Efficacy of Super Slow Inflation as Lesion Preparation for Drug-Coated Balloons in Femoropopliteal Lesions

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Background: Drug-coated balloon strategies in endovascular therapy often result in severe dissection, so lesion preparation must be improved. We evaluated the efficacy of a gradual inflation method, termed “super slow inflation” (SSI), in preparing lesions to avoid severe dissections.

Methods and Results: The association between balloon pressure and the dilatation of a model constricted vessel, as well as the load applied to the balloon surface, were determined using a burst leak detector for a quick inflation (QI; 1 atm/s) protocol and SSI (1 atm/20 s). A retrospective, single-center, non-randomized study evaluated differences in vessel dissection patterns after balloon angioplasty depending on inflation method in 81 consecutive patients (mean ±SD age 74.6±9.2 years; 54 males) who underwent balloon angioplasty for de novo femoropopliteal lesions between January 2017 and March 2019. In the constricted vessel model, vessel dilatation increased gradually using SSI, with the maximum dilatation load being approximately 100 g lower for the SSI than QI protocol. In patients, the rate of severe vessel dissection was significantly lower in the SSI than non-SSI group (17.6% vs. 55.2%, respectively; P<0.001). Multivariate regression analysis revealed that SSI was an independent factor preventing severe dissection (odds ratio 0.18; 95% confidence interval 0.06–0.53; P=0.002).

Conclusions: SSI is a gentle and effective method for the preparation of femoropopliteal lesions to reduce the incidence of severe angiographic dissection when using drug-coated balloons.

Key Words: Angioplasty; Balloon; Endovascular therapy; Peripheral artery disease

Self-expanding nitinol stents have improved the durability of revascularization in the femoropopliteal segment. Recently, some studies reported superior results with stents over balloon angioplasty for lesions of short to intermediate length in the femoropopliteal artery, with 1-year patency rates ranging from 63% to 83%, and long-term patency rates of 49–60%. However, the medium-term patency of standard balloon angioplasty or bare nitinol stents in Trans-Atlantic Inter-Society Consensus (TASC) II C or D lesions has not been demonstrated sufficiently.

Although recent studies have reported the efficacy of drug-coated balloons (DCBs) in femoropopliteal lesions as a long-term treatment option, some cases required bail-out stenting due to severe dissection during lesion preparation. Because provisional stents are not covered by the national health insurance in Japan, DCB and metallic stents cannot be used simultaneously. This system differs from that in other countries. Fully covered stents are not considered standard care. The frequency of restenosis following stenting in long superficial femoral artery lesions has been reported to be up to 50%. The pattern of restenosis for fully covered stents is either diffuse in-stent restenosis or in-stent occlusion, which are a challenge to treat. In contrast, using DCBs may result in favorable clinical outcomes in patients with severe TASC C and D femoropopliteal artery disease and be the optimal long-term therapeutic option for patients with claudication. However, even though DCBs exhibit promising primary patency rates after 1 year, the implantation of provisional stents remains necessary following DCB treatment in a substantial number of patients with complex lesions. Because DCB therapy is associated with elastic recoil or the development of flow-limiting dissections, the quality of lesion preparation with non-coated normal balloons must be improved. Some methods of lesion preparation have been proposed.
Efficacy of SSI as Lesion Preparation

Thus, we hypothesized that gradual balloon inflation using a super slow inflation (SSI) protocol may reduce the incidence of severe dissection because of a gentle and equal dilatation with minimal force. Therefore, in this study we compared a quick inflation (QI) protocol with the SSI protocol in a model of a constricted vessel model, and investigated the efficacy of angioplasty with SSI in femoropopliteal lesions to reduce the incidence of severe angiographic dissection.
Clinical Study

A retrospective, single-center, non-randomized study was performed to evaluate differences in vessel dissection patterns after balloon angioplasty depending on inflation method. This study was performed using data from 81 consecutive patients (mean [±SD] age 74.6±9.2 years; 54 males) with symptomatic peripheral arterial disease who underwent balloon angioplasty for de novo femoropopliteal lesions between January 2017 and March 2019. Patients with in-stent restenosis and acute limb ischemia were excluded from the analysis. The SSI protocol was used in 30 patients (mean [±SD] age 72.9±9.4 years; 24 males), whereas a conventional inflation method was used in 51 patients (mean [±SD] age 75.1±8.6 years; 30 males). Baseline patient and lesion characteristics are summarized in Table 1.

