Safety of the Atlas Gold Balloon in Treating Iliofemoral Veins: Experience From a Single Center

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ABSTRACT: Background. We report on intraprocedural and up to 1-year outcomes on the safety of the Atlas Gold balloon (Bard) in iliofemoral venous interventions. **Methods.** All patients who underwent iliofemoral vein compression treatment in our laboratory from September 1, 2013 to May 30, 2017 were identified and medical records were reviewed. The primary safety endpoint was the intraprocedural freedom from major device-related serious adverse events (≥95%) for the Atlas Gold balloon in iliofemoral venous treatment. **Results.** Seventy-seven patients with iliac vein compression underwent intervention. Predilation was performed in 20 patients with the Atlas Gold balloon (mean diameter, 12.1 mm). The mean pressure was 5.2 atm (range, 3.0-14.0 atm). Poststent dilation was performed in 61 patients treated with the Atlas Gold balloon (mean diameter: 17.0 mm; range: 12 to 22 mm), with a mean pressure of 6.8 atm (range, 2.0-20.0 atm). There was no stent thrombosis, target-lesion revascularization (TLR), or target-vessel revascularization (TVR) at 1 month. Symptom improvement was reported in 89% of patients. There were 58 patients assessed for patency in the total cohort at 262.7 days, of which 48 patients were postdilated with the Atlas Gold balloon. All stents were patent at 1 year, and there was no stent thrombosis, TLR, or TVR in the cohort treated with the Atlas Gold balloon. Symptom improvement continued at 1 year (37/45 Atlas Gold cohort). **Conclusion.** All patients postdilated with the Atlas Gold balloon exceeded the 95% safety benchmark set in this study. No balloon perforation, vessel laceration, or balloon-related intravascular events occurred.

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Endovascular stenting of iliofemoral veins is widely accepted as an effective treatment to improve patient symptoms and reduce lower-extremity swelling.[1-6] In contrast to stent placement, balloon angioplasty (PTA) alone provides poor long-term patency results; predilation and postdilation of a stent with PTA, however, helps achieve optimal stent expansion.[7-9] PTA has been performed with a variety of balloons, none of which are dedicated to the venous space. These balloons were designed for arterial use, and lack safety data when used for venous interventions. Risks of poststent dilation may include balloon rupture, perforation, lodging on the stent, stent migration or dislodgment, difficulty crossing a stented segment, and stent edge dissections or perforations.

We report our data on the procedural safety and outcomes using the Atlas Gold balloon (Bard) (Figure 1) in prestent and poststent iliofemoral venous dilation. These data have been recently used to support indication expansion in the United States for the balloon in iliofemoral venous interventions.

Methods

All patients who underwent iliofemoral vein compression treatment in our endovascular lab from September 1, 2013 to May 30, 2017 were identified, and medical records were retrospectively reviewed for procedural and follow-up data out to 1 year. The study was approved by the institutional review board of the Genesis Health System; this review included a waiver of consent and adhered to all HIPAA regulations.

Data reviewed included clinical, procedural, and venographic variables when available. The study was internally audited by a clinical research associate who reviewed 100% of all records and data entry. Quantitative analyses were performed on available computed tomography angiogram (CTA), intravascular ultrasound (IVUS), and venogram images; the minimal luminal area (MLA) (or diameter for venograms) at the compression site and ipsilateral reference area were measured,[11-13] and the percent stenosis was calculated. Adverse events were adjudicated by an interventional cardiologist experienced in deep venous treatment.

Clinical data collected included age, sex, race, presence of diabetes mellitus, history of prior ablation or vein stripping to the superficial veins, patient symptoms of lower-extremity discomfort, venous claudication, swelling or hyperpigmentation in the lower extremities (unilateral vs bilateral), claudication, ankle brachial index of the affected limb, chronic renal insufficiency (creatinine >1.5 mg/dL or creatinine clearance <50 mL/min), dialysis, venous ulcerations, venous reflux (superficial and deep) as evaluated by duplex venous ultrasound, deep vein thrombosis, and lower-extremity cellulitis. IVUS data included severity of the compression

