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Dr. Reddy's

EVALUATION OF EFFECTIVENESS AND TOLERABILITY OF FONDAPARINUX IN THE MANAGEMENT OF SYMPTOMATIC ACUTE CORONARY SYNDROME: A REAL-WORLD EVIDENCE-BASED STUDY ON AN INDIAN POPULATION

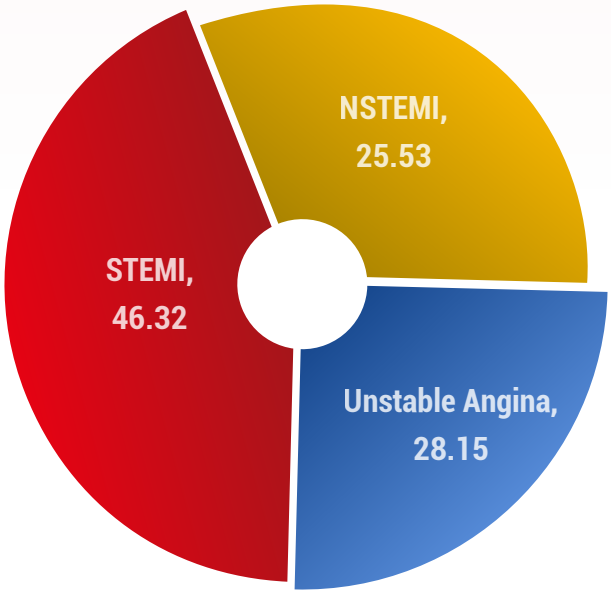
Background

- ACS is commonly associated with clinical manifestations that constitute a continuum of intensity from unstable angina to NSTEMI, STEMI.
- Regardless of the availability of these treatments, up to 10% of patients die or suffer from recurrent infractions during hospitalization and up to 7% die within 1 month of discharge.
- These outcomes might be unreliable pharmacokinetics and low bioavailability, nonspecific inhibition of different factors, incorrect dose, and frequent monitoring.
- Fondaparinux, the first synthetic pentasaccharide that selectively inhibits activated factor Xa by binding to a centrally located antithrombin coagulation factor.
- The prefilled 2.5-mg-once-daily subcutaneous injection of fondaparinux needs no dose adjustment for any age, it is absorbed rapidly and completely, and results in 24-h coverage with no need to monitor coagulation parameters with no clinically relevant interactions.
- Multiple RCTs have demonstrated the safety and efficacy of this prefilled anticoagulant in various clinical situations and have unequivocally proved that fondaparinux is better in reducing the incidence of recurrence and bleeding events.
- However, there are limited data showing whether the same results could be reproduced in the general Indian population in real-world practice with no pre-defined clinical settings like RCTs.

Objective

- Retrospective, longitudinal, real-world, observational study data was collected from the cardiology departments of multiple tertiary care centres over a period of 5 years.
- The EMR data of hospitalized ACS patients (n = 611), from January 2015 to January 2020, representing UA or NSTEMI or STEMI and were prescribed fondaparinux (2.5 mg once daily) to manage ACS were analyzed.
- Medical records of the patient visits from the baseline to a period of 180 days (6 months) were taken into consideration.

