

# Transulnar sheathless percutaneous coronary intervention during bivalirudin infusion in high-risk elderly female with non-ST segment elevation myocardial infarction

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## Abstract

Due to the ageing population and raised life expectancy, elderly patients are increasingly referred for percutaneous coronary intervention (PCI) during acute coronary syndromes (ACS). Bleeding complications are not infrequent during ACS, occurring in 2-5% of patients with prognostic and economic consequences. In particular, periprocedural bleeding and vascular complications are associated with worse clinical outcome, prolonged hospital stay and increased short- and long-term mortality, especially in elderly patients with acute coronary syndromes. We report the case of an 83-year old female referred to our hospital because of non-ST segment elevation myocardial infarction with high bleeding risk and unsuitable radial artery undergoing transulnar sheathless PCI during bivalirudin infusion. The clinical, technical, pharmacological and prognostic implications are discussed.

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## Introduction

Due to the ageing population and raised life expectancy, elderly patients (EP) are increasingly referred for percutaneous coronary intervention (PCI) during acute coronary syndromes (ACS). Although evidence from large randomized controlled trials is lacking, EPs seem to receive an equal or even greater benefit from PCI treatments with an improved long-term outcome.<sup>1</sup>

A disproportionately lower use of cardiovascular medications and invasive treatment in elderly compared to younger patients with ACS is observed, generally due to their fragile health status (*i.e.* comorbidities), diffuse coronary artery disease, increasing periprocedural complications and greater incidence of drug-related side-effects. Thus, the optimal antithrombotic treatment, the timing and the route for coronary revascularization strategy in EPs is still a question of debate.

The administration of a clopidogrel loading dose several hours before the procedure reduces the risk of periprocedural thrombotic events. As set out in the European Society of Cardiology Guidelines,<sup>2</sup> all patients with acute coronary syndrome should be pre-treated with clopidogrel + acetylsalicylic acid (ASA) with provisional use of GP IIb/IIIa inhibitor, especially if undergoing percutaneous coronary intervention with possible increase in bleeding complications. Notably, major bleedings have become an increasing concern for clinical and interventional cardiologists and different studies have demonstrated a higher mortality rate for patients with hemorrhagic complications.<sup>3</sup> Alternative pharmacological strategy to lower bleeding risk (*e.g.* bivalirudin) is advisable because of its favorable impact on prognosis.<sup>4</sup>

Although clinical trials have mostly evaluated different pharmacological strategies for reducing bleeding risk, adoption of a radial rather than a femoral access may allow greater reductions in bleeding complications than pharmacological strategies alone, with a pos-

sible synergistic effect on prognosis.<sup>5</sup> Vascular access-related bleeding accounts for more than 80% of all major bleeding events in PCI performed by the transfemoral approach.<sup>6,7</sup> In certain patients, transradial access may not be appropriate for various anatomical reasons. A series of cases has shown that when radial is not suitable, in case of failure or if the femoral access is not an option, ulnar access is a viable and effective alternative to perform coronary procedures with a similar safety profile. The success, advantages and complication rates for this procedure appear similar to those of the transradial approach (TRA).<sup>8-11</sup> Similar to TRA, the complications associated with the transulnar approach (TUA) increase with the size of sheath used and may theoretically be reduced by the use of a sheathless guide catheter system.<sup>12</sup>

## Case Report

We report the case of an 83-year old female with a history of hypertension and hypercholesterolemia referred to our hospital because of ST-segment shift in infero-lateral leads in non-ST segment elevation myocardial infarction (NSTEMI). On admission, the patient had CK-MB 12 ng/dL and TnI 2 ng/mL and was stratified for bleeding complications (CRUSADE bleeding score 68; risk of in hospital major bleeding 20.8%) and for *frailty* (Charlson comorbidity index: weighted index of comorbidity 5; combined condition and age-related score 9; estimated 10-year survival 0%) together with prognostic risk assessment (GRACE risk score 30% for in hospital composite death or myocardial infarction). Considering the higher risk profile, an early invasive management was planned and a coronary angiography was performed 6 h after hospital admission.

The antiplatelet pre-treatment consisted of ASA 300 mg and clopidogrel 300 mg loading dose in the Emergency Department. Considering the high risk of bleeding, an intrapro-

cedural infusion of bivalirudin was performed: bolus dose 0.75 mg/kg immediately followed by continuous infusion 1.75 mg/kg/h.

