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RESEARCH ARTICLE

FEMORAL SHEATH FRACTURE DURING PTCA: A RARE DEVICE-RELATED ADVERSE EVENT

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Abstract

Introduction:A femoral sheath catheter is a flexible tubeinserted into the femoral artery or vein during cardiaccatheterization to facilitate cath eter guidance into the heart.Itprovides temporary femoral arterial access and helps reducebleeding.The femoral artery is preferred for its large di ameter,superficial location, and case of compression, with closuredevic es used post-procedure**.**

Case Summary:A 72 year old male patient with coronar artery disease and inferior wall acute myocardial infarction was admitted for PTCA. T he procedure was completed withoutcomplications by trained personnel under the supervision of acardiac surgeon.The patient was transferred t o the ICU,whereactive bleeding was noted at the femoral access site. U ponremoval of the femoral sheath, it was observed that the sheathwas fractured. Procedure was without complications and all the procedures were done by trained personnel under the guidance of Cardiac surgeon. Patient was shifted to ICU.Patient had bleeding and had Femoral sheath removal and after removal it was observed that the femoral sheath was broken.

Management: Imaging confirmed the presence of the retainedbroken sheath fragment within the femoral artery.An exploratorysurgical proce dure was performed to retrieve the fragment.

Outcome: The patient required ventilator support postoperativelyand w as successfully extubated after three days.

Conclusion: Reporting rare complications like femoral sheath fractures to the Materiovigilance Program of India is essential for improving dev ice safety and clinical outcomes.Such vigilance ensures better manage ment and prevention of similar incidents.

Introduction: -

Femoral sheath catheters are essential devices in interventional cardiology, providing secure vascular access during procedures such as percutaneous transluminal coronary angioplasty (PTCA). Inserted into the femoral artery, they

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facilitate catheter navigation to the coronary vasculature while reducing arterial trauma and bleeding risks. This access site is favored due to its superficial anatomical location, large vessel diameter, and ease of manual compression or use of closure devices post-procedure [1,2]. Despite their widespread use and overall safety, serious complications—though rare—may arise. Common issues include local bleeding, hematoma, pseudoaneurysm formation, arterial dissection, or thrombosis.

Among the most uncommon yet grave events is the mechanical fracture of the sheath, which may result in intravascular retention of device fragments, leading to arterial thrombosis, distal embolization, limb ischemia, or myocardial infarction if migration occurs [1,3].

Fracture mechanisms may include manufacturing defects, structural fatigue due to prolonged dwell time, excessive manipulation, or resistance encountered during removal—often exacerbated by arterial spasm or tortuous anatomy [4]. Such events demand immediate recognition and intervention. In India, the MateriovigilanceProgramme of India (MvPI) monitors such device-related adverse events at a national level, enabling root cause evaluation, regulatory action, and design improvements [5]. Here, we report a rare case of femoral sheath fracture during PTCA, detail its management and highlight the critical role of rapid intervention and materiovigilance reporting in safeguarding patient outcomes.

Case Description:

A 72-year-old male with known coronary artery disease presented with signs consistent with inferior wall acute myocardial infarction. The patient was admitted for PTCA. The procedure was executed smoothly by experienced interventional cardiologists with support from a cardiac surgeon. Post-procedure, while in the ICU, active bleeding was noted at the femoral access site and the sheath was removed. The sheath appeared fractured, with a segment missing.

Emergent imaging—via fluoroscopy and Doppler ultrasound—confirmed a retained fragment lodged in the femoral artery. An attempt at percutaneous embolectomy was made but failed. An exploratory laparotomy was performed under vascular surgery, successfully retrieving the fragment. Postoperatively, the patient required ventilatory support and was extubated on the third day without neurological or vascular complications. The event was classified as a serious device-related adverse event and promptly reported to the MateriovigilanceProgramme of India for documentation and quality assurance purposes.

Figure 1. White arrow demonstaring the angiographic image of the trapped introducer sheath in the femoral artery.

Discussion:

Femoral sheath fracture during PTCA is exceedingly rare, with few cases documented in medical literature [1,3,4]. A retained intravascular fragment poses serious risks that vary depending on its location. When lodged in the coronary circulation, it may precipitate acute thrombosis leading to myocardial infarction. Peripheral retention, as in our patient, can result in distal embolization or acute limb ischemia. The underlying mechanism often involves structural failure—due to flaws in manufacturing or material fatigue—especially under conditions of prolonged use or repeated manipulation. Mechanical stress such as excessive torque, forceful withdrawal, or resistance encountered from arterial spasm, vessel calcification, or tortuosity may contribute significantly to device compromise [4].

Prompt detection via fluoroscopy or ultrasound is essential to guide retrieval efforts. While percutaneous snare techniques are preferred for accessible fragments, surgical intervention becomes necessary when these attempts fail, as seen in our case.

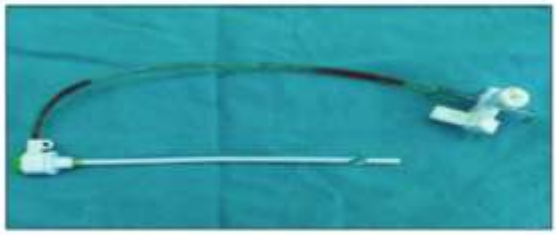

Figure 2. The main body and the fractured part of the introducer sheath after surgical retrieval.

Preventive measures revolve around meticulous device handling: inspecting the sheath before and after use for signs of crack or damage, avoiding forceful manipulation, and reducing dwell time when feasible. Furthermore, training interventional teams to recognize resistance during sheath maneuvers and to act swiftly is paramount. From a public health and regulatory perspective, materiovigilance reporting to MvPI plays a critical role. Documenting such rare but significant events enables pattern recognition, triggers action from manufacturers for redesign or recall, and informs institutional protocols to mitigate future risks [5].

In summary, while femoral sheath fracture is rare, its potentially life-threatening consequences call for heightened clinical vigilance, rapid management, and committed materiovigilance to ensure patient safety.

Conclusion:

This case underscores a rare yet serious complication of femoral sheath fracture during PTCA—highlighting how device failure can result in retained intravascular fragments with potentially grave consequences. Prompt imaging, timely intervention, and surgical retrieval facilitated complete patient recovery without lasting morbidity. Equally crucial is reporting such events to the MateriovigilanceProgramme of India for broader safety oversight. Adhering to careful device inspection, avoiding excessive manipulation, and fostering awareness among cath-lab personnel are key preventive strategies. Through vigilant practice and active materiovigilance reporting, similar adverse events can be minimized, reinforcing patient safety in interventional cardiology.

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