Compliance charts to guide non-complex small artery stenting: validation by quantitative coronary angiography

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ABSTRACT

Objective To determine whether stent sizing derived from manufacturers' compliance charts provides a reasonable in vivo estimate of final minimum lumen diameter (MLD) when compared with quantitative coronary angiography (QCA).

Design Single-centre measurement comparison study.

Setting Tertiary referral university hospital.

Patients Fifty cases receiving a single stent for non-complex de novo stenosis were randomly selected from the percutaneous coronary intervention database of our high-volume centre. Restenosis, stent thrombosis, bifurcational disease, rotablation, left main or graft stenting, intravascular ultrasound or kissing balloon inflations were exclusion criteria.

Main outcome measures Equality and limits of agreement (LOA) between compliance chart and QCA measurements of final MLD, especially focusing on patients with small stents<3 mm. The paired t test and Bland-Altman plots were used to compare measurements.

Results There was no significant difference between compliance chart-derived and QCA final MLD (n=50; mean −0.034 mm, SD 0.35, 95% CI −0.132 to +0.064; p=0.49), with reasonable Bland-Altman LOA between the two methods of assessing final MLD in the overall group (LOA −0.72 to +0.66 mm), as well as in the group of particular interest with Derived final MLD <3 mm (n=30; mean 0.019 mm, SD 0.27, 95% CI −0.082 to +0.119; p=0.71; LOA −0.52 to +0.56 mm).

Conclusions Compliance charts provide an acceptable estimate of final MLD and are a reasonable guide to sizing during non-complex stenting, especially in small vessels <3 mm.

BACKGROUND

Manufacturers' compliance charts are available for angioplasty balloons and stent delivery systems to help estimate the *maximum* diameter a balloon or stent may reach at various inflation pressures. These charts are derived from in vitro testing in a water bath or related phantom at 37°C, as previously described.[1] The accuracy of these charts based on in vitro measurements has been disputed by in vivo studies using quantitative coronary angiography (QCA) and intravascular ultrasound (IVUS).[1–4] Accordingly, the use of QCA or IVUS and most recently optical coherence tomography (OCT) has been advocated to accurately measure preintervention and postintervention lumen diameter and optimise stent apposition.[5–13]

However, at our institution and in the real-world setting, OCT or IVUS are infrequently used for straightforward cases. In such non-complex stenting, the synergistic strategy of angiographic assessment and reference to compliance charts may provide a clinically adequate indication of final lumen diameter and optimal stent apposition. We therefore tested the hypothesis that in non-complex stenting, manufacturers' compliance charts are a valid guide to stent expansion and a reasonable indicator of final minimum lumen diameter (MLD).

METHODS

Fifty cases undergoing single-vessel coronary stenting for non-complex, de novo stenosis were randomly selected from the percutaneous coronary intervention database of our high-volume tertiary centre. Stent thrombosis, instent restenosis, bifurcational disease, heavy calcification, rotablation, left main or vein graft stenting, IVUS or kissing balloon inflations were exclusion criteria.

Thirty cases with compliance chart-derived final MLD <3 mm, 10 cases with final MLD 3.00–3.99 mm and 10 cases with final MLD ≥4 mm, were randomly selected from the percutaneous coronary intervention database using computer-generated random numbers (random.org, Haahr M, Dublin, Ireland). Choice of stent and stent size was at the operator's discretion. High-pressure postdilatation to achieve an optimal angiographic result was performed as necessary and concordant balloon compliance chart measurements prospectively recorded.

The poststent lumen diameter is conventionally known as final MLD. However, variation in lumen diameter along the length of a stent is well-described.[4 14–16] QCA lacks consensus terminology to address this variation. All the studies to date have selected the absolute *smallest* diameter along the length of a stent to compare against compliance chart sizes.[1–3] It seems more intuitive that the balloon compliance chart should more closely correlate with the *largest* lumen diameter achieved across the stent length. We assume that this is particularly true for simple lesions. Hence, we have taken this measurement—final (poststent) lumen diameter derived from the compliance chart—as 'Derived final MLD'.

