Clinical trial protocol

Helical stent (SUPERA™) and drug-coated balloon (Passeo–18 Lux™) for recurrent cephalic arch stenosis: Rationale and design of arch V SUPERA–LUX Study

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Abstract

Background: The treatment options for cephalic arch stenosis are limited and standard of care remains at crossroads – none are ideal and there is currently no gold standard. Endovascular techniques are now the preferred primary therapeutic option because they are minimally invasive and better tolerated by haemodialysis patients who have multiple comorbidities. However, conventional plain old balloon angioplasty, bare metal stenting and stent grafts all have their limitations. The aim of this trial is to evaluate whether the helical SUPERA™ stent (Abbott Vascular, Santa Clara, CA, USA), which has a higher degree of flexibility and resistance to compressive forces compared to traditionally laser-cut nitinol stents, combined with a drug-coated balloon (Biotronik Passeo-18 Lux™) to minimize the neointimal hyperplasia effect, can improve patency and reduce reintervention rates.

Methods and results: Arch V SUPERA-LUX is a pilot investigator-initiated single-centre, single-arm prospective study. Twenty patients with a brachiocephalic fistula within 6 months of initial plain old balloon angioplasty for significant cephalic arch stenosis will be recruited for treatment with SUPERA and drug-coated balloon. The primary objectives are immediate angiographic and procedural success, primary patency and functional fistula at 1 week, 8 weeks, 6 and 12 months. The results from eight patients treated prospectively as proof of concept have shown primary patency of 83.3% at 1 year with 100% technical and procedural success rates. Enrolment for the Arch V SUPERA-LUX study is expected to be completed at the end of 2019.

Conclusion: The Arch V SUPERA-LUX study is the first trial to evaluate whether SUPERA stent implantation and drug-coated balloon use can provide superior protection against restenosis compared to traditional angioplasty, bare metal stents and stent grafts in recurrent cephalic arch stenosis. Initial pilot results are encouraging but longer follow-up is required to truly test this technique.

Trial registration: This study is registered on ClinicalTrials.gov NCT03891693.

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Introduction

For patients with end-stage renal failure (ESRF), the creation of an autogenous arteriovenous fistula (AVF) is the recognized current gold standard for providing vascular access.[1] Advantages include improved haemodialysis initiation time, improved dialysis quality, better maintenance of accesses and generally better patient outcomes. However, haemodialysis accesses eventually fail due to the formation of venous stenosis caused by trauma from the surgical access creation and repeated percutaneous punctures. The brachiocephalic arteriovenous fistula (BCF) is usually the second recommended choice if a radiocephalic fistula cannot be formed.[2] Unfortunately, the BCF is subject to dysfunction, most frequently due to stenosis formation in its only venous outflow tract, the cephalic arch.[3]

The cephalic arch is broadly defined as the final bridge of the cephalic vein before it joins the axillary vein to become the subclavian vein.[3] External compressional forces from the deltopectoral and claviculo-pectoral fascia, variability of the angle of the arch vein insertion into the axillary vein, and a large number of valves in the arch vein in close proximity to the insertion point are some unique anatomical properties that lend itself physiological peculiarities that lead to alterations in venous haemodynamics when arterialized.[3,4] Increased venous pressures and turbulent venous flow cause endothelial injury with resultant medial hypertrophy and neointimal hyperplasia (NIH).[5] The collective outcome is what we label as cephalic arch stenosis (CAS). CAS is seen in up to 77% of dysfunctional BCFs and in 15% of failing AVFs overall.[6] For patients with recurrent and tight CAS, the treatment options are limited and standard of care remains at crossroads – none are ideal.

