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Quick Pulse

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Is There a Problem with Taxus Stents?

Interventional cardiologists and cath lab managers at 11 large institutions were interviewed to determine if there is any substance to rumors of a deployment issue with Boston Scientific's Taxus paclitaxel-eluting stent, which was approved by the FDA on March 4, 2004. They were also asked about pricing. It appears there really is a retraction problem with Taxus, on occasion, and pricing for large labs is averaging $2,400 or higher.

There was an unconfirmed report on April 2, 2004, that up to five patients receiving a Taxus stent sustained adverse events caused by an inability to separate the balloon from the expanded stent. At least two of the affected patients were sent to surgery for bypass procedures. Boston Scientific reportedly acknowledged that one or two cases of failed balloon retraction did in fact occur, prompting surgical repair, and the company claimed that:

1. The events, while regrettable, had been known to occur on rare occasions with bare metal stents.
2. The rate of occurrence with Taxus seems to be in-line with that seen with conventional products. The company insisted these events don't herald a broad, emerging problem.

In the past, the conventional Express stent had a small number of dislodgement issues (in which the stent was inadvertently displaced from the balloon catheter system). At the time, Boston Scientific indicated that was an issue related ***only*** to the bare Express and no changes were being made to Taxus as a result.

Six of the sources questioned had not heard about the retraction issue, and none of these had experienced it. A Midwest doctor said, "I had not heard of any problems. We are implanting 10+ Taxus a day or so and have not run into any difficulties. We'll continue to use Taxus. It's much cheaper than (Johnson & Johnson's sirolimus-eluting) Cypher for us right now. Certainly if we have problems, this would change." Another cardiologist said, "We have had no problems with Taxus and are using the stent frequently. We have not been aware of the problem, although we have seen stent dislodgement with any number of vendors' stents." A third doctor said, "We have used Taxus in more than 150 patients and did not experience this problem although I heard about it from the Cordis (J&J) sales rep…I don't think that this is a common problem." A Pennsylvania cath lab manager said, "We have not experienced anything like this. I have not heard about concerns from the physicians." A Florida cath lab manager said, "I have not heard of this."

Five sources had heard of the retraction problem. One commented, "We really haven't heard anything beyond dislodgement and stickiness. We've heard that sometimes it is just a challenge to get the balloon inflated and out and other cases where patients had to go to surgery."

Two sources actually experienced retraction problems in their labs:

- A Midwest doctor said, "We've had one case with difficulty with delivery. We've seen retraction difficulty with long, small (narrow diameter) stents implanted in tortuous vessels. I cannot say this occurs more with Taxus than with Cypher...(This) reminds me a bit of the initial concerns regarding SAT (subacute thrombosis) with Cypher, but I'll need more information."
- A West Coast doctor said, "This is a real issue. We've had many stents where it felt like the polymer was sticking to the balloon. The company says that is not the case, but that's what it feels like. We've had many cases with major problems and two serious consequences. Both patients did okay, but it was not pleasant. We are still using Taxus, but I'm nervous about it, and I'm trying to find ways to use Taxus. Boston Scientific says that if you deflate the balloon carefully and slowly, you won't have the problem, but I can't say I'm convinced."

Sources all agreed that this retraction issue is potentially very serious and must be monitored. A doctor said, "If this is real, than I am very concerned. Dislodged stents can be retrieved or deployed elsewhere. Failed retraction is much more troublesome because of the need for surgery." Another doctor said, "We will continue to be vigilant in obtaining the most current data on all new products and report any adverse events."

Taxus has been on the market in Europe since January 2003, and no retraction problems had been reported there until recently. A U.S. source speculated that the problems may be more common with over-the-wire Taxus stents, which are rarely used in Europe. However, on April 8, 2004, three French doctors reported stickiness and retraction issues with Taxus, so the problem apparently is not unique to the U.S. Their talk, at the sixth annual symposium on Endocoronary Biomechanics beyond Restenosis in Marseilles, France, was titled, *"Non-uniform paclitaxel-eluting stent coating and unexpected balloon-stent stickiness*: *Any concern with routine practice?"* Dr. Gérard Finet (Lyon), Dr. Gilles Rioufol (Lyon), and Dr. Martine Gilard (Brest) wrote:

"Since Taxus Express 2 stent is routinely used in our institution, we experienced difficulties to withdrawal the balloon after stent deployment. For better knowledge of DES (drug-eluting stents), we performed a bench and optical microscopy observation with one Cypher Select and two Taxus Express 2 from two cath labs (Lyon and Brest). Balloon deflation is similar between stents (crossing profile 1.7 mm both), but only Taxus stent remains hanged on, and it is obviously sticky. By optical microscopy we observed only for Taxus stent that the coating is unstructured by the meshes sticking to one another. Coating is non-uniform with numerous smears especially around the bridges.

We conclude that:

1. Paclitaxel-coating is sticky and non-uniform leading to mechanical difficulties after stent implantation,
2. Paclitaxel local concentration may vary within stent, and
3. Manufacturer quality control is questioned.

Is the Taxus retraction/deflation/stickiness a relatively minor problem that will disappear as interventional cardiologists learn specific techniques for implantation as happened with Cypher and SATs? Or, are these reports the tip of an iceberg that could lead to an FDA warning letter or withdrawal of Taxus from the market the way the Nir on Ranger with Sox stent was withdrawn in 1998?

As a reminder, within a month of launch in September 1998, about 36,000 Nir/Sox stents had been shipped and about 25,000 of these implanted in patients. Reports started coming in almost immediately of pinhole(s) in the balloon that prevented them from properly inflating. A TCT speaker reported, "There has been some balloon leakage. The balloon occasionally doesn't expand and deploy properly. There have been about 30-40 episodes around the country, and Boston Scientific suspended distribution for a week, but I believe the problem is now fixed. I don't know what the fix was; the company has not been forthcoming about the details of the fix." In early October 1998, Boston Scientific recalled Nir/Sox, revealing that it had received more than 100 reports of balloon leakage as well as one death, several surgeries (four CABG operations to remove a misplaced Nir/Sox), and 26 patient injuries. The FDA charged that Boston Scientific had made manufacturing changes to Nir/Sox without FDA review or approval.

Pricing

There was a report that some cath labs are obtaining Taxus for $2,300 per stent, but none of the labs questioned have obtained – or even heard of anyone else obtaining – pricing that low. It appears that large, high volume labs are probably paying about $2,450-$2,500, with smaller labs and labs with a lower volume of Taxus paying more. Among the pricing comments were:

- "We are paying $2,700, but with volume discounts that comes down to about $2,450."
- "I have yet to hear of a $2,300 Taxus stent."
- "Our price is higher than $2,300, but not much higher. We get it for the same price as Cypher."
- "We are paying $2,400 after a hard negotiation."
- "We are paying $2,600, but that is soon to change downward."

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