Methods

Experimental Study

The experimental study was performed using a constriction vessel model (Hydraulic Burst-leak Tester; Crescent Design, San Diego, CA, USA) and 4.0-mm×40-mm high-pressure balloon (SHIDEN HP; KANEKA Medics, Osaka, Japan; see Figure 1). The association between balloon pressure and expansion of the model constricted vessel was measured using a laser and compared between the QI (1 atm/s) and SSI (1 atm/20 s) protocols (Figure 1A). The load applied to the balloon surface was also measured for both protocols using a contact load measuring instrument (STROGRAPH; TOYO Seiki Seisakusyo, Tokyo, Japan; see Figure 2).
Efficacy of SSI as Lesion Preparation

Procedures

A 4.5- or 6.0-Fr guiding sheath was inserted via the ipsi- or contralateral common femoral artery. Unfractionated heparin (5,000 units) was injected via the sheath. After the lesion was crossed successfully, balloon pressure was maintained at 1–2 atm until the balloon was filled with contrast.
Symptoms and ABI were worsened, patients underwent duplex ultrasound assessment. Restenosis was defined as a peak systolic velocity ratio of 2.4 on duplex ultrasonography, which was considered to indicate >50% narrowing.

Statistical Analysis
Statistical analyses were performed using Excel 2016 (Microsoft, Washington, USA) and EZR ver. 1.41 (Saitama Medical Center, Jichi Medical University, Tochigi, Japan) which is a graphical user interface for R ver. 3.5.2 (R Foundation for Statistical Computing, Vienna, Austria). More precisely, it is a modified version of R commander designed to add statistical functions frequently used in biostatistics.

Continuous variables are presented as the mean±SD and were compared between groups using t-tests. Categorical variables were compared between the groups using Chi-squared analysis or Fisher’s exact test. Multivariate analysis was performed by logistic regression analysis for independent variables that were related to severe dissection. Two-tailed P<0.05 was considered significant.

Baseline characteristics of atherosclerotic risk factors, lesion characteristics, and the procedural methods were prescreened using univariate logistic regression analysis to identify independent predictors of severe dissection. The lesion characteristics evaluated herein are based on those reported previously,15,19 and procedural methods were entered into a multivariate logistic regression analysis. Results are presented as odds ratios (ORs) and 95% confidence intervals (CIs).

Results
Experimental Results
The extent of dilation of a model constricted vessel was measured using laser distance measuring instrument for the QI (1 atm/s) and SSI (1 atm/20 s) protocols. The pressure to start dilatation of folded balloon of manual slow inflation and the SSI protocol was 1.7 atm lower than that for the QI protocol (Figure 3B). The extent of dilation with the SSI protocol increased gradually, with the maximum dilation from edge to edge. The balloon was equally dilated from edge to edge, leaving harder plaque in the lesion. After the surface of the balloon attached to the vessel wall, pressure was increased slowly and gradually. Balloon dilation was gradual depending on image of balloon indentation seen on the monitor. The residual stenosis was dilated gradually with minimum load. After balloon indentation disappeared, the balloon was dilated to the optimal diameter at a rate of 1 atm every 3 s (Figure 3). If there was any residual stenosis and/or flow-limiting dissection after balloon dilation, further balloon dilation was performed and/or a self-expanding stent was placed at the discretion of the operator.

Angiogram Evaluations and Definitions
All angiograms were evaluated independently by 2 experienced operators for procedural success, grading of vessel dissection, and complications. All lesions within the femoropopliteal segment were characterized according to the TASC II classification.17 Calcification in the femoropopliteal segment was assessed using unsubtracted angiography. The degree of lesion calcification was categorized according to the Peripheral Arterial Calcium Scoring System (PACSS) as follows: Grade 0, no visible calcification at the site of the target lesion; Grade 1, unilateral calcification <5 cm; Grade 2, unilateral calcification >5 cm; Grade 3, bilateral calcification <5 cm; and Grade 4, bilateral calcification >5 cm.18

Vessel dissection patterns after balloon angioplasty were classified according to the National Heart, Lung, and Blood Institute (NHLBI) classification system as follows: Type A, dissection with minor radiolucent areas; Type B, linear dissection; Type C, dissection with contrast outside the lumen; Type D, spiral dissection; Type E, persistent filling defects; and Type F, total occlusion without distal antegrade flow. Severe dissection was defined as Type C or higher, as reported previously.19 In the present study, if multiple dissection patterns were observed in a single lesion, the more severe pattern was used in analyses.

