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SPORTS Trial

Investigator-Sponsored[1], Core-lab Adjudicated, Randomized Controlled Trial Evaluating Drug-Eluting Stent or Primary Bare Nitinol Stent Application Versus Drug-Coated Balloons in Long SFA Lesions

OBJECTIVE

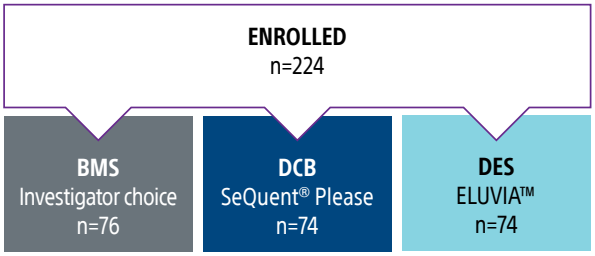
Compare angiographic and clinical outcomes of TASC C/D SFA lesions after treatment with BMS v. DCB v. DES

TRIAL DESIGN

Investigator-sponsored | Prospective | Core-lab adjudicated | Multi-center | Three-arm randomization (1:1:1) of BMS v. DCB v. DES

KEY INCLUSION CRITERIA

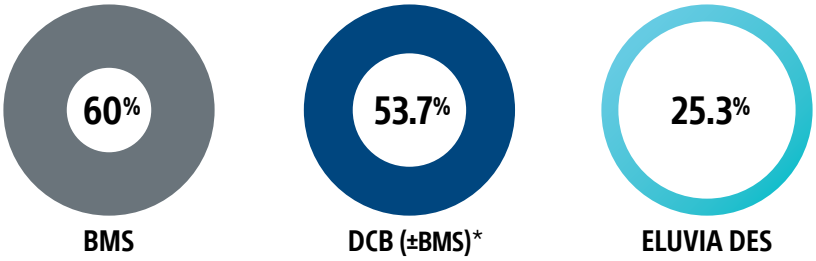
SFA/PPA lesion lengths at least 130mm (treatment length ≥ 150mm) | Rutherford classes 2–4 | Diameter stenosis ≥ 70%



Eluvia DES Proved Statistically Superior to BMS in Long, Complex Lesions.

- Eluvia vs BMS p for superiority <0.0001
- Percent diameter stenosis was 112% greater for DCB than Eluvia, but these groups were not compared statistically for the primary endpoint.
- DCB was non-inferior to BMS in terms of diameter stenosis at 1 year.

1-YEAR ANGIOGRAPHIC DIAMETER STENOSIS



BMS had **137% more** diameter stenosis than Eluvia DES at 1-year.

DCB had **112% more** diameter stenosis than Eluvia DES at 1-year.

High Rate of Bail-Out Stenting in DCB Arm

In long, complex lesions,

58%

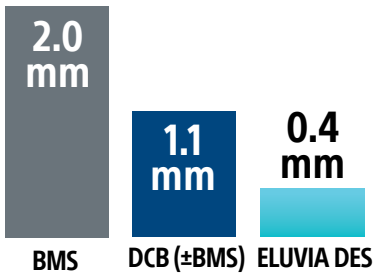
of lesions treated with a DCB required a bail-out BMS which provided no additional clinical benefit versus BMS alone.

* DCB in SPORTS trial was B. Braun SeQuent® Please Drug-Coated Balloon

1. Tepe, G. SPORTS Trial: Drug Eluting Stent or Primary Bare Nitinol Stent Application versus Drug Coated Balloons in Long SFA Lesions. Presented at TCT 24 Oct 2023.

