Improving Balloon Angioplasty: Lessons Learned from the DCB and Stent Trials

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For over 40 years, balloon angioplasty (POBA) has been used to treat vascular disease. Numerous randomized clinical trials (RCTs) confirmed superior outcomes of stents and paclitaxel-coated balloons (DCB) over POBA. Many of these studies, used the same control — POBA. So, if patient/lesion characteristics were similar, it would be reasonable to expect that results for the POBA control groups would be similar in these studies. An analysis was made of RCTs between 1996-2015 with similar endpoints, patient and lesion characteristics (Figs. 1-2).

Angiographic and clinical outcomes of DCB and stents were similar, and all were superior to POBA (Figs. 3-4). However, outcomes in the POBA control groups varied by as much as a factor of 4 (Fig. 5). Since standard POBA catheters were used in accordance with the investigators’ “standard technique,” the variance may be due to differences in POBA technique amongst the various investigators. For example, in the LEVANT 2 and IN.PACT SFA trials, outcomes for the PTA cohort appeared to be better in the hands of US operators than OUS operators (Fig. 6). POBA outcomes were superior when techniques were employed using a gradual step-wise expansion of the vessel, such as pre-dilatation (Fig. 7). Studies of smooth muscle cells showed that injury was a function of strain rate, not the magnitude of the applied stress, as the cell membrane is viscoelastic (Fig. 8). This was demonstrated in vivo, where a slow, gradual inflation to the balloon’s nominal pressure resulted in lumen expansion with no vessel injury. But when the same balloon was rapidly inflated to the same nominal pressure, there was extensive dissection and vasoconstriction (Fig. 9). In the PACIFIER trial, the DCB cohort had 2X more pre-dilatation than the PTA cohort, which resulted in a lower dissection rate; whereas in IN.PACT SFA, both arms had the same rate of pre-dilatation, and there was no difference in dissection rate (Fig. 10). In coronary artery studies, a number of investigators showed that slow, gradual, low-pressure inflation protocols often resulted in better acute outcomes (Fig. 11). These techniques also increase the inflation time. In a prospective RCT of short vs long inflation time in infrainguinal PTA, longer inflation times were shown to reduce severity of dissection and need for additional intervention (Fig. 12).

In randomized clinical trials, pay close attention to the control group. “Plain Old Balloon Angioplasty” remains to be a very important tool in the catheter lab, and like most tools, results are related to how they are used. Techniques that employ slow, gradual, low-pressure balloon inflations may help improve outcomes.

**Results and Discussion**

- **DCB vs POBA RCTs**
  - THUNDER
  - FEMPAC
  - LEVANT 1
  - PACIFIER
  - BIOLUX P-1
  - DEBELUM
  - IN.PACT-SFA
  - LEVANT 2

- **STENT vs POBA RCTs**
  - BENESTENT
  - ISAR-SMART
  - EPISTENT
  - ABSOLUTE
  - ZILVER PTX
  - RESILIENT
  - STRESS I-II
  - START
  - VIABAHN
  - FAST
  - ASTRON
  - SUPER

- **DCB vs. PTA: 6 Month TLR (%)**

- **US vs. OUS Sites — PTA Cohorts**

- **In Vivo Porcine Study of Balloon Inflation Rate**
  - Slow to 8 atm
  - Rapid to 8 atm

- **PTCA Clinical Studies**
  - Gradual, low pressure balloon inflation minimize trauma

- **Infrainguinal PTA — Short vs Long Inflation**

- **Pre-dilatation vs. Dissection**

- **Cellular Injury Model**
  - Vessel injury is related to the rate at which the vessel wall is stretched (strain rate)

- **Intraainguinal PTA**
  - Short vs Long Inflation

**Fig. 1**

**Fig. 2**

**Fig. 3**

**Fig. 4**

**Fig. 5**

**Fig. 6**

**Fig. 7**

**Fig. 8**

**Fig. 9**

**Fig. 10**

**Fig. 11**

**Fig. 12**