Retrospective Analysis of Peripheral Vascular Intervention Procedural and Safety Outcomes With Utilization of the Terumo Glidesheath Slender for Tibiopedal Access

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Abstract

Purpose. To demonstrate safety and performance of the Terumo Glidesheath Slender for tibiopedal access. **Methods.** This was a retrospective study of patients who underwent peripheral vascular intervention with tibiopedal access using the Terumo Glidesheath Slender. A subset of patients who underwent peripheral vascular intervention utilizing the tibiopedal arterial minimally invasive retrograde revascularization (TAMI) technique with the Glidesheath Slender were evaluated. **Results**. Among 445 subjects (mean age 71±9 years, 74.2% men, 94.6% CLI), tibiopedal access using the GlideSheath Slender was successful in 100% of cases. Revascularization devices used included plain angioplasty (97.3%), atherectomy (94.6%), stent placement (17.1%), and drug-coated balloon (8.9%). Freedom from a complication through 30 days was 86.8%. Among the 268 subjects treated using the TAMI technique, procedure success (stenosis <30%) was 93.2% and freedom from a complication through 30 days was 87.2%. **Conclusion.** Tibiopedal access is an ever-evolving technique that has grown in popularity and use for treatment of CLI patients. The use of the Glidesheath Slender in tibiopedal access represents a safe and effective technique for achieving successful access that allows for many treatment modalities and provides successful procedure outcomes.

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Key words: critical limb ischemia, pedal access, tibiopedal access, Glidesheath slender, TAMI, tibial artery minimally invasive

Introduction

Peripheral arterial disease (PAD) and critical limb ischemia (CLI) have garnered significant attention over the last decade as one of the most prolific and deadly diseases.[1] With disease numbers climbing to almost 10 million Americans with mortality rates of 70% at 10 years,[2] advances in treatment have proven necessary to better understand and adequately treat patients at risk for loss of limb or life. Retrograde tibiopedal access has been well documented as a safe and effective technique for increased treatment success for revascularization of the peripheral arteries as well as better patient outcomes.[3,4]

Chronic total occlusion (CTO) is well known to be the most complicated obstacle when dealing with advanced PAD and CLI, hence the need to search for alternative access to facilitate crossing complex CTOs, often at multiple levels and in multiple vessels above and below the knee. The CTOP Classification study describes the four CTO types and ideal crossing methods for each. The study showed that 63% of CTO crossing failed from an antegrade femoral or contralateral up and over femoral approach.[5] High failure rate demonstrated the need for retrograde tibial access as a viable alternative option.

More advanced techniques such as the tibiopedal artery minimally invasive retrograde revascularization (TAMI) technique have been described as innovative for treating patients with limited access site options and other physical barriers.[6,7] These methods allow for the same treatments to be performed safely and effectively due to the composition of CTO caps that tend to be easier to cross from retrograde tibial approach. The TAMI

FIGURE 1. Retrograde pedal access of the posterior tibial artery with Glidesheath Slender 5Fr.

Figure 2. Dual retrograde posterior tibial artery access and antegrade dorsalis pedis artery access for tibial artery minimally invasive (TAMI) approach of tibial and pedal loop reconstruction.

and CTOP analyses recommend consideration of retrograde tibial access when planning complex revascularization. The studies showed that early transition to retrograde tibial access can promote efficiency in crossing complex CTOs.[5,6]

Little attention has been paid to the safe and successful use of sheaths in the setting of tibiopedal access. Operators have documented concern over introducing a sheath to the tibiopedal circulation for risk of access site complication or vessel compromise based on earlier, less proficient endovascular techniques.[4] With proven procedure success utilizing tibiopedal access, the safe use of the Terumo Glidesheath Slender may provide a wider array of access and treatment possibilities in patients with complex disease and limited access options. The Glidesheath Slender, with its unique composition of thin wall design, allows for the same treatment modalities as femoral access with a smaller puncture profile **(Figure 1).**

Methods

Study design. WCG Institutional Review Board reviewed and approved this research. The requirement for informed consent was waived. A retrospective chart review of procedure data from the patients who underwent a peripheral vascular intervention at two sites with tibiopedal access using the Terumo Glidesheath 5-Slender, 6-Slender, and 7-Slender, between September 2018 and September 2020. Access site complications were defined as access site occlusion, access site hematoma, bleeding, infection, pain, or pseudoaneurysm up to 30 days post procedure.

