The introduction of coronary artery stents into widespread clinical use in the mid-1990s was a significant advance that almost rivals the introduction of balloon angioplasty itself 15 years earlier. It is noteworthy that the success of stents required several paradigm shifts. For example, higher-pressure balloon inflations and slight oversizing were needed to achieve full stent expansion (anathema in balloon angioplasty), and antiplatelet therapies were required rather than anticoagulation, including a reduction and now almost elimination of heparin. Yet, these changes were quickly accomplished. Technical advances in equipment also occurred, and now stenting, quite literally, has become the standard in clinical practice when it can be performed (which is most of the time).

One curious and intriguing question that arises with any new device, and stents are no exception, is whether they are needed in all situations where they are being used. Is it possible that balloon angioplasty alone might be sufficient for excellent immediate and long-term benefit, provided the final procedural result is good enough? If one could determine this to be true, then such a strategy would avoid the additional cost of a stent and the problem (or pseudo-problem) of in-stent restenosis. However, a provisional stent strategy raises the further and not inconsiderable question of how to decide when balloon angioplasty results are “good enough.” The limitations of standard angiography notwithstanding, is there anything better than the eyes and minds of experienced angiographers? Additional “objective” measures to assess procedural results have long been sought. A number of investigators have championed intracoronary ultrasound as a worthy companion to these 2 reports on provisional stenting.1,2 These measures are on-line quantitative coronary arteriography (QCA) and coronary flow reserve (CFR) measured with a Doppler wire. In addition, as a worthy companion to these 2 reports on provisional stenting, this issue also contains a report from a large-scale clinical registry, the National Heart, Lung, and Blood Institute (NHLBI) Registry,3 detailing the substantial improvements in the outcomes of coronary interventions in the years 1985/1986 through 1997/1998, during which time coronary stents were introduced. We offer some analysis, interpretation, and opinions on these reports.

The NHLBI Dynamic Registry
First established in 1979 at the dawn of coronary angioplasty, the NHLBI Registry has been a continuing source of valuable information through the years. The data reported by Williams et al3 compare the in-hospital and 1-year outcomes in patients treated in 1997/1998, which include those treated with stents, with the outcomes of patients treated in 1985/1986, before stents were used. Let us begin with the in-hospital outcomes. The Registry report documents dramatic reductions in the frequencies of adverse events occurring during index hospitalization for coronary intervention. The frequency of the combined triple end point of death, myocardial infarction, or coronary bypass surgery (CABG) fell from 9.8% in 1985/1986 to 5.9% in 1997/1998. This decline was due entirely to reductions in myocardial infarction (from 4.9% to 2.8%) and especially CABG (from 6% to 1.5%), because in-hospital mortality was unchanged (1.4% versus 1.9%). The frequency of stent usage in the 1997/1998 Dynamic Registry was 70%; no stents were used in 1985/1986.

These findings are consistent with other recent, large-scale reports and deserve brief elaboration here. Using Medicare data from 1994 and 1996, Ritchie et al4 found in patients without acute myocardial infarction that the frequency of same-admission CABG was cut in half after the introduction of coronary stents. In patients with acute myocardial infarction, the difference was even greater. Similarly, Hannan et al5 using the New York State Coronary Angioplasty Registry, found that stents reduced the frequency of same-admission CABG at hospitals in New York by more than one-third but did not change in-hospital mortality.

If the data from these 3 large reports,3-5 representing 293 000 patients, are combined, the introduction of stents reduced the already low CABG rates of the mid-1990s by 50% (from 2.55% to 1.26%) and the in-hospital mortality rates by 15% (from 1.28% to 1.08%). These are impressive numbers. Practicing interventionists and clinicians have many anecdotes that reinforce these statistics. Clearly, the widespread use of stents has favorably influenced early outcomes. The mechanisms for this benefit relate to the stent’s ability to prevent or treat threatening dissections and abrupt closures. These are the most common causes of failed balloon angioplasty leading to urgent bypass operations and...
deaths. In addition to these immediate benefits, the initial reports of 6-month and 1-year outcomes with coronary stents were favorable, and these also contributed to the eagerness of stent adoption. However, keen observers during these years noted that when balloon angioplasty results were good (“stent-like”), then both short- and long-term outcomes were favorable. Provisionalists used this to urge a cautious approach to stenting: if balloon angioplasty results were good enough, then stop; if they were not good enough, then stent.

