a lower total cost ($1,283), lower hospitalization costs (-$222), shorter length of hospital stay, lower risk of major adverse cardiac events, or post-PCI bleeding compared to TF intervention (Jin et al., 2016). Despite the potential benefits with TR CC, there is no consensus on whether TR is superior to TF approach, or vice versa. Previous studies compared both approaches but mainly focused on procedural and clinical outcomes rather than patient outcomes (Feldman et al., 2013; Rao et al., 2014). Additionally, previous studies included both coronary angiography and angioplasty patients (Rao et al., 2014; Valgimigli et al., 2015), such mixed population may interfere with the results as the risk of vascular complication may be increased in patients undergoing coronary angioplasty due to the higher heparin dosage and complicated procedure involved in coronary angioplasty. Moreover, most of the previous studies adopted a retrospective study design (Feldman et al., 2013; Hulme et al., 2017; Jin et al., 2016; Mamas et al., 2016), fewer of them employed a prospective method to evaluate the effects of TR on patient health outcomes.

Currently, there are no local data on comparing patient outcomes between TR and TF approach for CC. Therefore, this study adopted a prospective method to examine the effect of TR approach on patient outcomes including back pain, vascular complications, and urinary discomfort compared to TF approach in patients undergoing diagnostic CC. The results of this study would inform medical decision about which approach is more advantageous for patients' choice and inform nursing practice on caring patients undergoing diagnostic CC.

## METHOD

### *Study Design*

This study was a quasi-experimental design with secondary analysis. The original study was an RCT study and designed to compare patient out-

comes between patients ambulated at four and 12 to 24 (usual care) hours after transfemoral CC (Chair et al., 2007). However, the operators were asked to adopt TR access for CC before the completion of the study due to the change of department policy. As a result, a TR group was added as the third group of the study. In the current study, data were extracted from participants in TR group and those in TF group who ambulated at four hours after CC.

***Study Sample***

Chinese patients aged over 18 who admitted to a regional general hospital with a cardiac catheterization laboratory in the east part of Hong Kong for diagnostic CC were recruited. Patients were excluded if they were: 1) receiving emergency CC, 2) age <18 or >75 years old, 3) prior CC, 4) taking anti-coagulant medication within the previous 24 hours before the procedure, 5) having known bleeding disorders, 6) with presence of back pain before the procedure, 7) active bleeding from the access site before sheath removal or active bleeding after sheath removal but before ambulation, 8) medication complications, such as angina or myocardial infarction occurred during the procedure, 9) a systolic blood pressure ≥ 180 mmHg and/or diastolic blood pressure ≥ 110 mmHg before the procedure, and 10) unable to ambulate independently before the procedure (Chair et al., 2007). To detect a medium effect size of 0.5, a total of 126 participants were recruited in this study (with 63 participants in each group) to detect group difference at 80% power and 5% significance level.

***Data Collection and Instruments***

Eligible participants were invited to participate in the study. TR group received CC via radial access while femoral access for TF group. Additionally, participants in TR group could ambulate as early as they returned to unit whereas those in TF group were allowed to ambulate after 4 hours of bed rest (early ambulation than usual practice in Hong Kong). After obtaining written consent form from participants, demographic data and clinical information were collected from patient medical records as well as patients interview.

The primary outcome for this study was back pain. Back pain levels were assessed at three different intervals: 4 hours and 8 hours after returning to unit as well as at 8 AM in the next morning by using visual analogue scale which consists of a 100-mm long line with the left anchor representing "no pain" and the right anchor representing "the worst possible pain" (Turk & Melzack, 2011).

The puncture site was assessed for vascular complications hourly for the first four hours, pre and post of each ambulation. Bleeding guidelines (Christenson, Staab, Burko, & Foster, 1976) was used with significant bleeding defined as blood loss estimated at >100 mL and/or hematoma >5 cm in width. However, with close observation, extra criteria were added to capture bleeding case which is bleeding that led to further attempts to reestablish hemostasis by manual compression, sandbag application, or reinforcement of pressure dressing.

Urinary discomfort was assessed at 6 hours after the procedure by using a self-developed tool. This tool consists of four questions to evaluate participants' comfort level of urination after CC. The first question was to ask whether participants experienced any urinary discomfort before undergoing CC. The second and third questions focused on participants' experience about how comfortable and how difficult it was to urinate during the first 6 hours after CC. The last question asked how they deal with urinary discomfort after CC.