QCA was undertaken to measure maximum, mean and minimum poststent lumen diameter. To avoid bias, QCA was performed offline using Axiom Artis VB31E Software (Siemens AG, Berlin, Germany) by an experienced observer blinded to the Derived final MLD. Measurements were calibrated to the coronary guide catheter of known French size. Diastolic frames with the greatest

Figure 1 Derived versus quantitative coronary angiography (QCA) final minimum lumen diameter (MLD) (left) and Bland-Altman Analysis (right) (n=50). *Average final MLD=(QCA final MLD+Derived final MLD)/2.
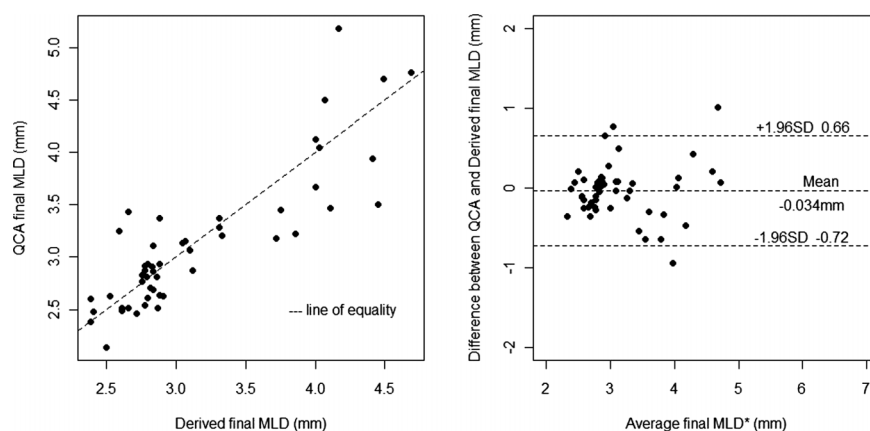
coronary artery contrast opacification and least foreshortening were used for measurements. Contour correction was manually applied if the computer-generated luminal contour was suboptimal.

Statistics

Data were analysed and plotted using SAS V. 9.1 (SAS Institute, Cary, North Carolina, USA) and R V.2.12.0 (R Foundation for Statistical Computing, Vienna, Austria). We used the paired t test to compare Derived final MLD with QCA final MLD, and Bland-Altman plots to depict the level of agreement between the two measurement methods. A line of equality was used and not a regression line as we were assessing equality between measurements of a single parameter rather than a simple linear correlation.[17][18] All statistical tests were evaluated at the 5% level of significance.

RESULTS

The mean age of patients was 59 years and 22% were women. Only 9% of these patients undergoing non-complex, single-vessel stenting were diabetic. The left anterior descending artery was most commonly stented (54%), followed by the circumflex (26%) and right coronary artery (20%).

Figure 1 shows that Derived final MLD and QCA final MLD correlate near the line of equality, suggesting the two measurements have good agreement.

The Bland-Altman plot (figure 1) shows the 95% limits of agreement, which suggest no consistent difference of one method of measurement over the other. The scatter however is greater at larger stent sizes. Overall (n=50), there is no

difference between Derived final MLD and QCA final MLD (mean 0.034 mm, SD 0.35, 95% CI −0.132 to +0.064; p=0.49).

Patients with stent size <3 mm are of particular interest because they are at greater risk of restenosis.[19][20] Figure 2 shows reasonable agreement between Derived final MLD and QCA final MLD. In this group (n=30), there is no significant difference between the two measurement methods (mean 0.019 mm, SD 0.27, 95% CI −0.082 to +0.119; p=0.71). The Bland-Altman plot shows narrow 95% limits of agreement between −0.52 and +0.56 mm (figure 2).

