Quality assessment of distal S²AS connector anastomosis by 13 MHz epicardial ultrasound

Ricardo P.J. Budde a, Willem J.L. Suyker b,c, Paul T.W. Suyker c, Cees W.J. Verlaan a, Rudy Meijer a, Cornelius Borst a, Paul F. Gründeman a,*

a Heart Lung Center Utrecht, University Medical Center Utrecht, Room G02.523, Heidelberglaan 100, 3584 CX Utrecht, The Netherlands
b Isala Clinics, Zwolle, The Netherlands
c iiTech BV, Amsterdam, The Netherlands

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Abstract

Objective: During application of a distal coronary bypass connector, we employed 13 MHz epicardial ultrasound to evaluate quantitative caliper measurements for vessel size matching and to assess anastomosis quality after connector deployment. Methods: Two S²AS connector anastomoses were constructed on ex vivo pressure-perfused porcine hearts. Epicardial ultrasound measurements of the connector ring and anastomosis were compared to intravascular ultrasound measurement and cast dimensions. In 21 pigs, anastomotic sites with internal diameter of 2.25—3.0 mm (internal mammary artery, IMA) and 1.8—2.2 mm (left anterior descending coronary artery, LAD) were selected using external caliper and epicardial ultrasound measurements. Anastomoses were visualized and assessed intraoperatively (beating heart, n = 21) and at 3 and 6 months’ follow-up (explanted heart, n = 10 each). Results: Epicardial ultrasound underestimated connector dimension by ≤5% versus intravascular ultrasound and deviated ≤13% from cast dimensions for other anastomotic measurements. Caliper estimates of internal IMA and LAD diameter differed from ultrasound by ≤3% and ≤2% (mean ± SD), respectively. Intraoperatively, the anastomotic orifice was flawless in all animals. It remained fully patent at 3 and 6 months by ultrasound, which was confirmed by histology. The connector to LAD percentage diameter stenosis changed from −12 ± 5% intraoperatively to −1 ± 7% at 3 months and from −5 ± 6% intraoperatively to −16 ± 13% at 6 months, in the growing pig model. Conclusions: In the pig, external caliper measurements provided a reliable quantitative estimate of inner graft and coronary diameter for connector size matching. Epicardial 13 MHz ultrasound is a promising method to assess coronary anastomosis quality even when connector metal is present.

Keywords: Anastomosis; Coronary artery bypass grafting; Echocardiography; Minimally invasive; Off-pump; Ultrasound

1. Introduction

The value of epicardial ultrasound for the assessment of hand-sewn anastomoses [1—3] and coronary arteries [4] has been shown previously. As novel facilitated anastomotic techniques emerge and are evaluated in animals [5] and humans [6,7], epicardial ultrasound would be a valuable intraoperative diagnostic modality for qualitative vessel wall assessment to help select an optimal anastomotic site as well as for verification of the integrity of the constructed anastomosis.

We evaluated the feasibility and validity of epicardial ultrasound to assess anastomoses constructed with one specific metal connector [5] on both the ex vivo and beating porcine heart and to validate quantitative caliper measurement for size matching.

2. Materials and methods

2.1. S²AS anastomotic system

The S²AS coronary connector (iiTech, Amsterdam, the Netherlands) has been described in detail recently [5]. In brief, the graft is connected side-to-side to the coronary artery by an intraluminal expanding metal ring with closing staples that appose donor and recipient vessel wall (Fig. 1). By clipping the graft’s distal free end, the anastomosis is converted into an end-to-side configuration (cf. Figs. 1 and 2 in Ref. [5]).

2.2. Ultrasound equipment

A commercially available, high-frequency (up to 13 MHz in B-Mode) ultrasound mini-transducer (dimensions: 15mm × 9mm × 6mm) was used as before (Fig. 2) [2,3,8]. Imaging was performed with an SSD-5000 ultrasound system (Aloka,
Tokyo, Japan). Measurements were performed with the electronic calipers of the system (increments of 0.1 mm, phantom lateral resolution < 0.25 mm).

2.3. Epicardial ultrasound measurement validation

Two S2AS internal mammary artery (IMA) to left anterior descending coronary artery (LAD) anastomoses were constructed, each on a single ex vivo porcine heart. The anastomosis was pressure perfused at both 80 and 100 mmHg with saline using a Langendorff set-up and visualized and measured by epicardial ultrasound (Fig. 3) as described below.

Subsequently, a 40 MHz intravascular ultrasound probe (IVUS) (Atlantis SR Plus Coronary Imaging Catheter, Boston Scientific, Natick, MA, USA) was advanced through the IMA to visualize the anastomosis and measure the connector diameter in triplicate (Galaxy II IVUS Imaging System, Boston Scientific, Natick, MA, USA).

Impression material (Kerr Co, Romulus, MI, USA) was introduced into the IMA to fill the IMA, anastomosis and LAD. Introduction pressure was measured intraluminally in the IMA, just above the level of the anastomosis. After hardening, the resulting 3D cast was removed and measured under 3.5× magnification using electronic sliding calipers (accurate to 0.01 mm) (Fig. 1, L2, T2, and T3 measurements, each performed in triplicate).