There are endovascular and open surgical therapeutic options to treat CAS but there has been a notable shift to a minimally invasive endovascular approach. It is believed that this strategy is associated with lower morbidity and mortality as well as quicker recovery, especially important in ESRF patients with multiple comorbidities.[7]

The SUPERA™ peripheral stent (Abbott Vascular, Santa Clara, CA, USA) is a self -expanding stent and has a high degree of flexibility and resistance to external compression compared with traditional laser-cut nitinol stents.[8] In particular, it maintains the round open lumen in challenging anatomies, such as in the popliteal artery.[9] With the SUPERA stent's ability to mimic the anatomy's natural movement while optimizing luminal gain, it has been shown to be effective when treating the dynamic environment of the superficial femoral artery (SFA) and proximal popliteal arteries.[8] Extending this concept to the cephalic arch, this type of stent technology may resist the compressive forces at work by the overlying clavi-pectoral fascia and harmonize with the multi-modal flexion/extension and adduction/abduction forces around the shoulder joint. The Passeo-18 Lux™ (Biotronik Asia Pacific Pte Ltd, Singapore) drug-coated balloon (DCB) is packaged with a low dose of paclitaxel. Recent studies have shown that low-dose coating of paclitaxel with this DCB is useful for preventing restenosis, decrease lumen loss and target lesion revascularization in the SFA.[10]

The use of the SUPERA stent in the cephalic arch has not been studied but may potentially offer protection from rupture of the arch vein and create a material barrier to prevent the development of NIH. With the additional use of a DCB, the NIH effect that is responsible for restenosis may be further impeded.

The hypothesis is that the use of SUPERA stent implantation and drug-eluting balloon (DEB) can provide superior protection against restenosis compared to traditional plain old balloon angioplasty (POBA) and/or bare stents in recurrent CAS.

Materials and methods

Patients

Arch V SUPERA-LUX is a Singapore General Hospital (SGH) investigator-initiated pilot single-centre, single-arm prospective study. Approval has been obtained from the local Human Research Ethics Committee (CIRB Ref: 2018/2557). Twenty ESRF patients who are on follow-up with the Departments of Vascular Surgery and Renal Medicine for recurrent stenosis within 6 months of initial POBA for significant CAS will be recruited for treatment with the stated stent and DEB. There are no restrictions based on gender and race.

Inclusion criteria

A patient is eligible for inclusion in the study if all the following criteria are fulfilled:

- Informed consent obtained;
- Patient aged ⩾21 years and ⩽90 years;
- Chronic background treatment with daily Acetylsalicylic Acid (Aspirin);
- Patients with significant recurrent CAS within 6 months of initial POBA, diagnosed either clinically or with Duplex ultrasound;
- Post angioplasty cephalic arch lumen size between 5 and 7 mm maximum diameter.

Exclusion criteria

- CAS <50% stenosis or diameter >7 mm;
- Patients with previous cephalic arch stenting bare metal stents or stent graft (SG));
- Concomitant fistula inflow problem (e.g. juxta-anastomotic) that cannot be corrected optimally

during the intervention (>30% residual stenosis or angiographic lumen of <3 mm);
– Patients with minor or major cephalic arch rupture during POBA procedure and the rupture point cannot be adequately sealed off during the procedure requiring a covered stent or open conversion;
– Cephalic arch lesion length of <10 mm or greater than 10 cm;
– Patients with uncontrolled hypertension;
– Pregnant women or women of childbearing potential who are not following an effective method of contraception;
– Contraindication to aspirin or clopidogrel usage;
– Mental condition rendering the subject unable to understand the nature, scope and possible consequences of the study, or language barrier such that the subject is unable to give informed consent;
– Uncooperative attitude or potential for non-compliance with the requirements of the protocol making study participation impractical;
– Patients who do NOT have impaired renal function;
– Occluded or thrombosed fistula;
– Concomitant central venous stenoses;
– Where final angioplasty treatment requires a stent or DEB of >8 mm in diameter
– Metastatic cancer or terminal medical condition;
– Blood coagulation disorders;
– Limited life expectancy (<6 months);
– Sepsis or active infection;
– Allergy or other known contraindication to iodinated media contrast, heparin or paclitaxel.

Data including demographics, haemodialysis parameters, sonographic findings and procedural details will be collected and stored in a password protected Excel database (Microsoft Excel 2010, Redmond, WA, USA).

SUPERA stent

SUPERA is a self-expanding stent that has a unique design of six pairs of nitinol wires interwoven to form a helical structure. This allows the stent to resist kinking while maintaining a large lumen through a 180° twist. It is delivered through a 6Fr sheath and is introduced over a 0.018″ delivery platform. In Singapore, it is available in 4–7 mm diameters and lengths from 40 to 150 mm.