Provisional Stenting

DiMario et al,1 for the Doppler End Point Stenting International Investigation (DESTINI) study group, report no benefit at 1 year with a provisional compared with a routine stenting approach. Serruys et al,2 for the second Doppler End Points Balloon Angioplasty Trial Europe (DEBATE-II) investigators, report that provisional stenting has less favorable 1-year outcomes and is more expensive than routine stenting. These 2 new reports closely parallel another recent report on provisional stenting by LaFont et al6 for the French Randomized Optimal Stenting Trial (FROST) study group. Taken together, these 3 studies constitute a uniform approach to provisional stenting: they use similar technologies (on-line QCA and Doppler CFR) and nearly identical definitions. In FROST, optimal balloon angioplasty that would not require a stent was defined as a final diameter stenosis <35% by QCA and a CFR >2.2. In DESTINI, the definition of an optimal result was a final diameter stenosis <35% and a CFR >2.0, and in DEBATE-II, it was a final diameter stenosis <35% and a CFR >2.5. Table 1 lists some of the important clinical features of patients enrolled in these 3 provisional stenting studies and the reported outcomes. For additional comparison, we also included data from another recent provisional stenting trial, the Optimum Percutaneous Transluminal Coronary Angioplasty Compared With Routine Stent Strategy Trial (OPUS-1).7

In FROST, the study end point was angiographic restenosis at 6 months. This occurred in 21.4% of the routinely stented group and in 27.1% of the provisionally stented group (P=0.37). Importantly, 48.4% (61 of 126) of the provisional patients required stents. In DESTINI and DEBATE-II, the end points were 12-month clinical outcomes, as determined by a combination of major adverse cardiovascular events (MACE). Target lesion revascularization (TLR) was also important. Overall in both DESTINI and DEBATE-II, the frequencies of TLR ranged from 7% to 16%, and the frequencies of MACE ranged from 13% to 19%. In OPUS-1, clinical outcomes were obtained at a shorter, 6-month follow-up, and both TLR and MACE were significantly less frequent in the routine stent group compared with the provisional stent group (5.2% versus 14.9% for TLR and 6.1% versus 14.9% for MACE; both P<0.01). The clinical event rates, as expected, are somewhat lower than the angiographic restenosis rates found in FROST. Of interest, all event rates in the 4 studies are uniformly lower in the routine compared with the provisional stent groups. Furthermore, a quick calculation reveals that the primary end points of either angiographic restenosis or MACE occurred in 14.5% (118 of 813) of routinely stented patients in these 4 studies and was more frequent (17.6%; 221 of 1254) in provisionally stented patients (2-sided P=0.062).

TABLE 1. Routine and Provisional Stenting in 4 Trials

<table>
<thead>
<tr>
<th></th>
<th>Routine Stenting</th>
<th>Provisional Stenting</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>FROST</td>
<td>DESTINI</td>
</tr>
<tr>
<td>No. of patients</td>
<td>125</td>
<td>370</td>
</tr>
<tr>
<td>Women, %</td>
<td>17</td>
<td>25</td>
</tr>
<tr>
<td>Diabetics, %</td>
<td>18</td>
<td>18</td>
</tr>
<tr>
<td>Unstable angina, %</td>
<td>67</td>
<td>46</td>
</tr>
<tr>
<td>LAD lesion, %</td>
<td>56</td>
<td>41</td>
</tr>
<tr>
<td>Type C lesion, %</td>
<td>66*</td>
<td>56†</td>
</tr>
<tr>
<td>Lesion length, mm, mean</td>
<td>9.7</td>
<td>12.7</td>
</tr>
<tr>
<td>Reference diameter, mm, mean</td>
<td>3.07</td>
<td>3.09</td>
</tr>
<tr>
<td>Final MLD, mm, mean</td>
<td>2.64</td>
<td>2.92</td>
</tr>
<tr>
<td>Final stenosis, %, mean</td>
<td>13.8</td>
<td>9.3</td>
</tr>
<tr>
<td>End points</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interval, mo</td>
<td>6</td>
<td>12</td>
</tr>
<tr>
<td>Event (frequency)</td>
<td>Angiographic restenosis (21.4%)</td>
<td>TLR (14.9%)</td>
</tr>
<tr>
<td></td>
<td>...</td>
<td>MACE</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(17.8%)</td>
</tr>
</tbody>
</table>

LAD indicates left anterior descending coronary artery; MLD, minimum lumen diameter.
*B or C.
†B2 or C.
‡Values for nonstented group/stented group.
#Percutaneous coronary intervention and CABG.
The small differences in angiographic and clinical outcomes between these 4 studies might easily be explained both by the slightly different criteria for success (in terms of CFR, where it was used) and the slightly different clinical characteristics of the patients. Overall, there is a sense of harmony in almost all respects in these 4 studies. The randomized lesions were short (≈9 to 12 mm) and were located in medium-to-large arteries (≈2.6 to 3.3 mm). The left anterior descending coronary artery may have been somewhat under-represented in the provisionally stented groups. The OPUS-1 and DEBATE-II trials are the only 2 with economic analyses, and both conclude that a provisional stenting strategy is more expensive than routine stenting.