2.4. Animals and surgery

All animals received humane care in compliance with the European Convention on Animal Care and the study was approved by the ethics committee of our institution. Epicardial ultrasound was included in the evaluation of 21 Dalland pigs (62—94 kg) that were part of a study (which will be reported separately) to investigate the S2AS constructed left IMA (LIMA) to LAD anastomosis at 3 and 6 months. The anastomosis was constructed off-pump using a median sternotomy approach as before [5].

The specific S2AS system used can accommodate coronary artery inner diameters of 1.8—2.5 mm. However, to adjust for expected vessel growth during follow-up in the growing pig model, LIMA and LAD sites with inner vessel diameter of 2.25—3.0 and 1.8—2.2 mm, respectively, were required. This practically corresponds to an outer diameter of 2.75—3.5 and 2.3—2.7 mm, respectively, due to the 1/7 inner diameter to wall thickness ratio in this species. The LAD was clipped proximal to the anastomosis. To prevent inadvertent occlusion of side branches, an LAD section of at least 7 mm without side branches was required proximal to the anastomotic site.

The LAD was exposed by dissecting the overlying epicardial tissue at a site, which appeared to be in the diameter range by visual inspection. The distal part of the semi-skeletonized LIMA was cleared of all loose periadventitial tissue.

After 5 min of soaking in a diluted papaverine solution (5 mg/mL), pressurized LIMA and LAD external diameters were first measured using custom made calipers (0.2 mm increments, Fig. 2). Subsequently, in still transverse B-Mode epicardial ultrasound images of these sites, the internal diameter was measured (horizontal and vertical axis) in
triplicate. For each measurement the transducer was positioned anew.

After construction, the stabilized anastomosis was scanned as described below. Graft flow was measured as before [5] using a transit time flow probe (Transonic, Ithaca, NY, USA). The reactive hyperemic peak response was calculated by dividing peak mean graft flow following 30 s of stop flow ischemia by baseline mean flow.

After 3 and 6 months’ follow-up, the animals were sacrificed as before [5] and the heart was taken out. The LIMA was cannulated to perfuse the anastomosis with formalin at 80 mmHg. The anastomosis was scanned as described below. Subsequently, histologic processing was performed as before [5].

2.5. Anastomosis visualization

After gel application, the IMA, LAD and anastomosis were visualized in longitudinal and transverse planes including segments of the IMA and LAD extending approximately 15 mm upstream and downstream from the anastomosis, respectively. The inner diameters of the anastomotic orifice and of the IMA and LAD just proximal and distal to the anastomosis were measured.

2.6. Statistical analysis

The mean of the triplicate measurements was used for further analysis. The difference between both intravascular ultrasound and cast measurements and corresponding epicardial ultrasound measurements is presented as a percentage of intravascular ultrasound and cast dimensions. Data are presented as mean ± standard deviation (SD).

3. Results

3.1. Epicardial ultrasound measurement validation

Epicardial ultrasound underestimated the connector ring dimension by ≤5% compared to IVUS measurements. All other epicardial ultrasound measurements, according to Fig. 3, differed ≤13% from cast dimensions (Table 1).

In the transverse scan image, the LAD diameter at the anastomosis could not be measured due to shadowing by the overlying metal connector. Macroscopically, cast geometry corresponded to ultrasound geometry.

<table>
<thead>
<tr>
<th>Ultrasound scan plane</th>
<th>Measurement</th>
<th>Heart #1</th>
<th>Heart #2</th>
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<td></td>
<td>Epicardial ultrasound</td>
<td>Intravascular ultrasound</td>
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<td></td>
<td>Connector L1 and T1</td>
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<td>2.62</td>
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<td></td>
<td>L2</td>
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Table 1

Dimensions (mm) of ex vivo heart S2AS anastomoses measured by epicardial ultrasound, intravascular ultrasound and sliding calipers for cast dimensions

The difference is presented as percentage of intravascular ultrasound or cast measurements. See Fig. 1 for explanation of L1, L2, T1, T2 and T3 measurements. Connector diameter is presented as the measurement at 100 mmHg for both epicardial and intravascular ultrasound. Intraluminal cast injection pressure was 90 mmHg in heart #1 and 110 mmHg in heart #2. For heart #1, the mean of ultrasound measurements at 80 and 100 mmHg was compared to cast measurements and for heart #2, ultrasound measurements at 100 mmHg were used.

3.2. Animal study

Both LIMA and LAD were easily measured by both caliper and ultrasound. Caliper estimates of internal LIMA and LAD diameter differed from ultrasound by −3 ± 6% and −2 ± 7%, respectively (Table 2). In 20/21 animals a LIMA diameter within the specified study range was found. In 18/21 animals an LAD site within the study range without side branches within 7 mm proximally could be found. In three animals, LAD side branches dictated the use of sites outside the originally intended diameter range.

All 21 device deployments were successful. The animals with an LAD slightly above the originally intended inner diameter of 2.2 mm, but still within the acceptable range of the device (1.8–2.5 mm), were accepted.

