IOSR Journal of Dental and Medical Sciences (IOSR-JDMS)
e-ISSN: 2279-0853, p-ISSN: 2279-0861.Volume 17, Issue 9 Ver. 6 (September. 2018), PP 09-14
www.iosrjournals.org

Prospective Randomized Comparative Study Between Vasculomimetic Supera Stent And Drug Coated Balloons For Superficial Femoral Artery Disease

Prof.Dr. C . Saravanan Robinson M.S., M.Ch
(Professor& HOD, Department of Vascular Surgery, Madurai Medical College and Hospital, INDIA)
DR. M. JOYNER ABRAHAM., M.S., (Post Graduate, Department of General Surgery, Madurai Medical College and Hospital, INDIA)
Corresponding Author: Prof.Dr. C . Saravanan Robinson

Date of Submission: 31-08-2018 Date of acceptance: 15-09-2018

I. Introduction:

- Prevalence of peripheral arterial disease in men >55years is 4.5%
- Superficial femoral artery and proximal popliteal occlusive disease makes the majority of it
- Therapeutic options range from conservative to endovascular procedures to surgical bypass
- In our study , we try to compare the efficacy of vasculomimmetic SUPERA stents and paclitaxel coated balloons in treating superficial femoral artery disease in our limited setting and follow up.

AIM:

Compare between the vasculomimetic SUPERA stent and drug eluting balloons for Superficial Femoral Artery(SFA) disease in terms of

- Operating time
- Intra operative challenges
- Post operative complications
- Morbidity
- Early Outcome
- Efficacy
- Cost effectiveness.

METHODOLOGY:

- Study period: May 2016 to April 2018
- Study population:
  - Patients admitted with superficial femoral artery disease in Department of Vascular Surgery, GRH, MMC in the study period.

KEYWORDS:

- Superficial Femoral Artery Disease, Supera Stent, DCBs

INCLUSION CRITERIA:

- ✓ Patient presenting a score from 4 to 6 following Rutherford classification
- ✓ Patient is >18 years old
- ✓ Patient understands the nature of the procedure and provides written informed consent, prior to enrolment in the study
- ✓ De novo lesions located in the superficial femoral artery, suitable for endovascular therapy
- ✓ There is angiographic evidence of a patent deep femoral artery
- ✓ The target lesion has angiographic evidence of stenosis > 50% or occlusion
- ✓ There is angiographic evidence of at least one-vessel-runoff to the foot

EXCLUSION CRITERIA:

- ✓ Presence of another stent in the target vessel that was placed during a previous procedure
- ✓ Previous open surgery in the same limb
- ✓ Patients with uncorrected bleeding disorders

✓ Patients contraindicated for antiplatelet therapy, anticoagulants or thrombolytics.
✓ Patients with known hypersensitivity to nickel-titanium and heparin, including those patients who have had a previous incidence of heparin-induced thrombocytopenia (HIT) type II
✓ Female patient with child bearing potential not taking adequate contraceptives or currently breastfeeding
✓ Any planned surgical intervention/procedure 30 days after the study procedure
✓ Any patient considered to be hemodynamically unstable at onset of procedure