Passeo-18 Lux DCB

The Passeo-18 Lux paclitaxel-releasing percutaneous transluminal angioplasty (PTA) balloon, received CE-marking in January 2014. The DCB is homogeneously coated with 3 μg paclitaxel/mm^2 balloon surface incorporated in a delivery matrix (excipient) of n-Butyryl tri-n-hexyl Citrate (BTHC). Paclitaxel is delivered to the vessel wall upon expansion of the balloon. A sheath protects the balloon in order to keep its factory-made profile and drug coating and is used as an insertion aid during insertion of the catheter through the introducer sheath. One radiopaque marker is located at each end of the balloon to facilitate fluoroscopic visualization and positioning of the balloon towards and across the lesion. Recommended delivery of the 7-mm-diameter DCB, which was routinely used in the pilot study, is through a 5Fr sheath but to minimize drug loss during passage, the sheath was upsized to a 6Fr system. The balloon is delivered over a 0.018 in platform.

Procedure

All procedures will be performed with the patient in the supine position and under local anaesthesia and sedation as required. No intravenous antibiotics are required. The BCF will be punctured in an antegrade fashion, usually just proximal to the antecubital fossa and an initial digital subtraction fistulogram will be performed with a 6Fr sheath. The CAS will be crossed with a Berenstein 1 catheter (Cordis Corporation, Milpitas, CA, USA) and a 0.018″ guidewire (V18 Control, Boston Scientific, Marlborough, MA, USA). DCB and SUPERA stent deployments need to be performed over a 0.018″ platform wire. The index lesion in the fistula is treated in the standard fashion. During the standard fistula intervention (SFI), an image must be acquired showing the trial index stenosis before intervention with a marker of known diameter in the image (e.g. a 6Fr sheath, a 5Fr catheter).

The lesion is pre-dilated with a standard high-pressure balloon (Biotronik Passeo-35 HP balloon). The DCB (Passeo-18 Lux) is subsequently implanted and inflated for 2 min to allow maximal drug transfer to the vessel wall. It should be 2 cm longer than the area treated during SFI (1 cm overlap proximal and distal) to avoid geographical miss (Figure 1(a)). The DCB will be 0.5–1 mm bigger at burst pressure than the biggest balloon used in the SFI (Figure 1(b)). The helical SUPERA stent is then implanted as per Instruction for Use (IFU) and should sit 2 mm distal to the cephalic arch and cover the original SFI but within the DCB zone (Figure 1(c)). The stent is then post-dilated with the standard high-pressure POBA balloon for the stent size and usually 1 mm bigger than the DCB used (Figure 1(b)). The balloon length should stay within the zone of the DCB to avoid unnecessary barotrauma and cause neointimal hyperplasia (NIH) outside the untreated DCB zone. The stent should not cage the axillary vein to prevent future access creation.

Two further images must be acquired:

