ONLINE FIRST

CARDIOLOGY JOURNAL

ISSN: 1897-5593

e-ISSN: 1898-018X

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DOI: 10.5603/cj.99667

Article type: Research Letter

Submitted: 2024-03-05

Accepted: 2024-10-07

Published online: 2024-10-24

Research Letter

The hypothetical detrimental dog-bone effect during coronary angioplasty with compliant or non-compliant balloon. An in vitro experimental study

Running title: Dog-bone effect during coronary angioplasty

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Keywords: angioplasty balloon, proximal optimization technique, post dilatation, high pressure

DOI: 10.5603/cj.99667

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Guidelines for coronary angioplasty [1] recommend a non-compliant balloon (NCB) for kissing balloon techniques and proximal optimizing technique. One of the main alleged justifications is to avoid a potential “dog-bone effect”, defined by an overdilatation of the balloon edges at high inflation pressure, especially in the case of a resistant lesion. This edge overdilatation could be complicated by excessive arterial stress and possible iatrogenic dissection. The mechanical properties of a compliant balloon (CB) would have higher risk of this potential dog-bone effect. However, to our knowledge, no clinical or experimental study has clearly demonstrated this hypothetical detrimental dog-bone effect. Our objective was to experimentally quantify the dog-bone effect in the case of NCB or CB inflation at increasing inflation pressure in the presence of a resistant lesion.

NCB (NC-Emerge™, Boston Scientific) and CB (Maverick™, Boston Scientific) were inflated at increasing pressure with 1-atm increments (from 4 to 20 atm for CB and 24 atm for NCB), precisely controlled by a pressure sensor (Gems Sensors, CO, USA). Inflation of 3.5 × 20 mm balloons (n = 5 by group) was performed in long and short cylindrical metal rings simulating resistant lesions (central figure). At each inflation step the balloons were photographed (central figure) to measure the proximal and distal edges of the balloon at the limit of the balloon parallelism (ImageJ and Matlab software, MathWorks, Inc., MA, US). All experimentations were performed in a bath held at a constant temperature of 37°C. Quantitative variables were presented as mean±SD.

During experimentation we observed no balloon rupture. The main results are shown in the central figure. Even at high inflation pressures (20 and 24 atm), the proximal and/or distal edges of the balloon diameters with striction never exceed the edges of the balloon diameters without striction, dismissing the dog-bone effect. Conversely, in the case of long striction, the measured balloon edge diameters were inferior to those of balloons without striction. The compliant balloon used in this study was twice as compliant as the non-compliant balloon (0.072 ± 0.024 mm/atm vs. 0.037 ± 0.013 mm/atm, respectively; $p < 0.005$).

The present *in vitro* study showed that even in case of resistant lesions, CBs or NCBs induce no dog-bone effect even at high pressure. In fact, in the model, the balloon diameters at the edges with striction never exceeded the balloon diameters without striction. Conversely, long striction hinders nominal deployment of balloons. Hence, the dog-bone effect cannot be an

argument to promote NCB versus CB. Likewise, the inflation pressure required to deploy a latest-generation metal stent is less than 1.5 atm [3], which is compatible with the inflation pressure range of a CB. The feasibility of using a CB for proximal optimizing technique in metal stenting has also been experimentally proven [4]. However, the mechanical properties of NCBs, especially the better resistance at very high pressures, may be useful in first intention in cases of resistant lesions.

Conflict of interest: None declared.