A subset of patients who underwent peripheral vascular intervention utilizing the TAMI technique,[7] were identified from the primary data set. Treatment modalities for this subset were evaluated to include the rates of the use of atherectomy, balloon angioplasty (plain and drug-coated), and stent deployment. Pre-intervention stenosis, procedure success rate (<30% residual stenosis), and time to discharge were also evaluated. Data were reported as mean and standard deviation for continuous data and counts and percentages for categorical data **(Figure 2)**.

Results

A total of 445 subjects underwent peripheral vascular intervention with tibiopedal access utilizing the Glidesheath

Table 1. Baseline patient characteristics.

Characteristic	All patients	TAMI
Age, yr	71 ± 9	71 ± 9
Male sex	74.2% (330/445)	72.8% (195/268)
Hypertension	88.5% (394/445)	89.6% (240/268)
Hyperlipidemia	84.9% (378/445)	85.4% (229/268)
Tobacco history	74.8% (333/445)	75.7% (203/268)
Diabetes mellitus	60.9% (271/445)	61.9% (166/268)
Coronary artery disease	51.9% (231/445)	52.6% (141/268)
Chronic kidney disease	27.6% (123/445)	31.0% (83/268)
Rutherford class	4.6 ± 0.8	4.4 ± 0.8
2-3	5.4% (24/444)	7.5% (20/268)
4	47.7% (212/444)	51.9% (139/268)
5	33.6% (149/444)	31.0% (83/268)
6	13.3% (59/444)	9.7% (26/268)

TAMI = tibiopedal minimally invasive revascularization

Table 2. Procedural details.

Characteristic	All patients	TAMI
Access site		
Posterior tibialis	53.0% (236/445)	54.5% (146/268)
Anterior tibialis	36.6% (163/445)	34.3% (92/268)
Dorsalis pedis	10.3% (46/445)	11.2% (30/268)
Sheath size		
5 Fr	87.9% (391/445)	86.9% (233/268)
6 Fr	8.3% (37/445)	9.3% (25/268)
7 Fr	3.8% (17/445)	3.7% (10/268)
Closure method		
Manual pressure	74.6% (332/445)	76.5% (205/268)
External device	13.9% (62/445)	17.5% (47/268)
Balloon	9.2% (41/445)	3.7% (10/268)
Other	2.0% (9/445)	1.9% (5/268)

TAMI = tibiopedal minimally invasive revascularization

Slender. Mean age was 71±9 years, 74% were men, and the most common comorbidities/risk factors were hypertension (88.5%), hyperlipidemia (84.9%), tobacco history (74.8%), and diabetes mellitus (60.9%). Critical limb ischemia was identified in 94.6% of subjects based on Rutherford class ranging from 4 to 6 **(Table 1)**. Tibiopedal access using the GlideSheath Slender was successful in 100% of cases, with the 5 Fr sheath most commonly utilized. The posterior tibial artery was the most common access vessel, accounting for 53.0% of the access sites **(Table 2)**. Among 441 (99.1%) subjects with available complication data, freedom from a complication through 30 days was 86.8%. The most commonly reported complications were access site occlusion (8.8%), access site bleed (3.2%), and access site hematoma (0.9%). All bleed and hematoma events resolved with manual pressure.