– An image of the cephalic arch post DCB and post stent deployment;
– A completion angiogram image with a marker of known diameter in the image.
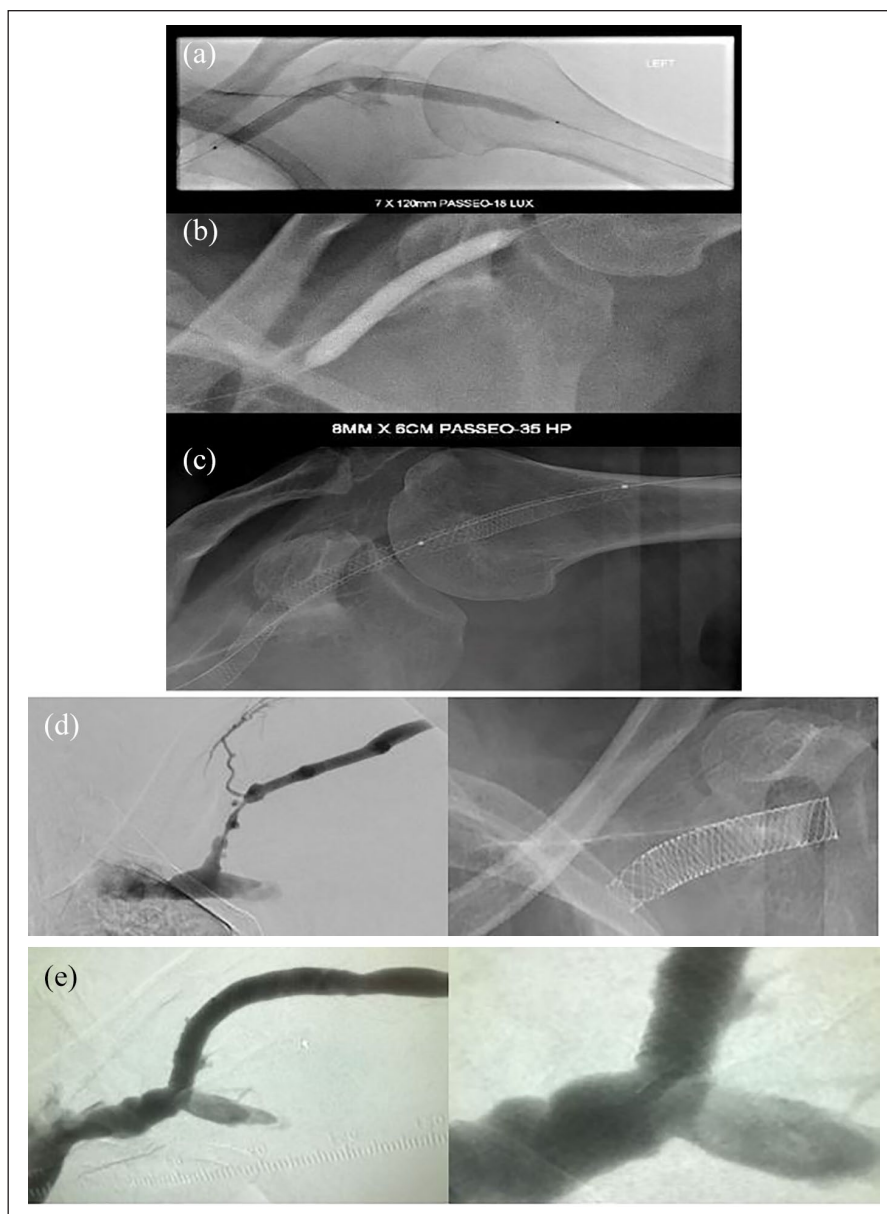
Figure 1. (a) The cephalic arch (CA) is prepped with a high-pressure (HP) balloon, which is appropriate for the vessel diameter and the same size drug-coated balloon (DCB) is used (usually 7 mm diameter) and inflated for a minimum of 2 min to allow optimal paclitaxel transfer to the vessel. (b) Biotronik Passeo-35 HP balloon used to prepare the CA prior to SUPERA™ stent implantation. Balloon size is normally 1 mm larger than the stent size to be deployed. Usually, we have been implanting 7 mm diameter stents in the CA, so an 8 mm diameter HP balloon is used for vessel preparation. (c) 7 mm × 100 mm SUPERA stent fully deployed. This should stay within the DCB zone to minimize the risk of edge stenosis from neointimal hyperplasia (NIH). (d) Tight CA stenosis which needs to be adequately prepared (shown on the left) prior to stent implantation. SUPERA packing technique should be employed in the tightest stenotic or calcified areas. (e) Stent deployment should be done under an intense magnification in an antero-posterior projection and the stent deployment should start about 5–7 mm into the axillary vein and stent gradually pulled back to lie finally 1–2 mm into the cephalic-axillary vein junction.

During each follow-up, ultrasound duplex will be performed (Figure 2). Patients will have to return for follow-up at:

1. Post-op (>24 h and <7 days post-trial procedure);
2. 8 weeks post-op (±2 weeks);
3. 6 months post-op (±2 weeks);
4. 12 months post-op (±2 weeks).

Post procedure, patients will be started on dual anti-platelet agents for 3 months with proton pump inhibitor cover.

