

A Retrospective Review of Premofix TRF Band, Andanza International, Meinhard, Germany for Hemostasis After Transradial Coronary Catheterisation

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Abstract

Transradial coronary catheterisation hemostasis strategies has been widely described having radial bands as golden standard. The present post marketing retrospective review assessed clinical outcomes of patients who have received TRF Premofix Band in real practice.

Aim to investigate the acute results of pain relief, comfort and possible complications.

Methods: Data obtained from the application of this bands in our centre from October 2022 to October 2023, in 1000 patients underwent radial approach. The primary purpose of this review is to determine the rate of possible complications and also the pain relief and the post procedural comfort.

Results: A total of 1000 patients were enrolled, all the patients underwent PCI procedures, having radial compression. Hemostasis was successfully performed to all patient.

In 3,8 % hematoma was observed. Radial artery occlusion (RAO) was discovered in less than 1% of cases. Due to the design of the product the ulnar artery was also observed. There was no obstruction of the ulnar artery (100%) and no aneurysms.

In total of 1000 patients with radial punctures, we have ret-respectively analysed that the mean age of patients was 64 ± 9.2 years age. Males were 687 and female were 313. BMI of patients was 27.6 ± 3.3 . 24% of patients were diabetics, and previous PCI underwent 16% of patients, CABG underwent 6% of patients.

Conclusion: Compared to analog bands the relatively smoother material, the 2ml semi automatic system, bigger compression pillow and extra fixation ability made the TRF Premofix Band is safe, comfort and effective, having low complications suggesting to be an effective approach for successful closure device of radial punctures.

Keywords: Hemostasis; Radial compression bands; Compression pillow

Introduction

First hemostatic bands were developed to achieve hemostasis in radial approach after invasive coronary procedures. While effectively reduce the time and minimise the complications of the bleeding after radial PCI, they did not improve the comfort and the potential risk of complications. Second generation of TR bands with improved design show better comfort and safety accompanied with high hemostasis results. In parallel with the intraoperative hemostatic agents and first generation of radial bands, the novel radial bands with bigger compression chambers, semi-automatic air deflation abilities, with softer and more flexible materials can contribute better to all the aims of hemostasis in our daily protocol in coronary interventions. Therefore, this review is conducted to demonstrate and highlight the advantages of Premofix TRF Band.

Methods

Study design and patient selection: Data obtained from one centre cohort of patients as a part of routine treatment after CAD between October 2022 to October 2023, there were no exclusion criteria and no patient was lost to the follow up.

Description of device: The Premofix TRF Closure band is a transparent compression band with semi-automatic syringe for a standardized aftercare of radial puncture. The device is designed for bilateral application and has a larger compression pillow that covers more surface. It has two sizes 23cm and 29 cm, consists out of transparent material, an innovative inflation syringe with standardized semi automatic deflation and extra fixation for syringe or connection valve.

Study procedure and data collection: This is an all-comer retro-

spective review; data are taken from clinical notes including in patient progress notes. Case report forms were completed for all patients and fully anonymized. Follow-up data were collected interviewing the patients.

Results

A total of 1000 patients were enrolled, all the patients underwent PCI procedures, having radial compression. Hemostasis was successfully performed to all patient.

In 3,8 % hematoma was observed. Radial artery occlusion (RAO) was discovered in less than 1% of cases. Due to the design of the product the ulnar artery was also observed. There was no obstruction of the ulnar artery (100%) and no aneurysms.

In total of 1000 patients with radial punctures, we have retrospectively analysed that the mean age of patients was 64 ± 9.2 years age. Males were 687 and female were 313. BMI of patients was 27.6 ± 3.3 . 24% of patients were diabetics, and previous PCI underwent 16% of patients, CABG underwent 6% of patients.

Discussion

The presented retrospective review was conducted to support the safety and the efficacy of Premofix TRF band in the real-world clinical practice. The acute results demonstrate the favourable safety and efficacy of the band.

Compared to first generation bands it is smoother, more comfortable and effective.

Study Limitations

The major limitation of the presented study is the observational design, and the retrospective analysis of the data. However, the observational data allow true representation of all comers population.

Conclusion

The relatively low rates of complications such as aneurysms, hematoma or obstruction of ulnar artery etc., after nearly a year and the comfort of pain relief demonstrates the unique product characteristics.

Premofix TRF band could be suggested as effective solution compared to other contemporary bands available in the market.

Disclosures

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