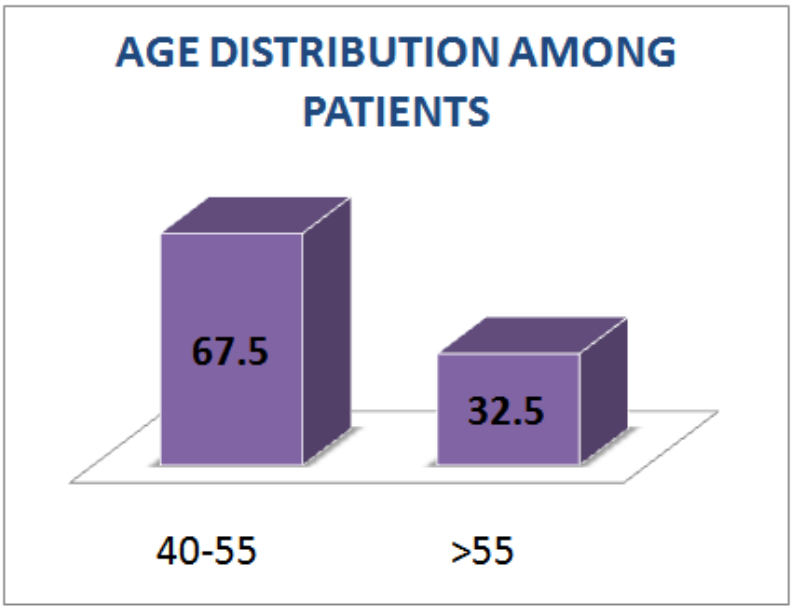
SAMPLE SIZE:
- Supera stent at 12 months patency varied between 85.6% to 89.8%
- At 12 months, the primary patency rates and TLR were both favorable for the DCB arm (primary patency, 82.2% *vs*. 52.4%, DCB *vs.* PTA, P<0.001) (ref)
- 95% - Confidence interval
- 80% - Power of the study
- Absolute error - 20
- Calculated required Sample size - 25.

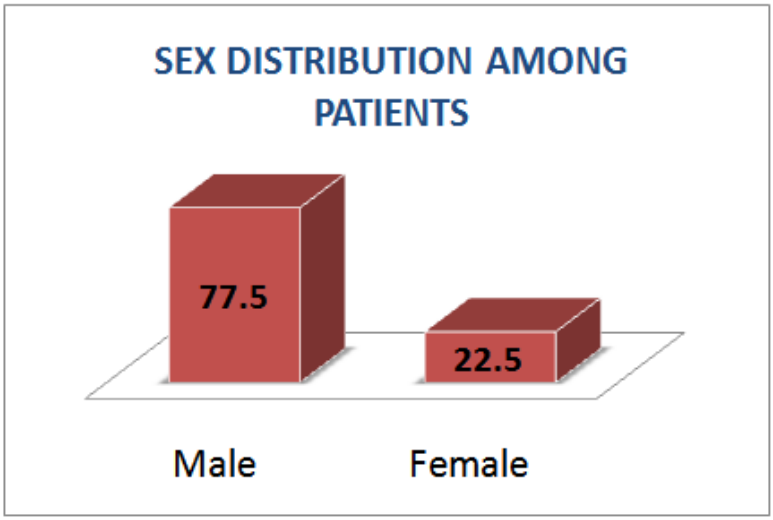
RANDOMISATION:
- Subjects were randomly allocated into two arms by BLOCK RANDOMISATION in order to ensure equal participants in both arms
- So 13 blocks with 4 patients in each were created
- Every 5th patients picked up their block number by lottery method
- In a period of two years the calculated required sample size of 25 in both arms could not be reached and hence a interim analysis with 20 in each arm is done

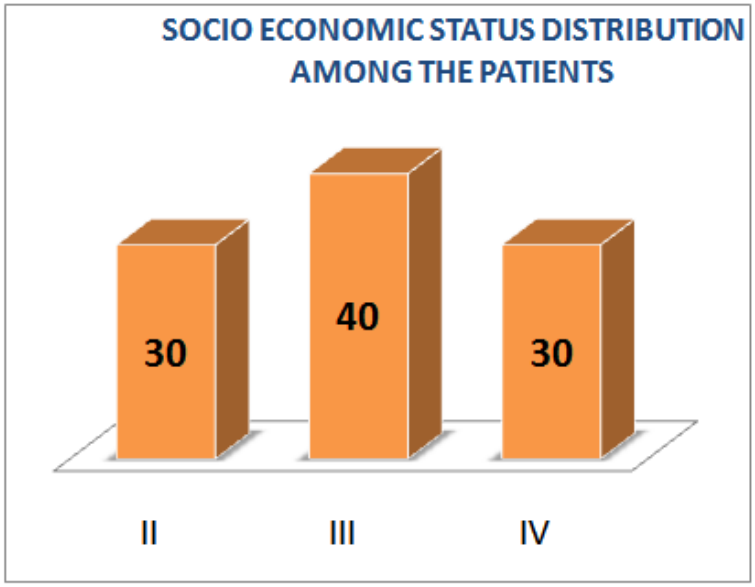
END POINT:
➢ PRIMARY
✓ Patency and
✓ Target Lesion Revascularisation(TLR)
➢ SECONDARY
✓ Complication
✓ Recurrence