**Frequency of Stenting in Provisional Arms**

The important point about these provisional stent trials is this: stenting was exceedingly common, even in these large and sophisticated centers seeking to avoid it. Table 2 lists the frequency of stent deployment in the provisional arms of FROST, DESTINI, and DEBATE-II, which used similar methodologies for decision-making. Overall, stents were needed for 520 of 1021 lesions (51%), which is more than half of the provisional lesions treated. In OPUS-1, stents were used in 37% of the 249 lesions randomly assigned to a provisional strategy. The proportions of stents deployed according to the specific provisional criteria are also listed in Table 2. Often (11% to 28% of lesions), a stent was used for a “bailout” condition, which was defined as either threatening dissection or abrupt closure. Furthermore, it is apparent that a failure to meet angiographic diameter stenosis criteria alone was not that frequent (only ≈5% to 18% of lesions stented); CFR criteria accounted for most of the provisionally stented lesions. In other words, in these situations, the operators were happy with the angiographic results and no threatening dissections were seen, but the CFR criteria were less than desired. *The physiological and clinical meaning of this is presently unknown.*

An evaluation of the immediate results of balloon angioplasty and stenting by anything other than standard angiography (meaning the eyes and minds of experienced operators) is not yet fully understood and accepted. The only technique that comes close is intravascular ultrasound, and its role has mainly been to confirm full stent expansion. Only recently have studies comparing various methodologies, including on-line QCA, fractional flow reserve using a pressure wire, intravascular ultrasound, and CFR using a Doppler wire, begun to appear.8–13 Very importantly, these technologies are not widely available, and there is as yet little agreement, even among the cognoscenti (like us) who use them occasionally. The desire to avoid stenting even an acceptable balloon angioplasty result on the basis of its having a good CFR result seems unwarranted at this time. Whether or not a stent can actually be placed technically is another matter.

**Optimal and Suboptimal Results**

The DEBATE-II investigators included a second randomization in their trial; it yielded some new insights on the meaning of good results and raised new questions. After excluding the 129 patients that required stents for bailout situations, they were left with 382 patients that either met the criteria for optimal balloon angioplasty or had suboptimal results but no threatening dissections or closures. These 382 patients were then randomly assigned either to required stenting or to no further treatments. This created 4 subgroups, 2 of which are very interesting: a group with “optimal” balloon angioplasty that was stented anyway and a group with “suboptimal” balloon angioplasty (but no threatening dissections) that received no further treatment. This last group would have received a mandated stent in the FROST or DESTINI trials.

Table 3 lists the clinical outcomes of these 2 interesting groups from DEBATE-II along with the outcomes of the bailout stent group from DEBATE-II and parallel groups from DESTINI. For the patients in DESTINI and DEBATE-II with optimal balloon angioplasty and no stents (ie, acceptable results with balloon angioplasty alone), the rates of TLR (17.6% and 13%, respectively) and MACE (20.1% and 15.9%, respectively) were similarly good. However, for the 77 patients in DEBATE-II with optimal balloon angioplasty that were stented anyway (achieving a final mean diameter stenosis of 8%), the rates were significantly better: only 3.9% underwent TLR and only 6.5% experienced MACE. Unacceptable results with balloon angioplasty alone are also revealing. In DESTINI, the provisional stent arm had a TLR rate of 14.1% and a MACE rate of 18.0%. The equivalent groups in DEBATE-II would be the suboptimal balloon angioplasty group that was stented and the bailout group. Interestingly, both had TLR and MACE rates lower than the rates in DESTINI. Finally, there were 86 patients in DEBATE-II with suboptimal results after balloon angioplasty (again, mostly on the basis of CFR criteria, because the final diameter stenosis was no different from that of the optimal balloon angioplasty group). These patients received no fur-
ther treatments, and they had the highest event rates of all: 20.9% required TLR and 26.7% experienced MACE.