	Enrolment	Allocation	STUDY PERIOD			
			Post-allocation			
TIMEPOINT	-t_1	Day 0	1 week post-op	8 weeks follow-up	6 months follow-up	12 months follow-up
ENROLMENT:						
Outpatient Visits	X					
Physical Examination	X					
Eligibility screen	X					
Informed consent	X					
Allocation		X				
INTERVENTIONS:						
Fistuloplasty with SUPERA™ stent and Passeo-18-Lux DCB		X				
ASSESSMENTS:						
Physical Examination			X	X	X	X
Duplex Ultrasound			X	X	X	X
Adverse Events			X	X	X	X

Figure 2. Schedule of enrolment, interventions and assessments according to the SPIRIT 2013 Statement: Defining Standard Protocol Items for Clinical Trials.

Endpoints

The primary endpoints are as follows:

1. Immediate: angiographic success (<30% residual stenosis within the stent and minimal luminal size should reach 5 mm). Any procedural complication such as cephalic arch rupture/bleeding/acute vessel thrombosis or stent migration/procedural related death;
2. Intermediate: functional fistula at 1 week, 8 weeks, 6 and 12 months;
3. Primary patency (stenosis <50%) by Duplex ultrasound at 12 months;

The secondary endpoints are to assess:

4. Access circuit thrombosis;
5. Interventions per year;
6. Access circuit restenosis/stent fracture;
7. Access circuit infection;
8. Need for bypass revision surgery;
9. Mortality.

The expected benefits include improved AVF patency, delay of onset of cephalic arch vein restenosis, reduced number of reinterventions and admissions to hospital and improved health economics. For our study, standard definitions based on the Society of Interventional Radiologists (SIRS) guidelines were used.[6] Technical success is defined as the successful implantation of the stent with <30% residual angiographic stenosis. Primary patency was defined as uninterrupted patency after intervention until the next access thrombosis or reintervention. Anatomic success was defined as having less than 30% residual diameter stenosis and procedural success was defined as anatomic success with at least one indicator of haemodynamic or clinical success.

Statistical analysis

Descriptive statistics will be presented as proportions or median (range) for categorical and continuous data, respectively. Patency of intervention is defined as the duration between the index intervention to the time another intervention was required to maintain access patency. Patency will be presented as the Kaplan–Meier curves and compared using the paired log-rank test. P values of less than 0.05 are considered to be statistically significant. Statistical analysis will be performed using R version 3.4.2.

Preliminary results

As a proof of concept, we have performed eight such cases (five females; mean age 69.3 ($\pm$8.7) years) of concomitant SUPERA CAS stenting and DCB and followed them prospectively. These patients are separate from the proposed 20 patients to be recruited to this study and all had a

single lesion at the arch with no other concomitant access circuit problems. All lesions bar one were restenosis within 6 months of POBA. There was 100% technical and procedural success rate. Two patients have subsequently died from unrelated causes and at 3 months, there were no further interventions on their access circuit. Primary patency at 1 year was 5/6 (83.3%). In one patient, around her 1-year follow-up, there was an in-stent stenosis of >80%, which was symptomatic and was POBA with no complications. One patient had to be re-imaged with a diagnostic fistulogram within 6 weeks of her procedure for persistent high venous pressure. There was no problem with her stent and no intervention was performed. There may have been a positional issue with the needles on dialysis as this problem resolved spontaneously. The median SUPERA stent diameter chosen was 7 mm (range = 6–7 mm) with a median stent length of 80 mm (range = 60–100 mm). There were no cases of arch vein rupture or dissection. There have been no stent fractures during follow-up. No BCFs have been lost or abandoned during follow-up.

Technical issues we have found from our experience of SUPERA stent deployment in the cephalic arch are that there is a tendency for the stent to be pushed in centrally during the post-dilatation process when introducing the balloon into the stent over the 0.018″ guidewire. We now routinely change out after stent deployment to a stiffer 0.035″ wire such as the Supracore® (Abbott Vascular) and have found that this platform gives more stability and prevents the stent from moving in while passing up the post-dilatation balloon (Figure 1(c)). We have also learned that the initial deployment of the stent should be done under high IR magnification with the road map so that you can clearly see the cephalic–axillary junction. It is easier to pullback the stent from a central position than to push it in. We have routinely 'packed' the stent where the stenotic lesion was located and it is important to vessel prep the cephalic vein to allow the stent to lie well otherwise stent elongation will ensue (Figure 1(d)). Sometimes, if the arch–axillary vein junction is not clear, the wire can be placed into the basilic vein to form a curve to identify the junction better (Figure 1(e)).