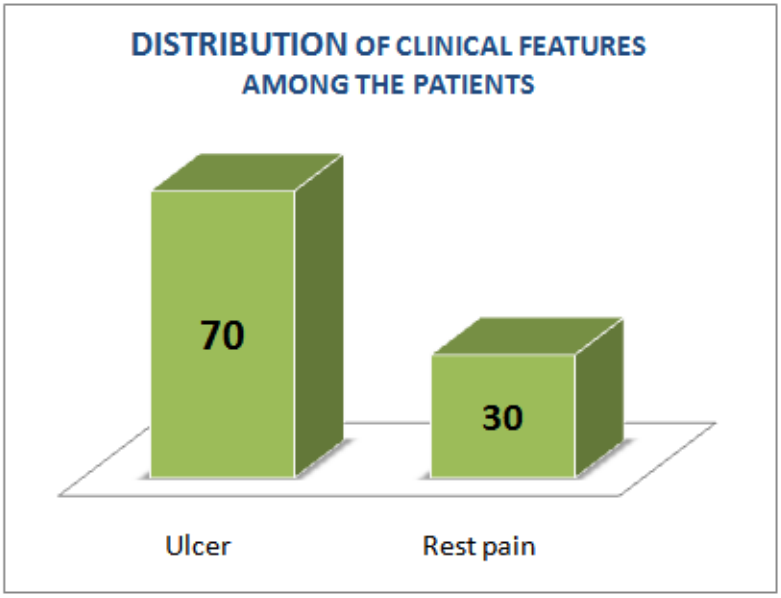
II. Results:

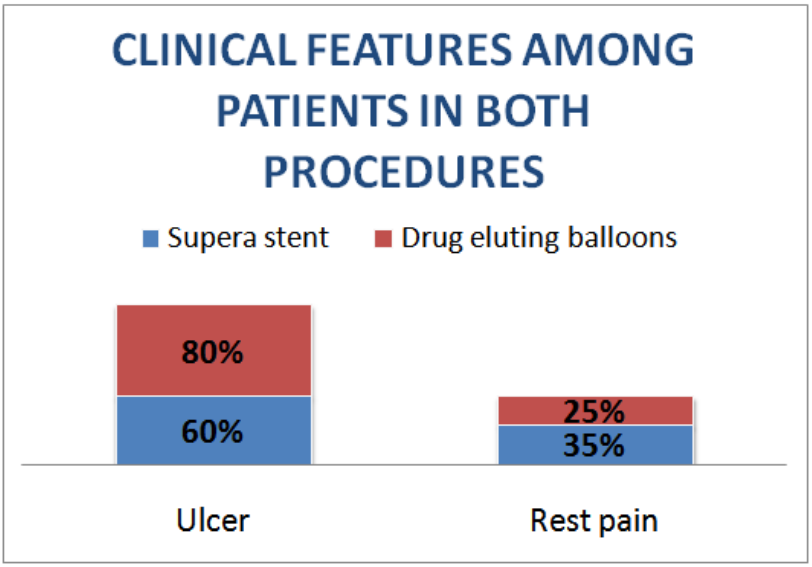
- A total of 20 patients were recruited and followed up in each of the two arms in a period of two years
- 80%(16) of them were males
- Only FIVE PATIENTS developed vessel complications
- All the 5 patients belong to the stented arm.