Re-examining these numbers leads to the conclusion that stenting after optimal balloon angioplasty is best (MACE rate of 6.5%), optimal balloon angioplasty without a stent or suboptimal balloon angioplasty with a stent is next best (MACE rate of 11% to 20%), and suboptimal balloon angioplasty with no stent is the worst (MACE rate of 27%). This clearly means that when a stent cannot be used (for whatever reason), achieving an optimal balloon angioplasty result is the next best thing. We all know and accept this. But why should stenting a patient who has an optimal balloon angioplasty result produce a more favorable long-term outcome than leaving well enough alone? The answer to this goes right to the core of whatever it is that stents do, whether that means mechanically supporting small and invisible dissections, preventing late elastic recoil, or somehow altering the biological course of restenosis. Using a stent to obtain a large, smooth (some would say “cosmetically pleasing”) lumen visualized by standard angiography to the satisfaction of the operator seems to provide the best results yet achieved.

Long-Term Outcomes
A final perspective on the long-term benefits of stenting in the real world comes from a reconsideration of the NHLBI Dynamic Registry that we started with, along with the previously mentioned New York State Registry and a recent study from the British Columbia Cardiac Registries in Canada. Table 4 lists the odds ratios for the long-term benefits of stenting compared with balloon angioplasty for each of these 3 reports. Both the Canadian and New York State Registries noted significant long-term benefits with stenting. In the Dynamic Registry, the 1-year outcomes of the 1997/1998 collection (stent era) were significantly better than those in the 1985/1986 collection. Admittedly, these are retrospective data. However, the studies are methodologically sound, and the results are consistent. The routine use of coronary stents is associated with improved clinical outcomes at 1 to 2 years compared with performing conventional balloon angioplasty.

**Limits of Technology**
The reasons why provisional stenting has not become common, and likely never will, are 4-fold. First, the proven results of routine stenting are excellent. Second, a large number (>50%) of the lesions where stents might wish to be avoided under a provisional strategy must be stented anyway. Third, the technology required to undertake provisional stenting is uncommon, and its applicability is unclear. This does not mean that intravascular ultrasound, QCA, and Doppler are not useful. They clearly can be valuable on an individualized basis. However, for the purpose of deciding whether to stent, at the present time and for the foreseeable future, they have not yet been proven to add anything of value to the eyes of experienced angiographers. Finally, 2 current studies indicate that routine stenting is less costly than provisional stenting. The increased procedure time required to use the additional technology and the greater numbers of repeat procedures in the provisional strategy probably account for this. Given the dramatic reductions in adverse clinical events that stents have brought about, the indications that long-term stent results are more favorable than balloon angioplasty, the high percentage of provisional strategy patients that ultimately receive stents, and the reportedly favorable economics of routine compared with provisional stenting, it is fair to say that routine stenting wins.

**References**

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**TABLE 3. Treatment of Patients With Optimal and Suboptimal Results and 1-Year Outcomes**

<table>
<thead>
<tr>
<th>No. of patients</th>
<th>DEBATE-II, Optimal BA</th>
<th>DEBATE-II, Suboptimal BA</th>
<th>DESTINI, Optimal BA and No Stent</th>
<th>DESTINI, Suboptimal BA With Stent</th>
</tr>
</thead>
<tbody>
<tr>
<td>TLR, %</td>
<td>17.6</td>
<td>16.3</td>
<td>19.0</td>
<td>20.9</td>
</tr>
<tr>
<td>MACE, %</td>
<td>20.1</td>
<td>19.0</td>
<td>19.0</td>
<td>18.0</td>
</tr>
</tbody>
</table>

BA indicates balloon angioplasty; DS, diameter stenosis.

**TABLE 4. Long-Term Outcomes of Stenting and Balloon Angioplasty in 3 Studies**

<table>
<thead>
<tr>
<th>Study</th>
<th>No. of patients</th>
<th>Follow-up interval</th>
<th>Odds ratio for Death</th>
<th>Odds ratio for TLR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Canadian Registry</td>
<td>9594</td>
<td>1 year</td>
<td>1.14</td>
<td>0.72</td>
</tr>
<tr>
<td>New York State Registry</td>
<td>19792</td>
<td>2 years</td>
<td>0.78</td>
<td>0.65</td>
</tr>
<tr>
<td>NHLBI Dynamic Registry</td>
<td>3990</td>
<td>1 year</td>
<td>0.9</td>
<td>0.6</td>
</tr>
</tbody>
</table>

Favors Stent Stent Stent Stent era


KEY WORDS: Editorials  ■  stents  ■  angioplasty
Provisional Versus Routine Stenting: Routine Stenting Is Here To Stay

H. Vernon Anderson and Blase A. Carabello

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