In contrast, when comparing the QCA measured absolute MLD across the length of the stent and *maximum* lumen diameter derived from compliance chart (Derived final MLD), the measurements do not correlate close to the line of equality (figure 3), depicting poor agreement between measurements. Balloon compliance chart-derived measurements were consistently greater than the minimum poststent lumen diameters measured by QCA (table 1).

DISCUSSION

Previous studies[1-3] have suggested that manufacturers' balloon compliance charts overestimate poststent lumen diameter, and so—in our opinion perhaps too dismissively with the growing popularity of intravascular imaging—cannot be relied upon in clinical practice. It was assumed that the discrepancy was because the in vitro method cannot account for vessel wall recoil, hydrostatic pressure in arteries and plaque characteristics including arc and length of coronary artery calcium. However, when formally tested, none of these mechanisms could fully

Figure 2 Derived final minimum lumen diameter (MLD) <3 mm versus quantitative coronary angiography (QCA) final MLD (left) and Bland-Altman Analysis (right) (n=30). *Average final MLD=(QCA final MLD +Derived final MLD)/2.
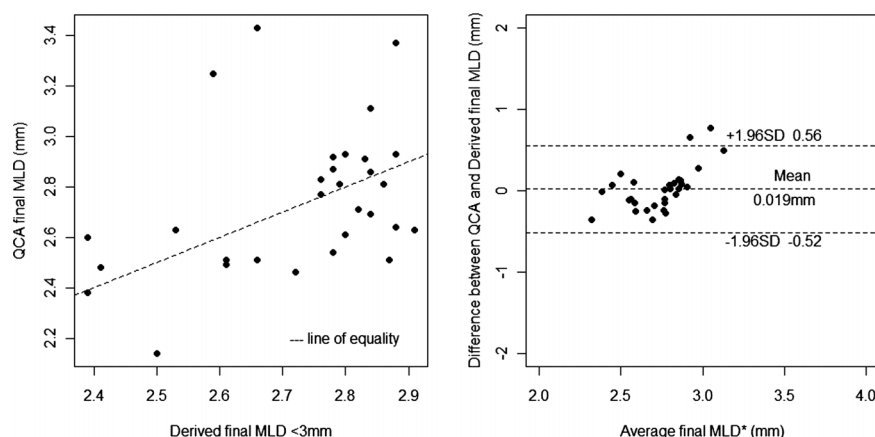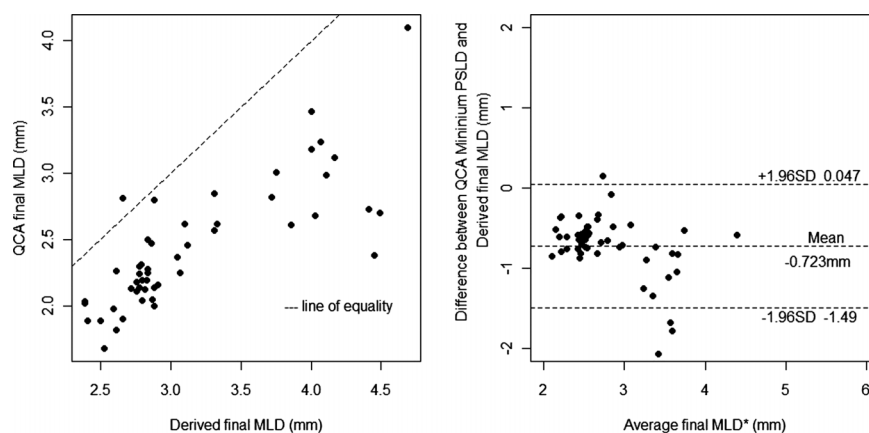
Figure 3 Derived final minimum lumen diameter (MLD) versus quantitative coronary angiography (QCA) *minimum* poststent lumen diameter (left) and Bland-Altman Analysis (right) (n=50). *Average final MLD=(QCA final MLD+Derived final MLD)/2.

account for disparity in measurement by balloon compliance charts. Measuring stent recoil in vivo is imprecise even with advanced imaging, as the margin of error (roughly 4–5%) approximates to measured stent recoil from in vitro simulations.[21] More recently, Kawasaki et al[22] described the correlation between longer balloon inflation time (60 s vs 20 s) and increased final MLD; to date, manufacturers' compliance charts do not specify the minimum inflation time needed to achieve specified sizes.