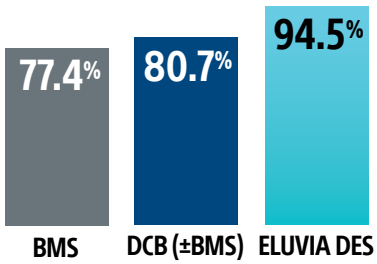
1-Year Late Lumen Loss and Freedom from CD-TLR Differed Statistically Across Groups, Favoring Eluvia DES

1-YEAR LATE LUMEN LOSS



p<0.0001

1-YEAR FREEDOM FROM CD-TLR



K-M, p=0.015

BASELINE CHARACTERISTICS

Patient Characteristics	BMS n=76	DCB n=74	DES n=74
Age (Years)	67	70	68
Male Gender (%)	72	66	60
Diabetes Mellitus (%)	26	30	23
Renal Disease (%)	3	12	8
Current Smoker (%)	58	60	55

Lesion Characteristics	BMS n=76	DCB n=74	DES n=74	p-value
Mean Lesion Length (mm)	**227**	**221**	**235**	**0.57**
Occlusion (%)	**74**	**70**	**85**	**0.08**
Occlusion length (mm)	151	175	179	0.18
RVD (mm)	5.2	5.0	5.3	0.01
MLD in lesion (mm)	0.3	0.4	0.2	0.18
Mod/Severe Calcification (%)**	67.1	71.7	58.1	0.36
Diameter stenosis in lesion (%)	94.2	92.6	96.8	0.10

AVERAGE LESION LENGTH & OCCLUSION PERCENTAGE IN PERSPECTIVE ACROSS ELUVIA V. BMS RCTs

** PACSS Grade 3/4 may be considered moderate to severe calcification

2. Gouëffic, Y, et al. Efficacy of a Drug-Eluting Stent Versus Bare Metal Stents for Symptomatic Femoropopliteal Peripheral Artery Disease: Primary Results of the EMINENT Randomized Trial. Circulation: Vol. 146, No. 21; 18 Oct 2022. https://doi.org/10.1161/CIRCULATIONAHA.122.059606

