Evaluate Vantage

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ESC 2018 – Small vessels could make a big difference to B Braun

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Balloons are as good as stents, but it can be hard to get cardiologists to change their habits.

Data showing that SeQuent Please, the paclitaxel-coated balloon sold by B Braun, is non-inferior to drug-eluting stents in the treatment of small blocked blood vessels ought to boost sales of the device, the company says.

The data, presented today at the European Society of Cardiology meeting, might also enable the company to secure widespread reimbursement of the product, which has been on the European market for nearly a decade but has not yet reached the US. But in one respect the data came too late – the ESC issued guidelines two days ago which recommend stenting in this population, and it will be another four years until they can be revised.

The Basket-Small 2 trial pitted SeQuent Please against Boston Scientific's Taxus and Abbott's Xience drug-coated stents in 758 patients with de novo blockages in blood vessels with diameter less than 3mm. At one year, the rate of major adverse cardiac effects was 7.6% among balloon-treated patients and 7.5% in those given stents.

Basket-Small 2 data			
Endpoint	**SeQuent Please**	**Taxus/Xience**	**P value**
MACE	7.6	7.5	0.918
Cardiac death	3.1	1.3	0.113
Nonfatal heart attack	1.6	3.5	0.112
Target vessel revascularisation	3.4	4.5	0.438
Major bleeding	1.1	2.4	0.183
Source: ESC presentation			

Around 40% of patients requiring treatment in the cath lab have blockages in blood vessels with diameter less than 3mm. Over two million interventional procedures performed each year on the three largest markets – the US, China and Germany – so this is a sizeable group of people.

A new standard?

Standard of care here is implantation of drug-eluting stents, but Michael Boxberger, director of medical scientific and regulatory affairs at B Braun, told *Vantage* on the sidelines of the ESC meeting that it was time for this to change.

“The guidelines say clinical data on DCBs [drug-coated balloons] for the treatment of de novo lesions in small vessels are conflicting and a large randomised controlled trial is missing. This is what Basket-Small 2 is all about – it’s the missing link, a first,” he said. The use of hard clinical endpoints adds weight to this argument.

Interestingly, the trial will probably not be interpreted as a win for DCBs in general. “ESC guidelines say data on individual products cannot be generalised to others,” said Mr Boxberger. If other DCB manufacturers such as Medtronic and Becton Dickinson want doctors to use their devices to treat small vessels, they will have to run their own trials.

Big in Japan

The degree to which sales of SeQuent Please might increase on the back of these data is not yet clear. Mr Boxberger said that in Japan usage more than doubled to over 5,000 per month in the wake of positive results from a trial of SeQuent Please versus angioplasty with an uncoated balloon.

“We expect that in other countries the use of the DCB will increase, [but] we do not expect such a dramatic change as in Japan,” Mr Boxberger said.

One factor at play here is that SeQuent Please is reimbursed in Japan for the treatment of de novo lesions – and hardly anywhere else. Basket-Small 2 could help change that.

Mr Boxberger noted that B Braun’s balloon is more expensive than Taxus and Xience in Germany, where the price of stents is unusually low, but cheaper than the implants in Japan.

B Braun has plans to grow sales of SeQuent Please in another fashion. It is in discussions with the FDA, Mr Boxberger says, and hopes to start a pivotal US trial next year; approval, if all goes well, could follow in 2022.

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