***Data Analysis***

Descriptive statistics were used to describe the characteristics of the sample, with mean (standard deviation) to present continuous data and frequency (percentage) to present categorical data. Group comparisons were performed using Chi-square or independent *t*-test as appropriate. Generalized estimation equation (GEE) model was used to detect the change difference in

repeated outcome variables (back pain in the current study) between two study groups across time. A $p$ value of less than 0.25 in group comparison was used to identify potential founders which were controlled in the GEE model. A level of $p < 0.05$ was set for statistical significance in this study.

## RESULTS

### *Demographic and Clinical Characteristics*

Among participants, 61.9% of them were male and the mean age was 62.1 (10.3) years old. Most of the participants (46.8%) had an education level of secondary school and above, and 87.3% were married. About 53% of participants had a monthly family income of less than 8,000 HK$. Regarding working status, approximately half of them (49.2%) were retired. In addition, 89.7% of the participants were comorbid with more than one illness. When comparing the demographic and clinical characteristics between two study groups, no significant difference was observed except for monthly family income, with a higher proportion of fewer than 8,000 HK$ in TF control group. Education level, monthly income, working status, and co-morbidity were the potential confounding factors (p-value of group comparison being less than 0.25) and were controlled in GEE analysis. Table 1 presents the demographic and clinical variables of the participants and the baseline comparison between study groups.

### *Comparison of Outcome Variables Between Study Groups*

After CC procedure, back pain at 4 hours, 8 hours, and 8 AM in next morning were significantly reduced in TR group compared to TF group (all $p < 0.05$) (Table 2). The results of GEE showed that both study groups demonstrated a significant reduction in back pain across time; when comparing the change of back pain between study groups, TR group demonstrated a significant decrease of back pain at tp 3 (8 AM in next morning) rather than tp 1 or tp 2 with reference to TF group after controlling founding factors, as shown in the adjusted GEE model (Table 3). However, no significant difference was found for other outcome variables in terms of puncture site bleeding and urination discomfort (Table 2).

## DISCUSSION

This study was a secondary analysis of a previous RCT study and aimed to compare patient outcomes in terms of back pain, vascular complications, and urination discomfort between TR CC and TF CC. Participants in TR group could ambulate as soon as they returned to the unit while those in TF group were allowed to ambulate after four hours of bedrest. The results showed that TR CC could significantly reduce the back pain level compared to TF CC, whereas no significant difference was found for other outcome variables. The findings of this study provided evidence for the safe of adopting radial access in CC procedure.

For patients undergoing TF CC, the most frequent complaint from them is back pain during bed rest (Chair, Fernandez, Lui, Lopez, & Thompson, 2008). Given the evidence that prolonged bed rest can result in severer of back pain (Chair et al., 2007; Chair, Taylor-Piliae, Lam, & Chan, 2003), we anticipated a significant reduction in back pain in TR group compared to TF group in the current study. As expected, TR group reduced more back pain than the TF group ($p < 0.05$). Such significant difference in back pain reduction may attribute to the difference of bedrest after CC between study group as participants in TF group were required to remain on bedrest for four hours before ambulation, while those in TR group could ambulate as early as they want after returning to the unit. Despite the significant group difference, participants in TF group also reported a significant reduction in the back pain across time. These findings suggest the benefits of early ambulation in reducing post-CC back pain. Previous studies also reported reduced back pain after early ambulation in TF CC (Chair et al., 2007; Höglund, Stenestrand, Tödt, & Johansson, 2011). However, compared to TF approach, adoption of TR access could allow much earlier ambulation which then reduces post-procedure back pain.

