



Trends-in-Medicine

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by Lynne Peterson and D. Woods

Quick Pulse

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Stephen Snyder, Publisher
2731 N.E. Pinecrest Lakes Blvd.
Jensen Beach, FL 34957
772-334-7409 Fax 772-334-0856
www.trends-in-medicine.com
TrendsInMedicine@aol.com

STENT UPDATE

Directors and managers of 15 cardiac cath labs across the U.S. were interviewed to check on stent trends, particularly drug-eluting stents (DES). Medtronic's Endeavor was approved on February 1, 2008, but there appears to be little enthusiasm for it. In contrast, there is a good deal of excitement about Abbott's Xience V (which will also be sold by Boston Scientific as Promus), which is expected to gain FDA approval by summer.

PCI volume

Compared to a year ago, these cath labs reported their percutaneous coronary intervention (PCI) volume is down an average of 11%, in part because more hospitals are offering PCI. Over the next 6-12 months, the outlook is for PCI volume to remain relatively flat at current levels. Comments included:

- "We had increased competition from another hospital last year, and we may see a continued decrease because of competition from another hospital opening a cardiac cath lab."
- "Some moderate-volume hospitals have maintained their PCI levels better. Why? No one knows. There are lots of elements – referrals dropped, negative press regarding late stent thrombosis, preventive medications...Over the next 6-12 months, it won't drop, and we may see a small increase this year."
- "The trend is going slowly back up, but it won't make up the 8% we lost last year."

DES outlook

The decline in DES use appears to have reached bottom and plateaued at these labs, and no real uptick is on the near horizon. On average, drug-eluting stents account for 63% of stent usage at these hospitals, and that is expected to increase very slightly to 67% by the end of 2008. Comments included:

- "I don't really see any change in the percentage. Use looks stable now."
- "Our DES use is 65%, but it will *eventually* go back to 80%-85%."
- "We won't go back to 90% DES use any time soon, so I don't see much change in 2008."
- "Our current DES share is 65%-70%, and it never really dropped as much as some others, so it could increase to 65%-75%."

Current DES choices: Cypher, Taxus, and Endeavor

Johnson & Johnson's Cypher has an average of 56% market share at these labs, Boston Scientific's Taxus 42%, and Endeavor 2%. All but one of these labs have

been detailed on Endeavor, are familiar with it, or have already started using it. However, only one lab has more than very niche plans for Endeavor. The tiny impact of Endeavor, at this point, appears to be affecting Cypher and Taxus relatively equally. Among the approaches labs are taking are:

- Five labs are currently using Endeavor. Among these, use is mostly “sampling” for three. At one it has gained 15% share, mostly at the expense of Taxus. The manager of that lab said, “Endeavor is the new kid on the block. It’s a second generation DES in the U.S., and we’re excited because we have another stent to rely on. It has a tremendous safety profile, and I say that because the differences in terms of preventing blockage (restenosis) are not tremendous, but what has been done to get FDA approval has been tremendous. The bar has been raised significantly.” The manager of the other lab said, “Endeavor has a 5%-10% share here. Maybe it is a honeymoon blip because it is new to us, and we’re playing with it.”
- Two labs have Endeavor on the shelf but haven’t seen any use yet. A manager said, “Endeavor is too new, but we will use it.”
- Three labs expect to get Endeavor soon, but they generally expect it to have only niche use. A manager said, “We do not expect Endeavor to have significant market share here.”
- Four labs do not plan to order or use Endeavor at all.
- One lab tried Endeavor and didn’t like it. The director of that lab said, “We may use some Endeavor, but I don’t like it. The main reason is that it doesn’t have the rapid exchange platform. What they have is MX, and that is not very good.”

Lack of rapid exchange is a problem for Endeavor, but that is not the only reason for lack of enthusiasm about this stent. Comments included:

- “The MX delivery system is a *major* obstacle since we are almost entirely rapid exchange.”
- “The speed of delivery is very important, but learning a new method would be acceptable if the doctors were convinced the stent had real advantages over current products.”
- “The MX is cumbersome. Rapid exchange is preferred, but doctors will use the MX.”
- “MX is a little bulkier, a little more cumbersome. We won’t shy away from Endeavor just because of that. For a very simple lesion, you’d probably pick the easier (stent), but there is a niche application for Endeavor, which is very deliverable. If you need a stent to go in a place that no other stent would go, you wouldn’t shy away from using Endeavor.”
- “In our experience, it’s a good stent. It’s maneuverable. It crosses easily. The delivery system is good.”

- “We just got Endeavor, but the doctors don’t like it because they don’t like MX compared to rapid exchange.”
- “We’re excited about Endeavor...The only thing that prevents us from using Endeavor more is the delivery system. Medtronic doesn’t have the patent to use rapid exchange...and that prohibits it from being used as a workhorse.”

