

REVIEWER'S REPORT

Manuscript No.: IJAR-53328

Date: 14/08/2025

Title: Medical Device-Related Adverse Event: Femoral Sheath Fracture During PTCA

Recommendation:

Accept as it is ☐☐☒☐☐

Accept after minor revision ☐☐☐☐

Accept after major revision ☐☐☐☐☐

Do not accept (*Reasons below*) ☐☐☐

Rating	Excel.	Good	Fair	Poor
Originality	✓			
Techn. Quality		✓		
Clarity		✓		
Significance	✓			

Reviewer Name: Sakshi Jaju

Date: 14/08/2025

Reviewer's Comment for Publication.

This case report describes a rare complication during percutaneous transluminal coronary angioplasty (PTCA) in a 72-year-old male with coronary artery disease. After the procedure, part of the femoral sheath broke and remained lodged in the femoral artery. Imaging confirmed the retained fragment, and surgical retrieval was performed after failed percutaneous removal. The patient recovered fully. The report emphasizes the importance of early recognition, careful device handling, and reporting such incidents to the Materiovigilance Programme of India to improve device safety and prevent future cases.

Strengths:

1. Clearly describes the case with patient background, diagnosis, management, and outcome.
2. Highlights an extremely rare but serious complication.
3. Stresses the role of materiovigilance for improving clinical safety.
4. Provides practical preventive measures for healthcare professionals.

Weaknesses:

1. No detailed analysis of device manufacturing or quality issues.
2. Lacks broader statistical data or literature comparison on sheath fractures.
3. Limited discussion on long-term follow-up or patient quality of life post-event.

Overall Assessment:

A concise and clinically valuable case report, raising awareness about an uncommon device-related complication in cardiology. It is useful for both clinicians and regulatory bodies but would benefit from more technical detail and literature-based comparison.

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Manuscript accepted for the publication.