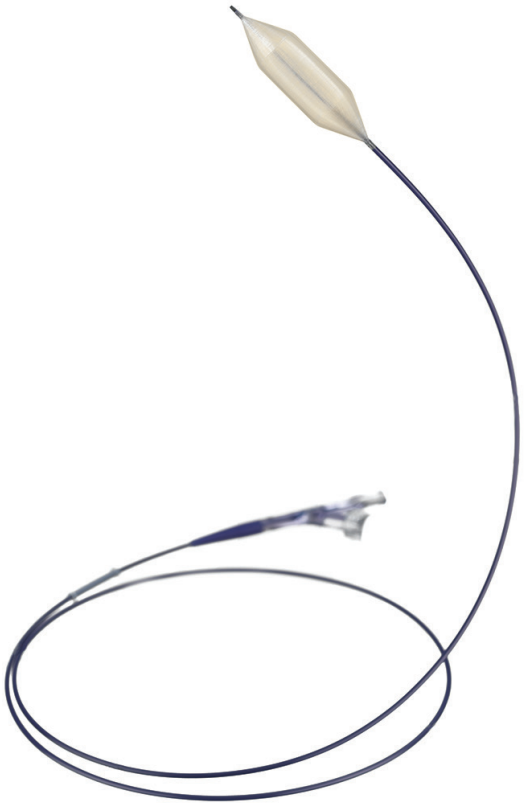

FIGURE 1. The Atlas Gold balloon (Bard).

(MLA and percent stenosis) and MLA following postdilation of the stent. Venography data included percent diameter stenosis of the compressed venous segment, and the presence of collaterals. Finally, data on balloon size, length, and pressure used during predilation and postdilation, presence of perforation post balloon inflation, distal embolization (causing documented pulmonary embolus), acute thrombotic occlusion, balloon rupture, and reported technical problems, such as the balloon getting lodged on the stent or stent dislodgment/migration, were also reported.

All consecutive patients who underwent iliofemoral venous interventions were considered for inclusion in this analysis. Patients were excluded from review only if imaging studies were incomplete, were of poor quality and could not be interpreted, or the type of balloon used for predilation or postdilation could not be identified.

Endpoints. The *primary safety endpoint* was intraprocedural freedom from major adverse event (MAE), defined as acute thrombosis, perforation, or device-related complications (eg, rupture, the balloon lodging on the stent, stent disruption/dislodgment or migration caused by balloon insertion or removal) when the Atlas Gold balloon was used. *Secondary endpoints* included: (1) in-hospital and 1-month freedom from MAE; (2) poststent MLA minus MLA present at stenosis pretreatment using IVUS (absolute MLA gain); (3) clinical improvement at 1 year (when available) ±2 months, with clinical improvement defined as reported by patients (less swelling and/or pain in the treated limb); and