Primary patency was assessed clinically based on patient symptoms and examinations, including the Rutherford classification and ankle-brachial index (ABI). If the symptoms and ABI were worsened, patients underwent duplex ultrasound assessment. Restenosis was defined as a peak systolic velocity ratio of 2.4 on duplex ultrasonography, which was considered to indicate >50% narrowing.

Statistical Analysis
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Clinical Outcomes

As indicated in Table 1, there were no significant differences in patient and lesion characteristics, including medications, between the SSI and non-SSI groups. However, the maximum inflation pressure was significantly (P=0.004) higher and inflation time was significantly (P<0.001) longer in the SSI than non-SSI group (Table 2). The use of a high-pressure balloon was also significantly (P<0.001) higher in the SSI than non-SSI group (Table 2).

Table 2. Procedure Characteristics and Results for Lesions Overall and in the SSI (1 atm/20 s) and Non-SSI Groups Separately

|                      | Overall (n=92) | SSI (n=34) | Non-SSI (n=58) | P value |
|----------------------|---------------|------------|---------------|---------|
| Balloon diameter (mm)| 4.79±0.72     | 4.79±0.73  | 4.79±0.72     | 0.99    |
| Maximum balloon diameter (mm)| 4.93±0.74 | 4.89±0.78  | 4.95±0.72     | 0.70    |
| Balloon to vessel diameter ratio| 0.97±0.14 | 0.94±0.15  | 0.99±0.13     | 0.19    |
| Maximum inflation pressure (atm)| 12.8±5.0 | 14.7±5.1   | 11.7±4.7      | 0.004   |
| Inflation time (s) | 214±126       | 342±64     | 139±86        | <0.001  |
| Use of high-pressure balloon | 41.3 (38) | 64.7 (22)  | 27.6 (16)     | <0.001  |
| Use of scoring balloon | 6.5 (6)    | 0          | 10.3 (6)      | 0.08    |
| Use of IVUS         | 66.3 (61)     | 70.6 (24)  | 63.8 (37)     | 0.64    |
| Dissection type     |              |            |               | <0.001  |
| None                | 16.3 (15)     | 35.3 (12)  | 5.2 (3)       |         |
| A                   | 25.0 (23)     | 32.4 (11)  | 20.7 (12)     |         |
| B                   | 17.4 (16)     | 14.7 (5)   | 19.0 (11)     |         |
| C                   | 18.5 (17)     | 2.9 (1)    | 27.6 (16)     |         |
| D                   | 20.7 (19)     | 14.7 (5)   | 24.1 (14)     |         |
| E                   | 2.2 (2)       | 0          | 3.4 (2)       |         |
| F                   | 0             | 0          | 0             |         |
| Severe dissection (C–F) | 41.3 (38) | 17.6 (6)   | 55.2 (32)     | <0.001  |
| Final device        |              |            |               |         |
| Drug-coated stent   | 28.3 (26)     | 11.8 (4)   | 37.9 (22)     | <0.001  |
| Drug-coated balloon | 19.6 (18)     | 50.0 (17)  | 1.7 (1)       | <0.001  |
| POBA                | 21.7 (20)     | 29.4 (10)  | 17.2 (10)     |         |
| Stentless           | 41.3 (38)     | 79.4 (27)  | 18.9 (11)     |         |
| ABI after the procedure | 0.95±0.16 | 0.98±0.17  | 0.93±0.16     | 0.23    |

Continuous data are presented as the mean±SD; categorical data are given as the percentage (number). IVUS, intravascular ultrasound; POBA, plain old balloon angioplasty; SSI, super slow inflation.