Physical examination revealed a very small right and left radial artery with a negative Allen's test and a palpable ulnar pulse with a positive reverse Allen's test (<10 s). After cannulation with a plastic coated needle, a 5F introducer using a 5 French sheath (Radifocus Introducer II, Terumo Corp., Japan) was placed inside the vessel, and a diagnostic coronary angiography was performed by transulnar right approach using a Judkins Right 4, 5 French and a Judkins Left 3.5, 5 French. The angiograms show normal left coronary artery system. The right coronary artery angiogram reveals the presence of critical and calcified stenosis in mid segment (Figure 1A).

PCI was performed with sheathless AL 1-6.5 French (Asahi, INTECC Thailand Co. Ltd.) guiding catheters (Figure 1B). We crossed the tight stenosis of mid segment of the right coronary artery with a 0.014 inch guide wire (BMW, Abbott Laboratories, Abbott Park, Illinois, USA). After predilation with a 2.0×12 mm semicompliant balloon (Sapphire, OrbusNeich Medical Co. Ltd, Shenzhen, China) expanded up to 10 atm, we successfully implanted a 3.0×18 mm stent (Genous, OrbusNeich Medical, Hoewelaken, The Netherlands) expanded up to 14 atm (Figure 2A). The final angiogram shows a good result with thrombolysis in myocardial infarction 3 flow (Figure 2B). The local hemostasis after the sheathless catheter removal was provided with a manual compression followed by small bendage. Twenty-four hours later a clinical evaluation of the vascular access was provided with reverse Allen's test and Echo Color Doppler analysis excluding vascular and/or ischemic complications. The bleeding outcome was excellent: neither site of access or non-access site bleedings were recorded. The post-procedural hospital stay was uneventful. Freedom from MACE at 30 days follow up together with ulnar artery patency (Figure 3) was observed.

## Discussion

Currently, EPs represent about a third of hospital admissions for acute coronary syndromes without persistent ST-segment elevation. The EPs are also a subgroup of patients at high risk of complications because of an excess of ischemic and bleeding events.

In these patients, the use of current ACS antithrombotic strategy reduces the risk of periprocedural thrombotic events but is associated with an excess of bleeding with a strong impact on prognosis. For these reasons, a number of data address the target of the treatment strategies in balancing avoiding the

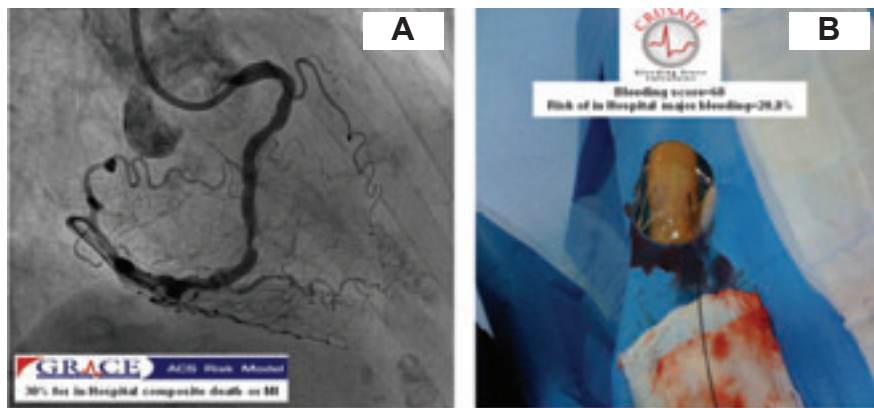


Figure 1. (A) Right coronary angiogram critical stenosis. GRACE risk score evaluation; (B) sheathless guiding catheter in the ulnar right artery. CRUSADE bleeding risk evaluation.

