

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-- Yes

Accept after major revision

Do not accept (*Reasons below*)

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

Reviewer Name: Dr. Shankar Sahebrao Yelmame(Reviewer ID: JPR-135) **Date:** 14/08/2025

Reviewer's Comment for Publication.

This manuscript presents a rare and clinically significant case of femoral sheath fracture during PTCA, emphasizing the importance of rapid intervention and materiovigilance reporting. The detailed case description, supported by relevant literature, offers valuable insights for interventional cardiology practice and patient safety enhancement.

Detailed Reviewer's Report

| Sr. No. | Section | Reviewer Comments |
|---------|----------|---|
| 1 | Title | Clear and specific, but could be made more concise. Consider shortening to 'Femoral Sheath Fracture During PTCA: A Rare Device-Related Adverse Event' for brevity. |
| 2 | Abstract | <p>If Possible You can use this Abstract</p> <p>Abstract</p> <p>Introduction: A femoral sheath catheter is a flexible tube inserted into the femoral artery or vein during cardiac catheterization to facilitate catheter guidance into the heart. It provides temporary femoral arterial access and helps reduce bleeding. The femoral artery is preferred for its large diameter, superficial location, and ease of compression, with closure devices used post-procedure.</p> <p>Case Summary: A 72-year-old male patient with coronary artery disease and inferior wall acute myocardial infarction was</p> |

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| | | <p>admitted for PTCA. The procedure was completed without complications by trained personnel under the supervision of a cardiac surgeon. The patient was transferred to the ICU, where active bleeding was noted at the femoral access site. Upon removal of the femoral sheath, it was observed that the sheath was fractured.</p> <p>Management: Imaging confirmed the presence of the retained broken sheath fragment within the femoral artery. An exploratory surgical procedure was performed to retrieve the fragment.</p> <p>Outcome: The patient required ventilator support postoperatively and was successfully extubated after three days.</p> <p>Discussion: This case underscores the importance of promptly identifying and reporting rare complications such as femoral sheath fractures to the Materiovigilance Programme of India (MvPI), to strengthen device safety monitoring, inform clinical practice, and improve patient outcomes.</p> |
| 3 | Introduction | Well written. |
| 4 | Case Description | Chronological presentation is logical and clear. |
| 5 | Discussion | Well Explained. |
| 6 | Conclusion | Concise and relevant. |
| 7 | References | Relevant and appropriate. If Possible you can add latest references. |