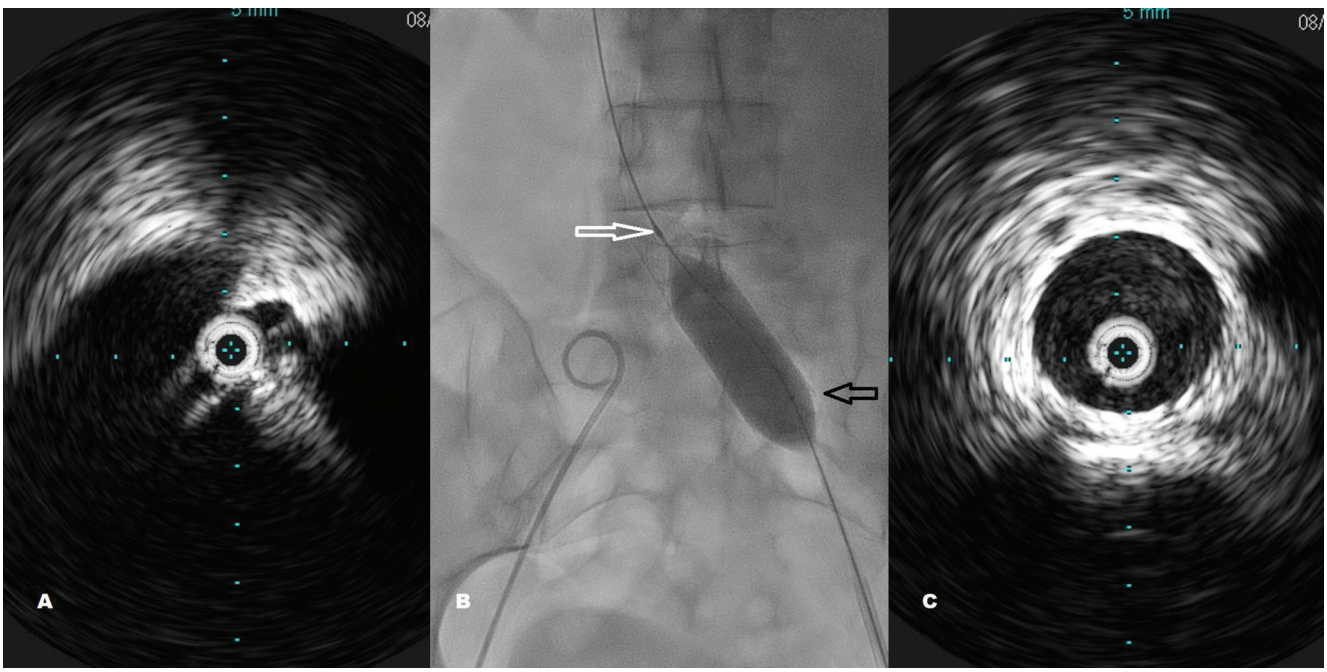

FIGURE 2. (A) Iliac compression as seen on intravascular ultrasound. (B) Post-stent dilation with Atlas Gold balloon. White arrow = tapered tip that prevents balloon from sticking on stents; black arrow = short and tapered shoulders on balloon that prevent dilation outside stent. (C) Post-dilation intravascular ultrasound showing a well-apposed and expanded stent.

Table 1. Balloon types used during the iliofemoral venous interventions.

Balloon Type	Manufacturer	(n = 96)
Unknown	N/A	1 (1.0%)
Armada	Abbott	4 (4.2%)
XXL	Boston Scientific	8 (8.3%)
Atlas Gold	Bard	61 (63.5%)
Armada + XXL		1 (1.0%)
Ultraverse	Bard	2 (2.1%)
No intervention	N/A	19 (19.8%)

Data provided as number (percentage).
N/A = not applicable.

(4) patency by Duplex ultrasound (defined subjectively by color Doppler and with the presence of normal phasic flow in the ipsilateral iliofemoral vein) at 1 month and 1 year when data are available.

Device design. The Atlas Gold PTA dilatation catheter consists of an over-the-wire catheter with a non-compliant, low-profile balloon fixed at the distal tip that is designed to provide consistent balloon diameters and lengths even at high pressures. Two radiopaque markers delineate the working length of the balloon and aid in balloon placement. The catheter is compatible with a 0.035″ guidewire and is available in 80 cm and 120 cm working lengths. The balloon has unique features that make it suitable for venous applications. It is a non-compliant balloon with shorter shoulders, and has a high burst pressure of 18 atm.[10] These properties allow venous fibrotic tissue to be dilated at high pressure with low risk of over-dilation or vessel straightening. The balloon comes in a broad range of diameters from 12 to 26 mm that is suitable for the various large sizes of the deep venous system.

Statistical analysis. The study had no predefined statistical analysis as no prior data on the safety of balloons in treating the deep venous system were available. We assumed, however, that intraprocedural freedom from device-related MAEs was ≥95% for a safe application of the Atlas Gold balloon in iliofemoral venous treatment. If patent at 1-year follow-up, the assumption of patency at 1 month was made when calculating follow-up time for patency. Analysis was done on an intention-to-treat basis. Missing data were replaced with

Table 2. Demographics and clinical variables of Atlas Gold balloon patients.