Type of ACS (%) - N=611



Outcome measured

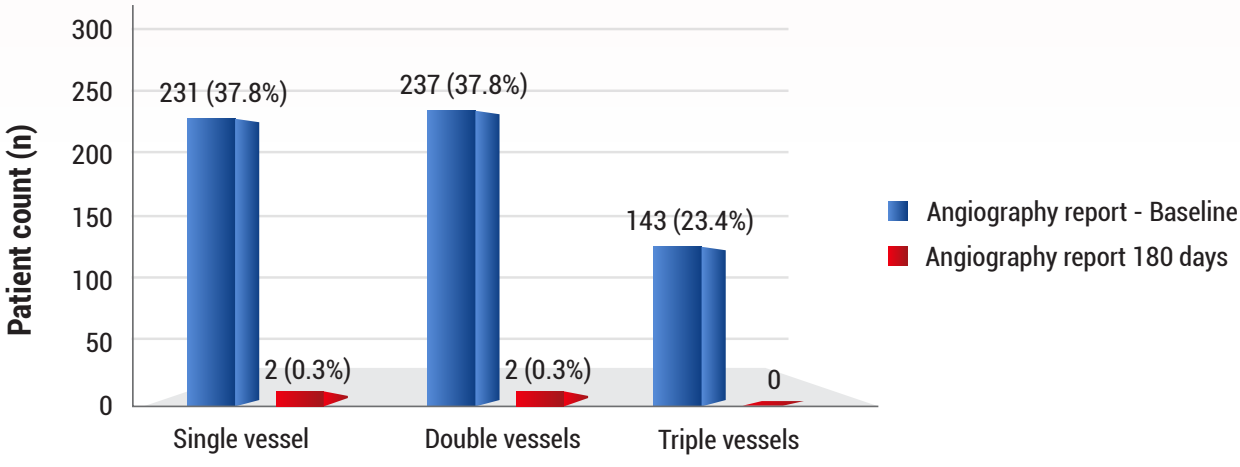
Effectiveness outcomes - Recurrence of symptomatic ACS event type of recurrence (STEMI, NSTEMI, UA) at initial hospitalization, at 30 and 180 days.

Tolerability outcomes - Major bleeding and minor bleeding at initial hospitalization, at 30 days, and at 180 days.

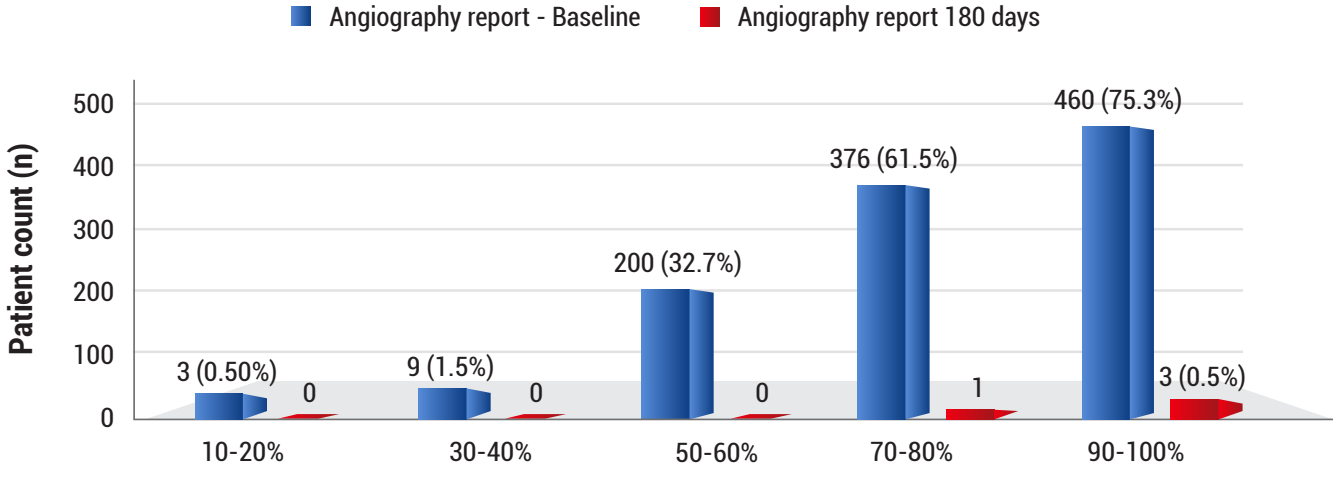
Results

- At baseline visit (during hospitalization) and at day 30, there were no recurrences (n = 0), while at day 180, only 0.65% (n = 4) events of recurrences had occurred, among which 0.16% (n = 1) recurrence events were NSTEMI and 0.49% (n = 3) were UA type.
- Major bleeding events did not occur during the entire study period, while minor bleeding events occurred in 0.98% (n = 6) patients during baseline (during hospitalization) and 0.16% (n = 1) patients within 30 days.
- None of the bleeding events were statistically significant (*P* value > 0.05).
- No incidences of stent thrombosis were reported during the entire study period.