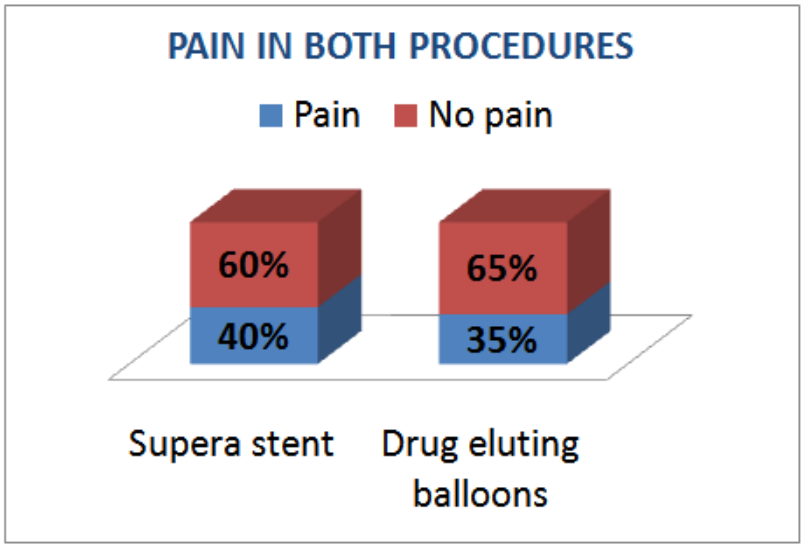


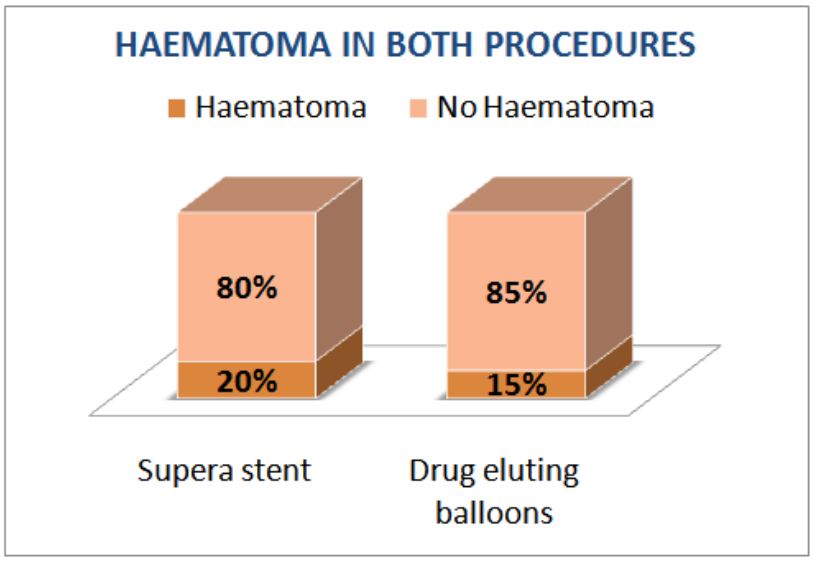

SEX DISTRIBUTION AMONG PATIENTS
77.5
22.5
Male
Female

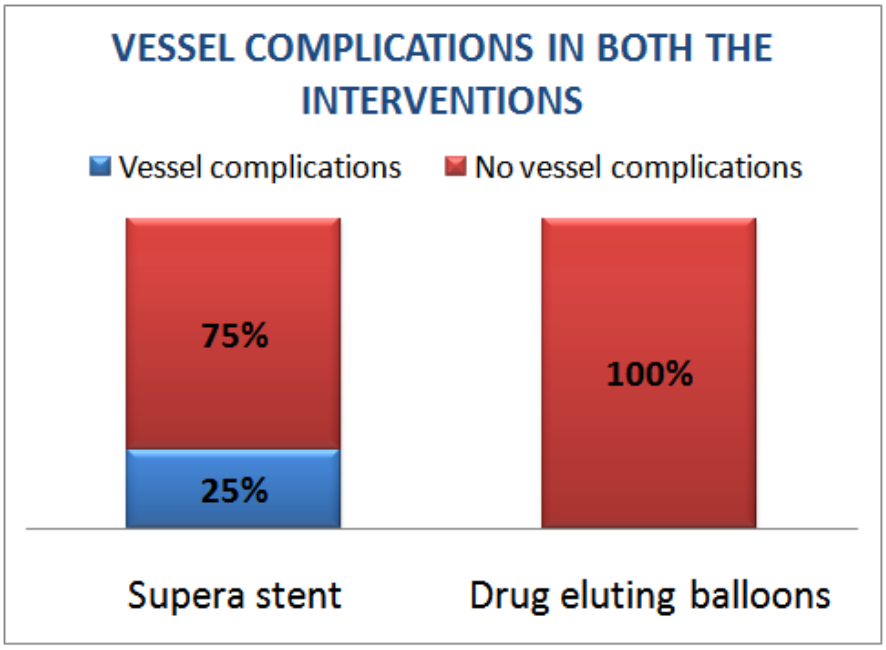

SOCIO ECONOMIC STATUS DISTRIBUTION AMONG THE PATIENTS
30
40
30
II
III
IV


DISTRIBUTION OF CLINICAL FEATURES AMONG THE PATIENTS
70
30
Ulcer
Rest pain


CLINICAL FEATURES AMONG PATIENTS IN BOTH PROCEDURES
Supera stent
Drug eluting balloons
80%
60%
25%
35%
Ulcer
Rest pain


PAIN IN BOTH PROCEDURES
Pain
No pain
60%
40%
65%
35%
Supera stent
Drug eluting balloons


HAEMATOMA IN BOTH PROCEDURES
Haematoma
No Haematoma
80%
20%
85%
15%
Supera stent
Drug eluting balloons



TYPES OF VESSEL COMPLICATIONS:

- 3 patients had distal embolization intra operatively while employing supera stent
- All the 3 achieved assisted primary patency by distal thrombolysis.
- 2 patients developed thrombus distally in the post op period in supera stent arm
- We had to do bypass procedure to achieve secondary patency in these two patients

	SUPER STENT	DRUG ELUTING BALLOONS	P VALUE
TIME FOR SURGERY	**1.28(0.17)**	**1.32(0.11)**	**0.467**
DISCHARGE FROM HOSPITAL	**4(0.85)**	**4.05(0.82)**	**0.852**
COST OF SURGERY	**1.67(0.22)**	**1.17(0.07)**	**0.000**

	SUPER STENT	DRUG ELUTING BALLOONS	P VALUE
PRIMARY PATENCY **ACHIEVED** **NOT ACHEIVED**	**18(90%)** **2(10%)**	**20(100%)** **0(0.0%)**	**0.037**
