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Original Article

Early Removal of the Arterial Sheath After Percutaneous Coronary Intervention Using the Femoral Approach: Safety and Efficacy Study

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ABSTRACT

Introduction: We evaluated the safety and efficacy of protamine administration, guided by activated clotting time, for the immediate femoral arterial sheath removal in patients undergoing percutaneous coronary intervention with unfractionated heparin in order to propose an algorithm for clinical practice. **Methods:** Prospective study with consecutive patients with stable angina or low-to-moderate risk acute coronary syndrome. We compared patients with an early removal of the arterial sheath to those whose sheath removal was based on a standard protocol. **Results**: The early removal group (n = 149) had lower access manipulation time than the conventional group (58.3 ± 21.4 minutes vs. 355.0 ± 62.9 minutes; $p < 0.01$), mainly due to a reduced time to sheath removal (42.3 ± 21.1 minutes vs. 338.6 ± 61.5 minutes; $p < 0.01$), with no impact on the duration of femoral compression (16.0 ± 3.6 minutes vs. 16.4 ± 5.1 minutes; $p = 0.49$). There was no stent thrombosis during hospitalization and no significant differences in the incidence of major vascular or bleeding events. The incidence of other bleeding events leading to a prolonged in-hospital length of stay was lower in the early removal group (1.3% vs. 5.1%; $p = 0.05$). **Conclusions:** The selective use of an approach for immediate femoral sheath removal, based on activated clotting time guidance and protamine administration, is a safe and effective option in patients undergoing percutaneous coronary intervention by femoral access.

DESCRIPTORS: Protamines. Heparin. Percutaneous coronary intervention. Femoral artery. Anticoagulants.

RESUMO

Remoção Precoce do Introdutor Arterial Após Intervenção Coronária Percutânea por Via Femoral: Estudo de Segurança e Eficácia

Introdução: Avaliamos a segurança e eficácia do uso deprotamina, guiada pelo tempo de coagulação ativado, para a remoção imediata do introdutor arterial femoral em pacientes submetidos à intervenção coronária percutânea com heparina não fracionada, com o objetivo de propor um algoritmo para a prática clínica. **Métodos:** Estudo prospectivo, com pacientes consecutivos, com angina estável ou com síndrome coronariana aguda de baixo ou moderado risco. Comparamos os pacientes com a retirada precoce do introdutor arterial àqueles nos quais o introdutor foi retirado de acordo como protocolo convencional. A decisão pela remoção precoce ou convencional do introdutor foi deixada a critério do operador. **Resultados:** O grupo de remoção precoce (n = 149) apresentou menor tempo de manuseio do sítio de punção que o grupo de remoção convencional (58,3 ± 21,4 minutos vs. 355 ± 62,9 minutos; $p < 0,01$), principalmente devido à redução do tempo até a retirada do introdutor (42,3 ± 21,1 minutos vs. 338,6 ± 61,5 minutos; $p < 0,01$), sem impacto sobre a duração da compressão femoral (16,0 ± 3,6 minutos vs. 16,4 ± 5,1 minutos; $p = 0,49$). Não houve trombose hospitalar de stent e nem diferença significativa na incidênciade eventos vasculares ou hemorrágicos. A incidência de outras hemorragias, que levaram à hospitalização prolongada, foi menor no grupo de remoção precoce (1,3% vs. 5,1%; $p = 0,05$). **Conclusões:** O uso seletivo de uma abordagem para a remoção imediata do introdutor femoral guiada pelo tempo de coagulação ativado e a administração de protamina são seguros e eficazes em pacientes submetidos à intervenção coronária percutânea pela via femoral.

DESCRITORES: Protaminas. Heparina. Intervenção coronária percutânea. Artéria femoral. Anticoagulantes.

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The radial approach for percutaneous coronary intervention (PCI) has gained much attention in recent years, due to its potential to reduce the bleeding rates related to the procedure,[1] especially in patients with acute coronary syndrome. However, the need for a femoral approach, after the failure of the radial approach, can reach up to 17% in certain subgroups of patients.[2] In practice, contraindications or impossibility of the radial access, along with the preference of the doctor and patient, still place the femoral approach as an obligatory technique in the portfolio of any interventional cardiology laboratory, particularly for patients with stable coronary artery disease and low risk of bleeding complications.