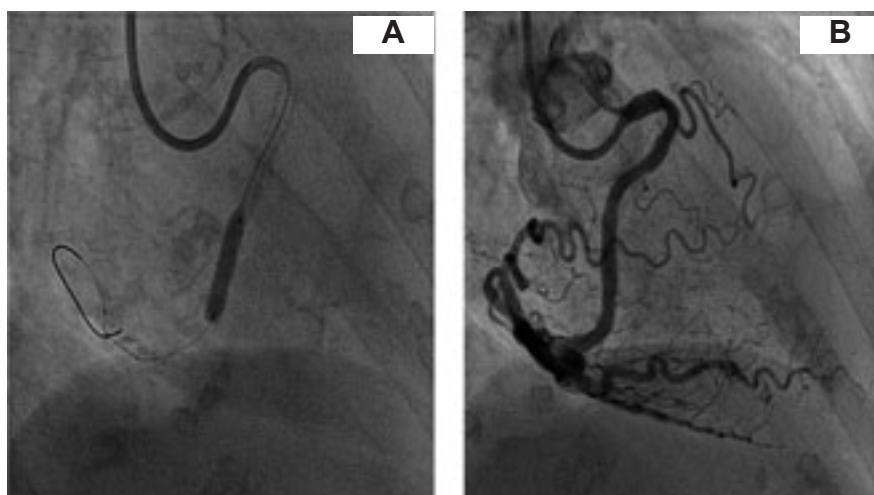


Figure 2. (A) Stent deployment; (B) final angiographic result.

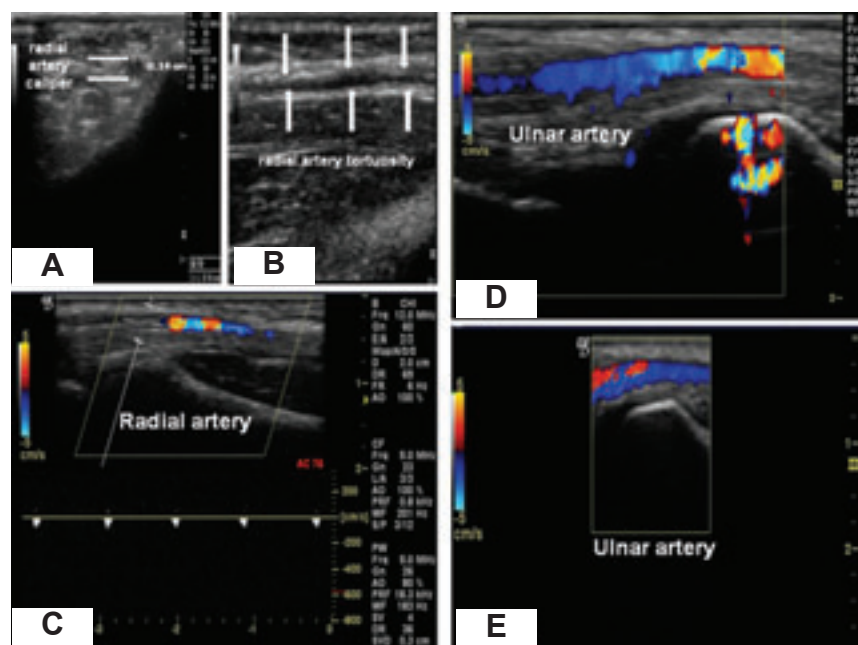


Figure 3. One month Echo Color Doppler analysis. (A,B) Radial artery caliper and tortuosity; (C) radial artery color Doppler; (D) ulnar artery proximal patency; (E) ulnar artery distal patency.

event with avoiding excessive bleeding.

It has been demonstrated that bleeding complications during ACS occur in 2-5% of patients;<sup>3</sup> in particular, either access site or non-access site bleeding is common after PCI especially when optimal antithrombotic therapy is given.

Recent studies point out that bivalirudin compared to heparin + GPIIb/IIIa inhibitors is associated with an approximately 40% reduction in both non-access site as well as access site bleedings, preserving similar antithrombotic protection if an adequate antiplatelet pre-treatment is provided.<sup>4,13,14</sup>

Otherwise, TRA, as mentioned, virtually eliminating access site bleeding and vascular complications, may result in a greater reduction in bleeding complications than pharmacological strategies alone, with a possible synergistic effect on prognosis in patients with ACS.

In our center, more than 96% of the annual total procedures are performed by TRA and the annual incidence of vascular complications is about 2.5%, including arteriovenous fistula (0.1%), side branch vessel perforation (0.3%) and acute radial occlusion/thrombosis (2.1%). The improvement in hemostasis care, based on accurate systematic vascular monitoring by nursing staff, has significantly reduced the incidence of vascular complications. During the last two years, when the radial artery has been unsuitable a transulnar approach has been attempted. From January 2010 to January 2011, 26 transulnar PCI were successfully performed.