**TABLE 1. Comparison of Demographic and Clinical Characteristics between Study Groups**

| | All ($n$ = 126) | TF Control ($n$ = 63) | TR Experimental ($n$ = 63) | $p$-value[b] |
|---|---|---|---|---|
| Sex[a] | | | | |
| Male | 78 (61.9%) | 36 (57.1%) | 42 (66.7%) | 0.271 |
| Female | 48 (38.1%) | 27 (42.9%) | 21 (33.3%) | |
| Age (yrs)[a] | | | | |
| < 65 | 66 (52.4%) | 34 (54.0%) | 32 (50.8%) | 0.721 |
| ≥65 | 60 (47.6%) | 29 (46.0%) | 31 (49.2%) | |
| Age (yrs) | 62.1 (10.3) | 62.0 (10.9) | 62.2 (9.7) | 0.938 |
| Weight (kg) | 65.8 (10.7) | 65.5 (11.4) | 66.1 (10.0) | 0.746 |
| Height (cm) | 160.3 (7.7) | 159.6 (8.1) | 160.9 (7.3) | 0.369 |
| Education level[a] | | | | |
| No formal education | 31 (24.6%) | 18 (28.6%) | 13 (20.6%) | 0.066 |
| Primary | 36 (28.6%) | 22 (34.9%) | 14 (22.2%) | |
| Secondary/university | 59 (46.8%) | 23 (36.5%) | 36 (57.1%) | |
| Marital status[a] | | | | |
| Single / divorced / widowed | 16 (12.7%) | 7 (11.1%) | 9 (14.3%) | 0.789 |
| Married | 110 (87.3%) | 56 (88.9%) | 54 (85.7%) | |
| Monthly family income (HK$) | | | | |
| < 8,000 | 67 (53.2%) | 41 (65.1%) | 26 (41.3%) | 0.006 |
| 8,000 –18,000 | 34 (27.0%) | 16 (25.4%) | 18 (28.6%) | |
| >18,000 | 25 (19.8%) | 6 (9.5%) | 19 (30.2%) | |
| Working status[a] | | | | |
| Retired | 62 (49.2%) | 27 (42.9%) | 35 (55.6%) | 0.141 |
| Housewife | 29 (23.0%) | 20 (31.7%) | 9 (14.3%) | |
| Unemployed | 6 (4.8%) | 3 (4.8%) | 3 (4.8%) | |
| Currently working | 29 (23.0%) | 13 (20.6%) | 16 (25.4%) | |
| Number of co-morbidity | | | | |
| 0 –1 | 13 (10.3%) | 4 (6.3%) | 9 (14.3%) | 0.226 |
| 2 | 40 (31.7%) | 18 (28.6%) | 22 (34.9%) | |
| 3 | 32 (25.4%) | 20 (31.7%) | 12 (19.0%) | |
| ≥4 | 41 (32.5%) | 21 (33.3%) | 20 (31.7%) | |

*Note*. TF = transfemoral; TR = transradial.
[a]Presented as frequency (%), all others are presented as mean (standard deviation).
[b]Categorical and continuous variables were compared using Chi-square test and t-test respectively.

Safety issue (e.g., vascular complications) regarding TF and TR approach is a major concern for choosing a puncture site for CC. The current study reported a low rate of puncture site bleeding in both groups, with four cases of puncture site bleeding (6.3%) in TR group and no such case in TF group. Moreover, the difference in the cases of puncture site bleeding between study groups was not significant, which may indicate that both TR and TF approaches are safe for performing CC. Similar findings were also reported in other studies. A RCT study investigating the effect of radial access on outcomes in women undergoing CC or PCI found a low rate of bleeding or vascular complications in both TR (0.4%, 2 out of 546) and TF (1.7%, 9 out of 539) group in

**TABLE 2. Comparison of Outcome Variables between Study Groups**

| Outcomes | TF Control (*n* = 63) | TR Experimental (*n* = 63) | *p*-value |
|---|---|---|---|
| Back pain | | | |
| Pre-procedure | 11 (17.5%) | 9 (14.3%) | 0.626 |
| Post-procedure (4 hours) | 31 (49.2%) | 16 (25.4%) | 0.006 |
| Post-procedure (8 hours) | 30 (47.6%) | 16 (25.4% | 0.010 |
| Post-procedure (next morning) | 31 (49.2%) | 8 (12.7%) | <0.001 |
| Puncture site bleeding | | | |
| No | 63 (100.0%) | 59 (93.7%) | 0.119 |
| Yes | 0 | 4 (6.3%) | |
| Urination discomfort | | | |
| No / mild | 52 (82.5%) | 48 (80.0%) | 0.718 |
| Very / unbearable | 11 (17.5%) | 12 (20.0%) | |
| Urination difficulty | | | |
| Minimal / little | 58 (92.1%) | 54 (90.0%) | 0.689 |
| Much / unable to urinate at all | 5 (7.9%) | 6 (10.0%) | |