Intraoperatively, all anastomoses were easily visualized and measured (Figs. 3 and 4, Table 3). No tissue ridges, intimal flaps or thrombi were observed. In one anastomosis, a hard to interpret non-obstructive “fold” of the LAD posterior wall was observed in the transverse scan image.

Intraoperative graft flow was 14 ± 7 ml/min (range 6–29 ml/min); the reactive hyperemic peak response was 6.7 ± 2.9 times baseline flow (range 2.5–13.3).

The 3 and 6 months’ follow-up periods were completed by 10 animals each (Table 3). The one death that occurred was not cardiac related. At 180 days’ follow-up (n = 10), mean graft flow and reactive hyperaemia peak response were 14 ± 7 ml/min (range 7–28) and 7.5 ± 2.5 times baseline flow (range 3.2–11). On the formalin-perfused hearts, the anastomoses were difficult or impossible to locate visually. The connector ring and the clip on the distal IMA provided echocardiographic landmarks to locate the anastomosis under the fibrotic tissue. The “fold” seen at implantation at the floor of one anastomosis had disappeared without

Values are presented as mean ± SD (n = 21). Ultrasound values are the average of triplicate measurements. Caliper outer diameter measurements were adjusted for vessel wall thickness by subtracting 2 mm × 0.25 mm to represent inner diameter.
causing apparent narrowing on either ultrasound or histology, thus making vessel spasm a likely explanation.

4. Discussion

The principal findings of this study are (1) epicardial 13 MHz ultrasound allowed assessment of anastomotic quality in the presence of a metal coronary connector; (2) in healthy vessels, caliper measurements provided a reliable indication of inner vessel diameter; and (3) epicardial ultrasound was an easy to use tool to select coronary anastomotic sites and to estimate the inner diameter.

4.1. Facilitated coronary anastomosis

Target vessel assessment is important for selecting the optimal anastomotic site and matching connector size. In healthy vessels, external diameter was easily measured by caliper and correlated well with the internal diameter measured by ultrasound. Caliper measurement, however, does not provide information about the presence of plaque and/or calcifications that should be avoided at the anastomotic site to minimize the risk of dissection during introduction of the anastomotic device into the coronary artery [7]. The two techniques are complementary: standardized caliper for obtaining a diameter measurement fast and ultrasound to assess wall pathology [4].

Similar to hand-sewn anastomoses, intraoperative quality control after facilitated anastomosis construction is important for allowing intraoperative revision of suboptimal anastomoses. Carrel et al. [7] describe one patient in whom re-operation was necessary to revise a connector constructed anastomosis that, despite adequate intraoperative graft flow, presented unsatisfactory immediate postoperative angiography findings due to capture of the coronary posterior wall by the connector. It is conceivable that intraoperative epicardial ultrasound would have detected that error. In the present study, however, no anastomotic errors were detected. With ample laboratory experience in visualizing conventional anastomoses with construction errors [2,3], we feel that the image quality was sufficient to detect abnormalities in connector anastomoses. Furthermore, it is unlikely that we missed severe narrowing of the anastomosis because in all animals, intraoperative graft flow (range 6—29 ml/min) and reactive hyperemia peak response (6.7 ± 2.9) were satisfactory, and both angiography (Fig. 5) and quantitative histology showed fully patent anastomoses at follow-up.

Connectors are being developed to facilitate off-pump and minimally invasive coronary surgery. A method to assess anastomotic quality intraoperatively needs to be applicable in these settings. First, the ultrasound mini-transducer fits between the suction pods of a coronary stabilizer [4]. Secondly, it can pass an 11 mm trocar and be used endoscopically on the anterior and posterior sides of the heart in the pig model [8]. In limited access approaches with angled visualization, epicardial ultrasound may be used for internal diameter measurement of a target artery that is difficult to access and assess by calipers.

Angiography is currently still regarded the gold standard for intraoperative anastomosis quality assessment but is
rarely used because it is invasive, time consuming and may prove difficult to interpret results [9]. Thermal and fluorescence imaging are available as well, but both techniques have a limited depth of penetration and do not provide detailed images of the anastomosis itself [10,11].

4.2. Limitations of the study

All anastomoses were constructed on healthy porcine coronary arteries. The human coronary wall thickness at the anastomotic site is likely to be more variable. However, results of 24 (conventional) anastomoses on the post-mortem human heart indicate that plaque and calcifications do not prevent assessment of coronary anastomoses by epicardial ultrasound [3].

It is conceivable that vascular connectors with a relatively large amount of metal [6] cannot be evaluated properly by epicardial ultrasound because of metal-induced imaging artefacts.

5. Conclusion

Epicardial 13 MHz ultrasound enabled intraoperative assessment of the S2AS coronary connector anastomosis in considerable detail, in spite of some metal-induced echo artefacts. To match connector size to graft and coronary size in open-chest procedures, caliper measurement provided a reliable estimate of inner vessel diameter. Epicardial ultrasound was also easy to use for qualitative vessel assessment and may be used for quantitative assessment as well.

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References