A **Number of Coronary Vessel Involvement (N=611)**

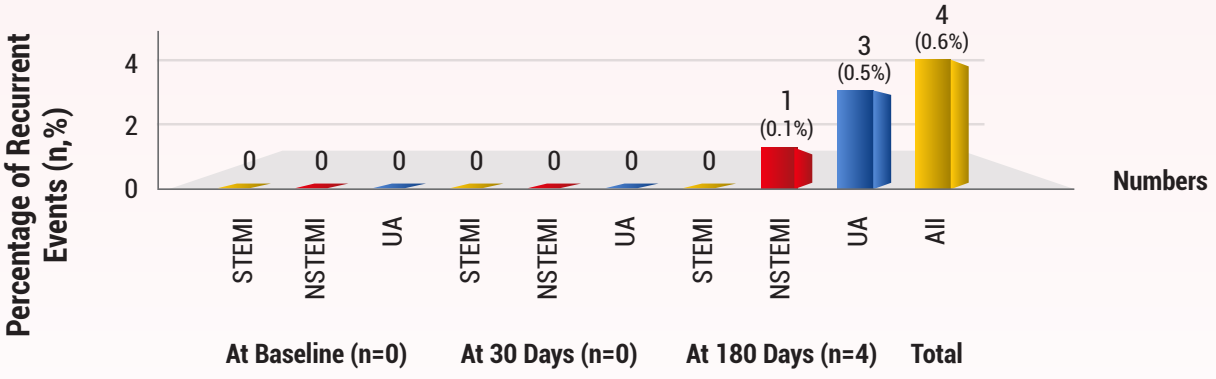


B **Severity of Stenosis (N=611)**

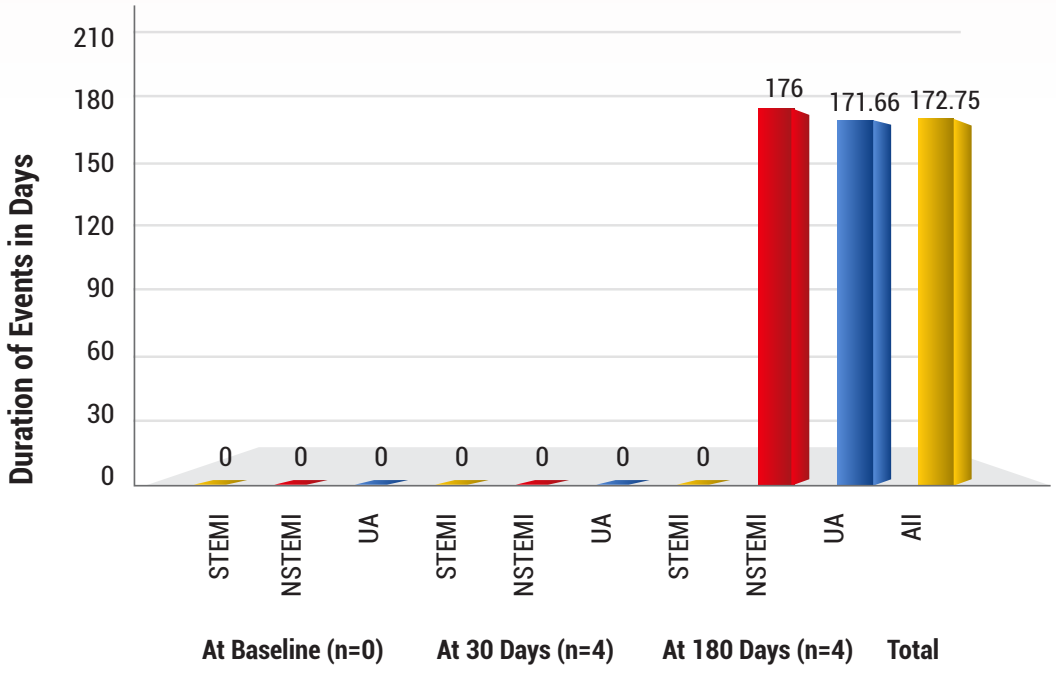


Results

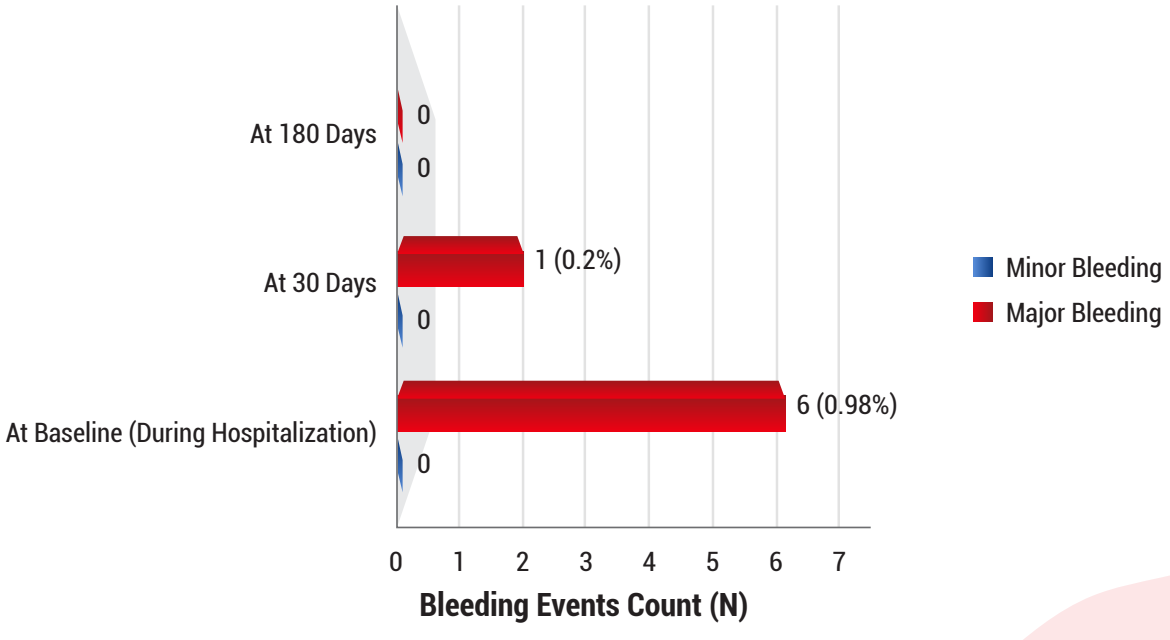
A Count of Recurrent Events (N=611)



B Duration of Recurrent Event from Baseline (N=611)



Bleeding Complication (n,%)



Conclusion

In the real world, fondaparinux was found to be effective and tolerable when used to manage symptomatic ACS patients regardless of revascularization procedure with no incidence of stent thrombosis, and minimal recurrent ACS and insignificant increase in bleeding events.

Take home points

1. The current RWE study was specifically designed to determine the effectiveness and tolerability of the fondaparinux prophylaxis in symptomatic Acute Coronary Syndrome (ACS).

2. The effectiveness was analyzed as recurrence of ACS and tolerability as total incidence of major bleeding during hospitalization, at 30 days and 180 days.

3. The study provided evidence of effectiveness and tolerability of fondaparinux and demonstrated it as a preferable choice in terms of management and prevention of ischemic events and major bleeding after initiation of the treatment in ACS patients in a real-world setting.

4. The positive effects of fondaparinux are due to its ability to initiate selective inhibition of factor Xa. It is also easy to use (2.5 mg pre-filled injection once daily for all ACS patients) as no dose adjustments are necessary, which limits dosing errors.

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