RANGER DRUG COATED BALLOON

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Instructions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions. **INTENDED USE / INDICATIONS FOR USE:** The Ranger Drug Coated Balloon (DCB) is indicated for percutaneous transluminal angioplasty (PTA) of de novo or restenotic lesions up to 180 mm in length located in native superficial femoral and proximal popliteal arteries (SFA/PPA) with reference vessel diameters of 4 mm to 7 mm. **CONTRAINDICATIONS:** Use of the Ranger DCB is contraindicated in: • Patients with known hypersensitivity to paclitaxel (or structurally-related compounds). • Patients who cannot receive recommended antiplatelet and/or anticoagulation therapy. • Women who are breastfeeding, pregnant, or men intending to father children. • Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the delivery system. • Coronary arteries, renal arteries, and supra-aortic/cerebrovascular arteries. **WARNINGS:** • To reduce the potential for vessel damage, the inflated diameter of the balloon should approximate the diameter of the vessel segment to be treated. The inflated length of the balloon (shoulder to shoulder) may exceed the length of the lesion/stenosis by approximately 10 mm on either side within the targeted artery. • The safety of using multiple Ranger DCBs with a total drug dosage exceeding 9266 µg of Paclitaxel in a patient has not been studied. • Using a drug-eluting stent in conjunction with Ranger DCB at the same treatment site has not been studied. **PRECAUTIONS:** • The balloon catheter should be used only by physicians trained in the performance of percutaneous transluminal angioplasty. • The balloon catheter should be used with caution for procedures involving calcified lesions due to the abrasive nature of these lesions. • The balloon catheter is not intended for injection of contrast medium. • Full arterial wall apposition of the Ranger DCB is necessary for proper drug transfer to the vessel. • Do not touch, wipe, bend, or squeeze the balloon. Do not allow it to contact any liquids including organic solvents such as alcohol or detergents prior to insertion. Damage to the balloon coating or premature release of the drug may occur. • This product should not be used in patients with uncorrected bleeding disorders or patients who cannot receive anticoagulation or antiplatelet aggregation therapy. • If treating a long lesion (longer than the maximum balloon length available), each individual segment should be treated only once with a drug-coated balloon. Treat each segment with a new balloon and minimize overlapping of treated segments. **Pregnancy / Lactation** This product has not been tested in pregnant or breastfeeding women or in men intending to father children; effects on the developing fetus have not been studied and the risks and reproductive effects remain unknown. It is not recommended that the Ranger DCB be used in women attempting to conceive, or who are pregnant. Prior to use, careful consideration should be given to the continuation of breastfeeding, taking into account the importance of the procedure to the mother. It is not known whether paclitaxel is distributed in human milk. In lactating rats, milk concentrations appeared to be higher than maternal plasma levels and declined in parallel with the maternal levels. Mothers should be advised of the potential for serious adverse reactions to paclitaxel in nursing infants. **Drug Information** The mechanism of action by which paclitaxel reduces or reverses neointima formation and proliferation, leading to restenosis, as demonstrated in clinical studies has not been established. It is known that paclitaxel promotes the assembly of microtubules from tubulin dimers and stabilizes microtubules by preventing depolymerization. This stability results in the inhibition of the normal dynamic reorganization of the microtubule network that is essential for vital interphase and mitotic cellular functions. **Drug Interaction** Possible interactions of paclitaxel with concomitantly administered medications have not been formally investigated. Drug interactions of systemic chemotherapeutic levels of paclitaxel with possible concomitant medications are outlined in the labeling for finished pharmaceuticals containing paclitaxel, such as TAXOL™. **Carcinogenicity, Genotoxicity, and Reproductive Toxicology** No long-term studies in animals have been published in peer-reviewed literature to evaluate the carcinogenic potential of paclitaxel. Paclitaxel interacts with microtubules; this is the major mechanism by which it inhibits cell growth. One consequence is the loss of whole chromosomes via interactions with spindle microtubules during cell division. As such, paclitaxel is defined as an aneugen (agent causing an alteration in chromosome number). This indirect action is consistent with positive responses in in vitro and in vivo micronucleus genotoxicity assays, which detect DNA fragments. Positive results have also been reported for chromosomal aberrations in primary human lymphocytes. It is not known whether paclitaxel has a separate direct action on DNA in the generation of DNA strand breaks or fragments. It is negative in assays for gene mutation, including salmonella and CHO/HPRT. Paclitaxel administered via IV prior to and during mating produced impairment of fertility in male and female rats at doses > 1 mg/kg. Administration of paclitaxel during the period of organogenesis to rabbits at doses of 3 mg/kg/day caused embryo- and fetotoxicity. Maternal toxicity was also observed at this dose. No teratogenic effects were observed at 1 mg/kg/day; teratogenic potential could not be assessed at higher doses due to extensive fetal mortality. For comparison, the worst-case dose of paclitaxel delivered by the Ranger DCB (assuming maximum size and number of balloons used in a lesion) is 9266 µg, which is approximately 6 and 19 times less than the dose that saw effects in rats and rabbits, respectively, when normalizing to body weight. **Pre and Post Procedure Antiplatelet Therapy** It is strongly advised that the treating physician follow the Inter-Society Consensus (TASC II) Guidelines recommendations (or other applicable country guidelines) for antiplatelet therapy pre- and postprocedure. **ADVERSE EVENTS:** Potential adverse events include, but are not limited to, the following: • Allergic reaction (device, contrast medium, medications) • Arteriovenous fistula • Death • Hematoma • Hemorrhage/Bleeding • Hypotension/Hypertension • Infection/Sepsis • Pseudoaneurysm • Thromboembolic episodes • Vascular thrombosis • Vessel injury (e.g., dissection, perforation, rupture) • Vessel occlusion • Vessel spasm Potential adverse events not captured above that may be unique to the paclitaxel drug coating: • Allergic/immunologic reaction to drug (paclitaxel or structurally-related compounds) or coating or its individual components • Alopecia • Anemia • Blood product transfusion • Gastrointestinal symptoms • Hematologic dyscrasia (including leukopenia, neutropenia, thrombocytopenia) • Hepatic enzyme changes • Histologic changes in vessel wall, including inflammation, cellular damage or necrosis • Myalgia/Arthralgia • Peripheral neuropathy Apart from hypersensitivity reactions (allergic/immunologic reactions), the likelihood of paclitaxel related adverse events is low, due to the low exposure. There may be other potential adverse events that are unforeseen at this time.

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PI-1733104-AB