Discussion

The cephalic arch vein is unique in that it is subjected to both the compressive forces from the overlying clavi-pectoral fascia as well as the NIH effect from altered haemodynamics and wall shear stress (WSS) from the BCF. The literature has shown that usually only one of these components is altered during treatment at one time, for example, stenting will deal with compression but not with the NIH effect and with DCB vice versa.

POBA is associated with technical failure (24%) and rupture of the arch vein (6%), with very low primary patency rates of 42% and 23% at 6 and 12 months, respectively,[6] while bare metal stents fair equally poorly, with reported patency of 39% and 0% at those same time-points with a high rate of stent fracture.[11] There has been recent interest in the use of SGs as a primary treatment of CAS. The use of an SG not only offers protection from rupture of the arch vein but may also create a material barrier to prevent the development of NIH.[12] In addition, SG with greater flexibility may conform better to the hostile anatomy of the cephalic arch, reducing risks of stent migration, stent collapse and in-stent stenosis.[13] A recent CAS meta-analysis from our group found 82.7% and 44.0% primary patency at 6 and 12 months, respectively, using SG,[14] but problems remain with development of edge stent stenosis requiring reintervention.

The poor results shown with bare metal stents are because NIH can work in between the struts and at the edge of the stent and the unique forces around the shoulder joint subjects the bare metal stents to forces that are likely to lead to stent fracture. The SUPERA stent is more flexible and conforms to the different forces around the knee joint with excellent patency outcomes after femoral-popliteal artery stenting. In the same way using this stent around a highly mobile shoulder joint, we hope to achieve similar high patency rates. By changing the geometry of implantation of the arch vein onto the axillary, we hypothesize that this increases the WSS and minimizes the NIH effect along with the added effect of drug elution.

There are no studies to date, to our knowledge, that report simultaneous use of both the SUPERA stent and Passeo-18 Lux DCB to treat either peripheral arterial disease or AVF stenosis. However, the RAPID Trial recently reported their short-term results comparing the Legflow DCB and SUPERA stenting to SUPERA stenting alone in patients with intermediate to long SFA occlusions.[15] They found that combination therapy was safe and feasible with a higher 1-year primary patency of 68.3% versus 62% and a freedom from clinically target lesion revascularization of 83% versus 77.8%, although this was statistically insignificant. In relation to AVF stenosis, a recent meta-analysis from our group showed that DCB angioplasty appears to be a better and safe alternative to POBA in treating patients with haemodialysis (HD) stenosis in terms of 6- and 12-month primary patency.[16] However, a larger trial is warranted to establish these findings.

Conclusion

The treatment options for CAS are many and none of the current endovascular modalities are ideal. There is a high frequency of reintervention due to restenosis because of NIH. None of the current regimes address all the issues acting on the cephalic arch – compression from the overlying fascia and the altered haemodynamics from the BCF causing NIH. The Arch V SUPERA-LUX trial is the first study to use multiple modalities (flexible kink resistant stent and DCB) to address these harmful influences. Initial results for proof of concept have been encouraging but longer-term

data will only tell whether this two-pronged attack strategy is durable.

Author contributions

T.Y.T. (senior author) was primarily involved in study design, protocol development, protocol implementation at study site, as well as patient recruitment. C.S.T., R.Y.T., E.T.C.C., C.T.T. and H.H.T. were involved in patient recruitment and edited the final draft of the manuscript. C.J.Q.Y. coordinated the project and was involved in manuscript preparation with T.Y.T. All authors have read and approved the final manuscript.

Declaration of conflicting interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship and/or publication of this article.

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Sponsor

Singapore General Hospital will act as the main sponsor for this study.

Trial status

Study protocol Version 3.0 dated 11 April 2019. Recruitment is currently ongoing.

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