SECONDARY PATENCY **ACHIEVED** **NOT ACHIEVED**	**20(90%)** **0(30%)**	**20(100%)** **0(0%)**	

LIMITATIONS OF OUR STUDY:

- Short duration of study
- Smaller sample size
- Ongoing study & interim results

- DCBs cannot be used in calcified vessels and hence excluded from the study
- Multicentric Randomized Control study and meta analysis needed to emphasize the results of our study

III. Conclusion:

- Between the two procedures, in limited period of follow up in our limited setting DCB's had statistically significant better outcome compared to vasculomimetic supera stent in superficial femoral artery disease.
- We have to further follow up for longer periods and conduct multi centric randomized control trials to determine the long term outcomes.

Bibliography:

[1]. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2842962/
[2]. Madhan Shanmugasundaram, Drug coated balloon in Peripheral artery disease. doi:10.1016/j.carrev.2018.04.017
[3]. https://clinicaltrials.gov/ct2/show/record/NCT02804113
[4]. URL: http://www.clinicaltrials.gov. Unique identifier: NCT00986752.
[5]. http://circinterventions.ahajournals.org/

Dr Nandyala Pushpamala" . Prospective Randomized Comparative Study Between Vasculomimetic Supera Stent And Drug Coated Balloons For Superficial Femoral Artery Disease."IOSR Journal of Dental and Medical Sciences (IOSR-JDMS), vol. 17, no. 9, 2018, pp 09-14.