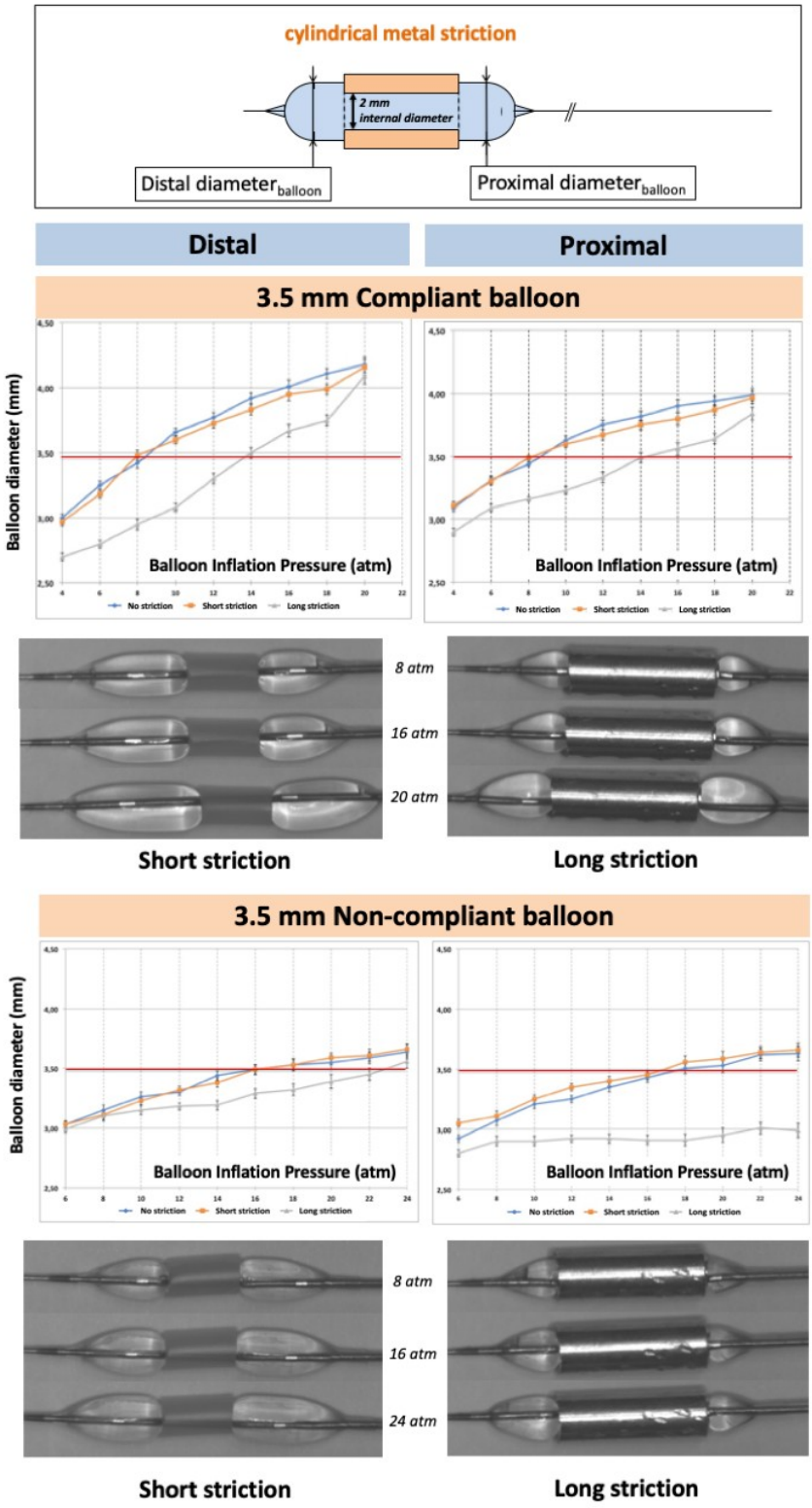

Figure 1. Determination of possible "dog-bone effect" during compliant (CB) or non-compliant balloon (NCB) inflation at high pressure. Inflation of a 3.5 × 20 mm CB (Maverick™, Boston Scientific) until 20 atm and NCB (NC-Emerge™, Boston Scientific)

until 24 atm in a thick metal cylinder (internal diameter of 2 mm and a length of either 10 mm [short] or 20 mm [long]). There is no dog-boning effect observed. *Diameters are reported as mean ± SD*

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