	(n = 61)*
Age (years)	61.9 ± 14.7
Body mass index (kg/m²)	32.6 ± 7.9
Systolic blood pressure (mm Hg)	122.7 ± 14.3
Pulmonary artery pressure (mm Hg) (n = 14)	32.9 ± 11.1
History of deep vein thrombosis	11 (18.0%)
History of pulmonary embolism	8 (13.1%)
History of cellulitis in affected leg	2 (3.3%)
Hypertension	35 (57.4%)
Hyperlipidemia	37 (60.7%)
History of smoking	21 (34.4%)
Diabetes mellitus	9 (14.8%)
History of peripheral arterial disease	3 (4.9%)
History of coronary artery disease	7 (11.5%)
History of pulmonary hypertension	3 (4.9%)
History of sleep apnea	14 (23.0%)
History of lymphedema	0 (0.0%)
History of chronic renal insufficiency	0 (0.0%)
Inferior vena cava filter	1 (1.6%)
Known thrombophilia	1 (1.6%)
CEAP class	
II	3 (4.9%)
III	28 (45.9%)
IV	12 (19.7%)
V	2 (3.3%)
VI	16 (26.2%)
Heaviness/pain in lower extremity	
No	18 (29.5%)
Unilateral	43 (70.5%)
Bilateral	0 (0.0%)
Lower-extremity edema	
No	14 (23.0%)
Unilateral	47 (77.0%)
Bilateral	0 (0.0%)
Venous claudication	
No	11 (18.0%)
Yes	8 (13.1%)
Missing	42 (68.9%)
Superficial vein reflux in affected limb	
No	8 (13.1%)
Yes	43 (70.5%)
Missing	10 (16.4%
Reflux in deep venous system	
No	43 (70.5%)
Yes	9 (14.8%)
Missing	9 (14.8%)

Data provided as mean ± standard deviation or number (percentage).
*Total n = 61 patients unless otherwise noted.
CEAP = clinical, etiologic, anatomic, pathologic.

Table 3. Imaging variables.

	(n)	Mean ± SD
Minimal luminal area at lesion by CTA (mm²)	43	146.1 ± 67.3
Minimal luminal area at lesion by IVUS (mm²)	40	72 ± 40
Post-stenting minimal luminal area by IVUS (mm²)	39	218.8 ± 75.6
Minimal luminal area ipsilateral reference area by IVUS (mm²)	40	226.7 ± 83.6
Stenosis at compression using ipsilateral reference by CTA (%)	41	51.8 ± 21.9
Stenosis at compression by IVUS (%)	40	66.2 ± 17.3
Stenosis at compression by venography (%)	31	50.8 ± 14.2
	(n = 61)	
Iliac vein compression location		
Left common iliac vein	52 (85.2%)	
Both right and left common iliac vein	2 (3.3%)	
Right common iliac vein	3 (4.9%)	
Missing information	4 (6.6%)	

Data provided as mean ± standard deviation or number (percentage). CTA = computed tomography angiography; IVUS = intravascular ultrasound.

multiple imputations.[14] Descriptive analysis was performed on all variables. Two-sample t-test was performed as appropriate. Statistical analysis was done with Minitab 17 (Minitab, Inc) and SPSS software (IBM).

Results

A total of 96 patients with iliofemoral compression were identified as having a venogram and IVUS by three operators; 19 patients did not have an intervention because the lesion was deemed not significant. Of the 77 remaining patients, 61 were treated with the Atlas Gold balloon prestent or poststent placement in the iliofemoral vein. The remaining 16 patients were treated with a variety of other balloons (Table 1). Table 2 displays the demographics of patients treated with the Atlas Gold balloon. Mean age was 61.9 years and 37/61 patients (60.7%) were females. Average body mass index was 32.6 kg/m². A history of deep vein thrombosis (DVT) was present in 18% of patients. Advanced venous insufficiency (clinical, etiologic, anatomic, pathologic [CEAP] class IV to VI) was present in 49.2% of patients. The majority of the patients were symptomatic with unilateral leg swelling, pain, or the presence of venous reflux. Table 3 displays imaging variables from venography, CTA, and IVUS before and after treatment. The majority of patients had May-Thurner syndrome of the left common iliac vein (85.2%), which was compressed by the right common iliac artery.