In order to increase the success rate of the arterial puncture in reducing vascular complications, the artery pulse, the Allen's and the reverse Allen's test are routinely checked and reported by nursing staff before the procedure. This strategy has increased the percentage of successes from wrist catheterization reducing the need for transfemoral shift.

Often the patients with unsuitable TRA are the same as those at higher risk of vascular and/or bleeding complications (*i.e.* elderly, obese, female, NSTEMI, rescue PCI after failed thrombolysis).<sup>6,7</sup> In these cases, the TUA approach represents the best and safest alternative option when an interventional procedure is required. In our experience, the more frequent reasons for unsuitability or failure of TRA are: i) radial spasm irresponsive to spasmolytic cocktail; ii) anatomic variation, *e.g.* extreme vascular loop generally accompanied by a remnant radial artery irresponsive to wire distension (0.025" or 0.014" hydrophilic wire); iii) hypoplastic radial artery in the context of small artery diameter and/or pulsus absence; iv) radial artery occlusion after a previous transradial PCI.

Among the strategies used in case of transradial approach failure due to radial loop, recently Agostoni *et al.*<sup>15</sup> reported the feasibility

and safety of ulnar access when a homolateral radial sheath is put in place in order to evaluate the suitability of the ulnar artery.

TUA is feasible for percutaneous coronary interventions. However, it has a higher access site failure rate in an unselected patient population ranging from 85.2-90.9% according to two different reports.<sup>10,11</sup> In particular, the failure rate is strictly correlated with the operator's experience and is generally lower among *skilled radialists*. The ulnar artery is deeper and frequently smaller (mean diameter 2.76 ± 0.08 mm compared with radial artery 3.11 ± 0.12 mm) with respect to the other forearm artery. Several authors report higher spasm frequency and anatomical anomalies than those reported for TRA. Despite the risk of complications that might be increased in case of a smaller artery with a deeper course, there are no data to confirm this. Indeed, vascular complication occurrence remains low also when the ulnar artery, usually deeper and smaller than the radial artery, is used (from 4.6-5.7%).<sup>8,10,11</sup> Different authors report a similar incidence of artery occlusion one day and 30 days after TRA and TUA procedures. Interestingly, asymptomatic access site artery occlusion occurred more frequently after transradial than transulnar procedures at these time points. The effective outer diameter of the sheathless guiding catheter is approximately 1.5 French smaller than the labeled size of the regular guiding catheter. In particular, several authors report a lower rate of arterial spasm and or occlusion facilitating the possible use of adjunctive devices (*i.e.* IVUS, double balloon for bifurcation treatment, distal protection devices, thrombectomy catheters, covered stent) usually limited when a standard 5 French or 6 French regular guiding catheter are used. Use of the 6.5 French or 7.5 French sheathless guide catheter system, which has an outer diameter less than 5 French sheath, as the default system in routine PCI is feasible and gives a high rate of procedural success not only via the radial but also via the ulnar artery,<sup>12</sup> as confirmed from our experience.

There is virtually no occurrence of ischemic complications after transulnar coronary procedures if the assessment of the integrity of the deep palmar arch by the reverse Allen's test is checked. In fact, the presence of a complete deep palmar arch in approximately 95% of the population, as well as the great capacity of the collateral circulation of the hand, might justify these findings. The rate of asymptomatic occlusion of the ulnar artery was 3% without any ischemic complication. Although some authors believe that the performance of the Allen's test is not necessary when using TUA,<sup>15,16</sup> this test is important for unskilled transradial operators in order to reduce complications and increase the success rate of the procedure.

## Conclusions

An *ad hoc* management aiming to minimize treatment risk should be carefully considered in order to improve outcome in high-risk elderly patients with ACS. This case demonstrates that an integrated reperfusion strategy based on radial or ulnar approach, sheathless guiding catheter for PCI and use of bivalirudin, seems to be safe and effective with a reduced risk of coronary events and bleeding in high-risk elderly patients with ACS treated with an early invasive strategy.

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