Table 3. Results of Univariate and Multivariate Analysis for Factors Associated With Severe Dissection

|                      | Univariate analysis | Multivariate analysis |
|----------------------|---------------------|-----------------------|
|                      | OR (95% CI) P value | OR (95% CI) P value   |
| Male sex             | 0.93 (0.33–2.62) 1.00 |                       |
| Hypertension         | 1.59 (0.31–10.6) 0.72 |                       |
| Diabetes             | 1.16 (0.41–3.33) 0.81 |                       |
| Dyslipidemia         | 1.96 (0.69–6.17) 0.23 |                       |
| CKD                  | 0.75 (0.28–1.99) 0.65 |                       |
| Hemodialysis         | 0.60 (0.15–2.2) 0.57 |                       |
| CLTI                 | 0.98 (0.39–2.46) 1.00 |                       |
| CTO                  | 1.59 (0.63–4.08) 0.30 | 1.92 (0.70–5.30) 0.21 |
| Small vessel (RVD <4 mm) | 0.62 (0.22–1.67) 0.37 |                       |
| Long lesion (length >150 mm) | 1.59 (0.63–4.01) 0.29 | 0.99 (0.35–2.76) 0.99 |
| PACSS Grade4         | 1.15 (0.45–2.9) 0.83 |                       |
| Balloon to vessel diameter ratio >0.9 | 2.72 (0.98–8.2) 0.04 | 1.92 (0.67–5.46) 0.22 |
| Use of high-pressure balloon | 0.47 (0.18–1.19) 0.09 | 0.78 (0.27–2.23) 0.65 |
| SSI                  | 0.16 (0.05–0.49) <0.001 | 0.18 (0.06–0.53) 0.002 |

CI, confidence interval; OR, odds ratio. Other abbreviations as in Table 1.
In terms the final device used, the rate of use of drug-eluting stents (DES) was significantly higher in the non-SSI than SSI group (37.9% vs. 11.8%, respectively; P<0.001). In contrast, the rate of DCB use was higher in the SSI than non-SSI group (50.0% vs. 1.7%, respectively; P<0.001). The rate of severe vessel dissection was significantly lower in the SSI than non-SSI group (17.6% vs. 55.2%, respectively; P<0.001). In terms of clinical outcomes, the ABI improved significantly after the procedure in both groups.

The results of logistic regression analyses to determine factors associated with severe dissection are given in Table 3. Univariate regression analysis demonstrated that a balloon to vessel diameter ratio >0.9 (OR 2.72; 95% CI 0.98–8.20; P=0.043) and SSI (OR 0.16; 95% CI 0.05–0.49; P<0.001) were significantly associated with the absence of severe dissection. Multivariate regression analysis demonstrated that SSI was an independent factor preventing severe dissection (OR 0.18; 95% CI 0.06–0.53; P=0.002).

In additional analyses taking into account lesion characteristics, the efficacy of the SSI procedure was demonstrated for complex lesions, namely those with chronic total occlusion (CTO), long (>150 mm) lesions, and those with calcification (PACSS Grade 4). In small vessels (reference vessel diameter <4 mm), the SSI procedure was not associated with a significant reduction in the occurrence of severe dissection (OR 0.19; 95% CI 0.02–1.34; P=0.11; Figure 4).

Primary patency over a 12-month period was 85.2% in the SSI group and 68.0% in the non-SSI group.
Meier estimates of primary patency did not differ signifi-
cantly between the SSI and non-SSI groups (P=0.11; Figure 5).

Discussion

The main findings of this study are that the SSI protocol
can dilate plaques using lower force and that this method
is associated with a lower risk of severe dissection. To the
best of our knowledge, there are no studies reporting on
experimental evaluations of the dilatation process and the
clinical efficacy of the SSI protocol.

In the experimental study, we demonstrated that the
pressure to start dilatation of folded balloon was approxi-
mately 2 atm (Figure 1B). With the SSI protocol, it is
important to wait until the relief of balloon lapping. By
waiting, equal dilatation from edge to edge of the balloon
is attained. The SSI protocol dilated the model constricted
vessel gradually and with lower load than the QI protocol
(Figure 1C). To obtain good dilatation of vessels, some
dissection is necessary. The distribution of soft plaque and
minimal dissection of hard plaque are key to achieving better
results of lesion preparation. Based on the assumption
that dissection will occur when a balloon presses
against the plaque surface, redistribution of the plaque at
the start, using equal balloon dilatation with minimum
pressure, is the most important aspect of the SSI protocol.
The possibility of equal and gradual dilatation of the plaque
was demonstrated by the experimental study. In our clinical
experience, most lesions were dilated at approximately
2 atm.; this means that the plaque is dilated equally with
minimum load when a balloon comes in contact with the
plaque first.