Contracting does not appear to be a barrier to Endeavor uptake at most labs. If interventional cardiologists at most of these labs wanted to use it, the managers said they could. Comments included:

- “Our doctors will get what they want, but they are not pushing for Endeavor.”
- “We are not faced with this (contract) issue.”
- “We don’t have exclusive contracts, but some of our contracts are dependent on percentage use. If we use $\geq 50\%$ Cypher, we get one price. If our use drops below 50%, then the price goes up...But Endeavor is available here, and it isn’t being used yet.”
- “We can change contracts as events change...A lot will be driven by pricing...We’ve decided not to give Medtronic a contract, saying it is not clinically significant to put this on our formulary.”
- “We have volume contracts. We tend to hit the number for Cypher (70%), and then split up the rest. We are coming up to negotiations now (which we do every two years because we hated doing it every year). Now, we are asking, ‘Do we want to do it (a volume contract) this time around, given that there will be four stents on the market?’”
- “With our contract, it benefits us to only use Cypher stents. We’re satisfied with what we use.”

Pricing

So far, the launch of Endeavor does not appear to have brought stent prices down, but hospitals are expecting companies to offer better deals going forward. Among the comments on price were:

- “Most of the stents are comparable in price. They’re coming in between \$2,000-\$2,500 per stent, depending on the contract.”
- “Endeavor has had no effect at all on pricing.”
- “We’re getting good prices for Taxus and Cypher. With Endeavor, there are no price decreases, but we’re getting quite a bit of help and promotion from Medtronic... Everything is negotiable. The companies have been flexible, unlike before when there was only J&J and it was very difficult. But J&J isn’t going to have another stent for 3-4 years, so they’re stuck, and people are bending backwards.”

- “We told Medtronic that they had to match our Cypher price or we weren’t going to use it...I honestly think price will be the key thing. When there are four stents on the market, you can start playing with prices. Right now, everyone is holding pat (on pricing). Nobody is budging...I don’t think anybody is light years ahead of anyone else, so price is important.”

Xience V outlook

There is a great deal more interest in Xience than Endeavor. Only one lab questioned has no plans to use Xience (or Promus); that lab intends to stay 99% Cypher. Right now it appears that Boston Scientific’s Promus and Abbott’s Xience will split the zotarolimus-eluting stent market, with Xience capturing more share than Promus, though sources said price is likely to determine their choice. Comments included:

- “We are contracted with Boston Scientific, so we will wait for Promus. We’ll buy Promus rather than Abbott’s Xience because of our existing relationship.”
- “I think the choice will depend on pricing.”
- “We just revised our contractual agreements with Boston Scientific over the last few months, just before Endeavor was approved. We went to everyone, including Medtronic, to see if they wanted to give us a better deal than Boston Scientific, and they didn’t.”
- “We will probably buy from Abbott, depending on pricing.”
- “We will probably buy from Abbott because we are participating in their post-marketing study, but I think Promus will also be available (in our lab).”
- “We’re very excited about Xience, but we can’t predict our use yet. It has a better safety profile but also has more of a difference in terms of restenosis in clinical trials...I think it has more of a completeness in terms of delivery safety.”

The launch of Xience is likely to have a negative effect on Endeavor. One lab manager said it will choose two DES after Xience is approved, but isn’t sure which two that will be. Another manager said, “I have used the Endeavor over-the-wire MX platform, and I like it. I really like Xience, too. Given that Xience has both platforms (over-the-wire and rapid exchange), I can easily see us gravitating toward the use of that or Promus.”

The DES market a year from now

Asked to predict market share in their lab for each of the DES at the end of 2008 (assuming Xience is approved in the first half of 2008), the clear winner is Xience/Promus, which managers predicted would account for almost half the market – comparable to Cypher and Taxus together. Xience would outsell Promus, and Endeavor would be a niche player. Use of both Cypher and Taxus would be cut by more than half.

Comments included:

- “It would be easy for someone to jump ship from Boston Scientific. We’ve had Boston Scientific for a large market share for quite some time, but if Abbott were to step up and say they’ll give us a good price – and the Boston Scientific price was across product lines – we’d be inclined to go to Abbott. I think when Xience comes out, Abbott will come knocking at the door.”
- “I don’t know how the Taxus/Promus thing will fall out, but we should be 75% Boston Scientific.”
- “I suspect we will still go with Cypher for the majority, then after that whether it is Endeavor or Boston Scientific is up in the air, but Boston Scientific is home grown to us, so it will be either Endeavor or Promus splitting what’s left.”

DES Usage Outlook

Company	DES	Current use	Expected use at end of 2008
Johnson & Johnson	Cypher	52%	26%
Boston Scientific	Taxus	48%	22%
Medtronic	Endeavor	0	7%
Abbott	Xience V	0	26%
Boston Scientific	Promus	0	19%