Despite the fact that anticoagulation with bivalirudin during PCI has been proven to be beneficial, especially in patients with acute coronary syndrome, unfractionated heparin (UFH) still remains as the main anticoagulant agent among many, if not the majority, of the procedures around the world.[3] Previous studies have evaluated the use of protamine after PCI to reverse anticoagulation as a strategy to allow for an early removal of the sheath and potentially to reduce bleeding complications.[4,5] In a meta-analysis with 6,762 patients, protamine significantly reduced bleeding without increasing thrombotic adverse events.[4] Conversely, another study comparing bivalirudin with UFH in association with protamine showed better results with the first anticoagulation protocol.[5]

The present study was conducted with the aim of evaluating the efficacy and safety of a new algorithm for early femoral arterial sheath removal after PCI, compared to the conventional protocol, in patients treated in the daily practice of a laboratory of interventional cardiology with a large volume of procedures.

METHODS

Study design and population

Between August 2012 and March 2013, 228 consecutive patients with stable angina or moderate- or low-risk acute coronary syndrome undergoing PCI were prospectively included in this study. The decision in favor of early or conventional removal of the sheath was left to the discretion of the surgeon. Patients with early removal of the arterial sheath (Early Removal Group) were compared versus those in which the sheath was removed according to the conventional protocol (Conventional Group) followed by the institution.

The exclusion criteria were: (1) PCI performed by radial approach; (2) use of subcutaneous enoxaparin in the last 12 hours; (3) use of oral anticoagulation; (4) high-risk coronary syndrome (Thrombolysis in Myocardial Infarction [TIMI] > 4);[6] (5) presence of an intracoronary thrombus; (6) hemodynamic instability. Bivalirudin was not available in Brazil at the time of inclusion of patients; thus, all procedures were performed with the use of UFH.

At the time of the procedure, all patients were being treated with dual antiplatelet therapy with acetylsalicylic acid (100-300 mg daily) and clopidogrel (loading dose 300 to 600 mg, at least 6 hours before the procedure, followed by 75 mg daily). During the procedure, UFH was administered at a dose 70-100 IU/kg.

Baseline data, on the procedure and the in-hospital lenght of stay were prospectively collected as part of a dynamic registration approved by the ethics committee of our institution.

Protocol of early removal of the sheath

The early removal of the arterial sheath was based on an activated clotting time (ACT)-guided algorithm, which included the use of intravenous protamine to neutralize the effect of UFH, when necessary (Figure). Immediately after the procedure, the ACT was measured. The femoral sheath was removed if ACT < 180 seconds. If the ACT was between 180 and 250 seconds, or if > 250 seconds, 25 mg or 50 mg of protamine (diluted in 100 mL of 0.9% saline) was administered intravenously during ten minutes, respectively. Five minutes after administration of protamine, a new ACT-guided cycle was repeated, as described above. An extra dose of protamine was administered, up to a maximum dose of 1 mg/100 IU of UFH used in the procedure.

Patients included in the Conventional Group had the sheath removed after 4 to 6 hours of the last dose of UFH, without measurement of ACT.

In both groups, the femoral hemostasis was obtained by manual compression during at least 15 minutes. After removal of the sheath, patients remained on bed rest for 6 more hours.

Definitions

The treated lesions were classified according to the American College of Cardiology/American Heart Association (ACC/AHA). Success of the angiographic procedure was defined as the presence of a residual stenos is < 30%, absence of dissection, and final TIMI flow 3.

The primary efficacy endpoint was the total time of handling of the access site, defined as the sum of the time spent for removal of the sheath and the total time of compression. The time spent for removal of the sheath was computed from the end of the procedure until the time at which the sheath was removed.

The primary safety endpoint was composed by cardiovascular and cerebrovascular adverse events (death, myocardial infarction, stroke, and unplanned myocardial revascularization), and by major bleeding and vascular complications, combined during hospitalization. All causes of death were considered in the analysis. After