With regard to the process of plaque dilatation, the yield
or tensile strength of the plaque are not known. If the
dilatation strength is small, the plaque will recoil; if the
dilatation strength is excessive, the plaque will be greatly
dissected. However, we can determine whether a plaque is
softer or harder by observing the SSI process. Gradual
inflation is important at the beginning of balloon dilatation
in the SSI protocol, and the balloon must be dilated to the
optimal extent after indentation disappears so that optimal
dilatation is obtained. In the present study, the rate of use
of high-pressure balloons was higher in the SSI group.
Although there were no significant differences in maximum
balloon diameter, maximum inflation pressure was higher
in the SSI group. This means that the lesions may be
dilated by optimal balloon diameter with enough pressure
using high-pressure balloons. Generally, a balloon begins
to elongate and twist when the dilatation pressure is beyond
a nominal pressure, because the balloon mechanics consist
of radial and circumferential strength. This phenomenon
was tends to be seen with semicompliant balloons rather
than high-pressure balloons and means that unequal force
will be applied to the plaque. High-pressure balloons may
apply enough force equally because the nominal pressure
of the balloon is relatively high. Although a benefit of
using high-pressure balloons for lesion preparation with
the SSI protocol was not demonstrated by logistic regression
analysis, the SSI protocol may become more effective by
using high-pressure balloons from the point of view of
equal and optimal dilatation.

In fact, the present study found that lesion preparation
with the SSI protocol produced better results in the clinical
setting than conventional balloon angioplasty. Fujihara et
al reported that dissection grades above type C were
observed in 42% of cases, and smaller vessel diameter
and/or longer lesions were related to a high incidence of
dissection. Horie et al reported on the angiographic
outcomes of balloon angioplasty with inflation times >3 min
and demonstrated that higher success rates were achieved
by preventing severe dissection. Because gradual and
gentle inflation takes a long time, total inflation time is also
quite long with the SSI protocol. Gradual, gentle, and long
inflation times would reduce long dissections and enable
the balloon to fix the flap on the vessel wall even if dissection
occurs. Plaques that can be spread at low pressure are
already compressed evenly, preventing longitudinal exten-
sion of the dissection when hard plaques are dilated. This
is why the total length of dissections is shorter and dissection
grades are reduced. Compared with previous studies, the
lesions in this study included complex lesions, such as long
lesions, small vessels, and CTO lesions, but the incidence
of severe dissection in the SSI group was lower. Although
statistically significant differences were not demonstrated
between SSI and non-SSI groups for small vessels, a trend
in favor of SSI was seen. This SSI protocol may be effective
for any lesion.

The results of the present study indicate that the SSI
protocol may be effective for avoiding unwanted dissection;
it does not require any special devices and can be performed
in an easy, safe, and inexpensive manner. The SSI protocol
as a form of lesion preparation may lead to increased
treatment options.

Study Limitations

This study has several important limitations. First, the
study was a non-randomized, retrospective, single-center
analysis with a small sample size. Second, selection bias
regarding balloon selection and the inflation method could
not be eliminated. Final devices were chosen at the discre-
tion of the operator depending on patient characteristics,
the severity of vessel dissection, and lumen area after
predilatation. Third, this study did not demonstrate statisti-
cally significant differences in primary patency, although
the primary patency rate was relatively high in the SSI
group. Finally, this study lacked independent angiographic
core laboratory adjudication.

Conclusions

SSI is a gentle and effective method for the preparation of
femoropopliteal lesions that can reduce the incidence of
severe angiographic dissection in the DCB era.

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IRB Information
This study was approved by the Ethics Committee of Fukuoka University (No. 2018M087).

Data Availability
The data analysis file and all annotated data files are available from J-STAGE data.

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