Predilation was performed in 20 patients with the Atlas Gold balloon. The mean pressure was 5.2 atm (range, 3.0-14.0 atm). All balloons used were 40 mm in length, with a mean balloon diameter of 12.1 mm. The Wallstent (Boston Scientific) was the most commonly used stent in the study; the Veniti stent (Boston Scientific) and Venovo stent (Bard) were also implanted as part of investigational device exemption (IDE) studies in which our lab participated as an investigational site. The mean stent diameter was 18.3 mm (range, 10-24 mm) and the mean stent length was 49.5 mm (range, 10-125 mm). Poststent dilation was performed with the Atlas Gold balloon in 61 patients. The mean balloon diameter used for postdilation was 17.0 mm (range, 12-22 mm); again, all balloons were 40 mm in length, and the mean inflation pressure was 6.8 atm (range, 2.0-20.0 atm). Post stenting, the IVUS MLA was markedly improved (Figure 2) and became nearly the same as the reference ipsilateral common iliac vein.

There were no intraprocedural MAEs reported for 97.4% of the total cohort and 96.8% of the Atlas Gold patients, which met the primary safety endpoint of ≥95%. The 2 intraprocedural complications that occurred for the total cohort and the 1 complication for Atlas Gold were attributed to stent migration when the stent delivery sheath was withdrawn; none were adjudicated as balloon related. There was no perforation or balloon rupture, and no balloons lodged in the stents while tracking. In addition, there was no stent thrombosis, target-lesion revascularization (TLR), or target-vessel revascularization (TVR) at 1 month. Symptom improvement was reported in 54/61 patients (88.5%), and active ulceration was numerically less than baseline (11.5% vs 26.2%, respectively). Forty of 61 patients had duplex ultrasound exams to assess patency at 1 month. All stents were patent.

Patients treated with the Atlas Gold balloon had a mean follow-up time of 269.6 days (range, 13-606 days). A total of 35 patients had duplex ultrasound exams at 1 year, and the stents were all patent. At 1 year, there was no stent thrombosis, TLR, or TVR in the cohort treated with the Atlas Gold balloon. There was 1 case of stent thrombosis and 2 cases of TLR/TVR in the non-Atlas Gold patients. Symptom improvement continued to be seen at 1 year in the majority of patients as reported subjectively by patients (51/59 in the overall cohort and 37/45 in the Atlas Gold cohort).

Discussion

In this retrospective analysis, the Atlas Gold balloon exceeded the safety benchmark of 95% freedom from MAEs. No balloon perforation, vessel laceration/perforation, or balloon-related intravascular events occurred. The 1-month and 1-year follow-up exams were encouraging with no adverse events related to balloon use and with marked symptom improvement. Finally, imaging analysis showed that stent expansion post Atlas Gold balloon dilation yielded

excellent stent expansion at the level of the target compression site.

In this study, no comparisons can be made between the Atlas Gold balloon group and patients dilated with other balloons, given the small number of patients that received the non-Atlas Gold balloon. The Atlas Gold balloon has a tapered tip with a low profile when crossing stents, making it less likely to lodge on the stent. In addition, it has short shoulders that allow high-pressure dilation at the stent edges. Iliac compression is generally characterized by a high degree of fibrosis; generally, high-pressure dilation is needed to stretch the vessel and to allow good stent expansion. The Atlas Gold balloon allowed dilation up to 18 atm; stent expansion was excellent in our study, with the MLA post stent placement reaching the reference lumen diameter in most cases (218.8 ± 75.6 mm^2 vs 226.7 ± 83.6 mm^2, respectively; P=.66). It should be noted, however, that this is likely due in part to the high crush resistance and strong radial force of the dedicated venous stents used in this study (Venovo and Veniti).

Conclusion

In summary, the Atlas Gold is the first balloon to gain United States Food and Drug Administration approval for iliofemoral venous treatment partly based on the data presented in this study. In this retrospective analysis, we observed that the balloon could be used safely in iliofemoral veins. This was an observational analysis that hopefully will help generate hypotheses for future prospective registries and randomized trials needed to validate these findings.

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