**TABLE 3. Generalized Estimation Equation (GEE) Models for the Comparison of Back Pain Across Time Between Study Groups**

| | Crude model | | Adjusted model | |
|---|---|---|---|---|
| **Back pain** | **$\beta$(95% CI)** | ***p*** | **$\beta$(95% CI)** | ***p*** |
| group | −0.24 (−1.20, 0.72) | 0.626 | −0.31 (−1.30, 0.69) | 0.543 |
| tp1 | 1.52 (0.83, 2.21) | <0.001 | 1.54 (0.84, 2.24) | <0.001 |
| tp2 | 1.46 (0.63, 2.28) | 0.001 | 1.48 (0.64, 2.31) | 0.001 |
| tp3 | 1.52 (0.66, 2.38) | 0.001 | 1.54 (0.67, 2.42) | 0.001 |
| group*tp1 | −0.81 (−1.80, 0.19) | 0.111 | −0.78 (−1.80, 0.24) | 0.132 |
| group*tp2 | −0.74 (−1.80, 0.31) | 0.166 | −0.73 (−1.81, 0.35) | 0.185 |
| group*tp3 | −1.66 (−2.95, −0.37) | 0.012 | −1.69 (−3.04, −0.34) | 0.014 |

*Note*. For back pain, only the model estimates of the dummy variables for the groups (group: 0 = TF, 1 = TR, time points (tp1: 1 = post-procedure 4 hours, tp2: 1 = post-procedure 8 hours, tp3: 1 = post-procedure next morning), time points and groups interaction terms group*tp1, group*tp2, group*tp3 were showed for the GEE models.

patients undergoing diagnostic CC (Rao et al., 2014). Moreover, the subgroup analysis indicated a favor but non-significant effect of radial access in reducing bleeding in this subgroup patients (Rao et al., 2014). Another large, randomized, multicenter trial confirmed that radial and femoral approaches are both safe and effective for PCI in patients with acute coronary syndromes (Jolly et al., 2011). However, unlike the current study, above studies reported a beneficial effect of radial approach in lowering rate of puncture site vascular complications than femoral approach (Jolly et al., 2011; Rao et al., 2014). Such difference may attribute to the difference in sample size, with only 126 patients involved in the current study while 1,085 in Rao et al.'s study (2014) and 7,021 in Jolly et al.'s (2011). Thus, the findings of the current study should be interpreted with caution.

Fewer studies examined the effect of CC on urinary discomfort. Chair et al. (2012) compared

the effect of early ambulation (four hours after CC procedure) and the usual care practice (12–24 hours after CC procedure) in Hong Kong. The results showed that early ambulation could significant reduce urinary discomfort for "very or unbearable urination discomfort" (*OR* = 0.35, 95% CI: 0.14–0.90, $p$ = 0.03) and for "much difficulty or unable to urinate at all" (*OR* = 0.22, 95% CI: 0.06–0.74, $p$ = 0.0015). This finding suggested that early ambulation is beneficial for reducing urinary discomfort in patients undergoing CC. However, the current study found no significant difference in urinary discomfort between those who ambulated after 4 hours of bedrest (TF group) and those who could ambulate as soon as possible without any bedrest (TR group). On one hand, although participants in TR group were allowed earlier ambulation than the TF group, they usually preferred bedrest for some time after CC procedure, which may partly explain above non-significant difference. On the other hand, such non-significant finding may indicate that both early ambulations after TF and TR are effective in reducing urinary discomfort.

Several limitations should be acknowledged in this study. First, the quasi-experimental design of this study may introduce bias to the findings as confounders may be introduced with such study design since participants may not be randomly assigned to each group as a randomized controlled trial dose. Second, the secondary data analytic approach may preclude the author from controlling over the problems which may affect the data as well as the results. Third, the sample size of this study is small, which may decrease the power of the study and result in imprecise findings.

## CONCLUSION

Data demonstrates that TR approach still can retain its significant advantages by reducing vascular complications and length of hospital stay, and improving patient comfort while maintaining procedural success, despite the documented benefits of femoral approach (Nathan & Rao, 2012). Similarly, the findings of this study suggest that TR approach could significantly reduce back pain level without increasing the incidence of vascular complications compared to TF approach. Thus, TR access can be used as an alternative approach for TF CC.

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