All these studies have not accounted for the reported variation in poststent lumen diameter. They have compared balloon compliance chart values with only the 'tightest' or absolute *minimum* stent diameter along the length of the stent, leading to the conclusion that compliance charts grossly overestimated final stent diameter. Our study also showed that compliance charts overestimated QCA-measured absolute *minimum* poststent lumen diameter.

Compliance charts provide only a single maximum size at the corresponding atmospheric pressure in vitro, not a range. Assuming that this maximum diameter should more closely correlate with the *largest* lumen diameter achieved across the stent length, and that this must be particularly true for simple lesions, our study also evaluated compliance chart sizes against the *maximum* lumen diameter along the length of the stent and documented that they were comparable measurements.

Furthermore, our study is unique as it included and focused on patients with final stent lumen diameter <3 mm. This group is at higher risk for restenosis and stent thrombosis[19][20] and were excluded from previous analyses.[1][2][4][14] We showed that there was actually less variation between the two measurement methods when final lumen diameters were <3 mm, implying that balloon compliance charts are even more reliable as a guide to non-complex stenting in smaller coronary arteries. In larger vessels, there clearly is more room for variability in size

measurements, but any increased variability has lesser clinical importance. In common with previous similar work, the evaluation of clinical outcome was beyond the scope of our study.

Compliance charts are meant only as a guide for interventional cardiologists and as a sizing tool cannot be as dynamic or accurate as online QCA, IVUS or OCT. A limitation of our study was that IVUS or OCT measurements were not compared also. However, the use of these imaging tools is not routine in many centres due to time and fiscal constraints, and for the purpose of our analysis, we deliberately focused on coronary lesions that were straightforward. We included only those patients with de novo coronary stenosis undergoing non-complex single-vessel stenting, so our results obviously cannot apply to all cases. In our study population however, we demonstrate that manufacturers' compliance charts provide a valid estimate of final MLD in vivo, and this is especially true in small coronary artery stenting. Our findings provide support for the popular practice that seems to be adequate for straightforward cases but previously lacked an evidence base: real-time visual assessment of the angiographic images coupled with occasional reference to compliance chart sizes to help optimise the final stent result.

CONCLUSION

In non-complex stenting that does not mandate adjunctive IVUS or OCT, our findings provide robust evidence to validate the simpler synergistic strategy of combining real-time visual angiographic assessment with reference to compliance charts to provide a clinically adequate indication of sizing and final MLD.

Table 1 Derived final minimum lumen diameter (MLD) versus quantitative coronary angiography (QCA) maximum and minimum poststent lumen diameter

Derived final MLD		vs QCA *maximum* post stent lumen diameter (*QCA final MLD*)	vs QCA *minimum* post stent lumen diameter
Overall (n=50)	Mean difference (95% CI) (mm); p value	−0.034 (−0.13 to +0.06); p=0.49	−0.723 (−0.83 to −0.61); p<0.0001
	Bland-Altman 95% LOA (mm)	−0.72 to +0.66	−1.49 to +0.05
Derived Final MLD <3 mm (n=30)	Mean difference (95% CI) (mm); p value	0.019 (−0.08 to 0.12); p=0.71	−0.563 (−0.65 to −0.48); p<0.0001
	Bland-Altman 95% LOA (mm)	−0.52 to +0.56	−1.01 to −0.12

95% LOA, 95% limits of agreement from Bland-Altman analysis.

Ethics approval Princess Alexandra Hospital HREC/09/QPAH/191.

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