A total of 268 (60.2%) subjects were treated using the TAMI technique. These patients had tibiopedal access only without concurrent common femoral access and all access was obtained with extravascular ultrasound (EVUS) guidance. Baseline patient characteristics and sheath utilization were comparable to the overall sample of subjects **(Tables 1-2)**. Chronic total occlusion was identified in 70.6% of subjects. Treatment modalities included plain angioplasty (97.3%), atherectomy (94.6%), stent placement (17.1%), and drug-coated balloon (8.9%). Mean procedure time was 103±41 minutes. Procedure success was 93.2% among all subjects treated with the TAMI technique, and remained high among subgroups of interest **(Table 3)**. Freedom from a complication through 30 days was 87.2%, which was comparable to the overall sample of subjects and remained high among subgroups of interest **(Table 4)**.

Discussion

In this large study of subjects who underwent peripheral vascular intervention with tibiopedal access, utilization of the Terumo Glidesheath was associated with high treatment success rates, low complication rates through 30 days, with comparable performance and safety when used in both populations reported in this study. Trials evaluating use of tibial access to facilitate treatment or tibiopedal artery minimally invasive retrograde revascularization (TAMI) did not comment on access site patency at 30 days. To our knowledge, this is the first study that specifically evaluated pedal access site patency independent from vessel patency. This retrospective analysis was performed in a tertiary critical limb ischemia center where patients are referred for limb salvage. All arterial access obtained in this analysis was performed utilizing extravascular ultrasound (EVUS) guidance.

The decision-making process of choosing an access site is complicated. Multiple factors are taken into consideration and reviewed prior to proceeding with needle insertion. Location of the lesion, lesion pathology, body habitus, and operator skill are just a few factors considered. All these factors help steer endovascular interventionalists toward the most clinically appropriate point of access. The initial techniques described by Drs. Sven-Ivar Seldinger, Charles Dotter, and Andreas Roland Gruentzig brought about refinements in every aspect of intervention, including access points.[8] In 2003, Dr Botti and colleagues reported six patients with CLI that had failed traditional antegrade femoral approach but were successfully revascularized through the posterior tibial artery access.[9,10] Dr Charles Dotter stated that refinements come from a working beginning,[8] so in 1988 Dr

TABLE 3. TREATMENT SUCCESS IN SUBGROUPS OF INTEREST WITH TAMI.

Characteristic	Value
Overall	93.2% (234/251)
Age	
≤ 70 yr	93.7% (119/127)
>70 yr	92.6% (112/121)
Sex	
Male	91.7% (165/180)
Female	97.2% (69/71)
Diabetes mellitus	
Yes	96.1% (148/154)
No	88.7% (86/97)
Chronic kidney disease	
Yes	96.2% (76/79)
No	91.9% (158/172)
Rutherford class	
2-4	90.6% (135/149)
5-6	97.1% (99/102)
Chronic total occlusion	
Yes	92.0% (161/175)
No	95.9% (71/74)
Sheath size	
5 Fr	92.7% (204/220)
6 Fr	95.5% (21/22)
7 Fr	100% (9/9)
Atherectomy	
Yes	94.5% (224/237)
No	71.4% (10/14)
Stent	
Yes	97.6% (41/42)
No	92.3% (191/207)
Drug-coated balloon	
Yes	100% (20/20)
No	92.6% (214/231)

TAMI = tibiopedal minimally invasive revascularization

TABLE 4. COMPLICATIONS THROUGH 30 DAYS.

Characteristic	All patients	TAMI
Freedom from complication	86.8% (383/441)*	87.2% (231/265)**
Access site occlusion	8.8% (39/441)	7.5% (20/265)
Access site bleed	3.2% (14/441)	4.2% (11/265)
Hematoma	0.9% (4/441)	1.1% (3/265)
Infection	0.2% (1/441)	0.4% (1/265)
Pain	0.2% (1/441)	0% (0/265)
Balloon	9.2% (41/445)	3.7% (10/268)
Other	2.0% (9/445)	1.9% (5/268)

TAMI = tibiopedal minimally invasive revascularization
*59 complications in 58 patients.

Iver and Dr Dorros and colleagues first described a retrograde posterior tibial pedal technique using a cutdown to facilitate the insertion of a wire and crossing of occluded tibial arteries that had failed an antegrade crossing attempt. By the time their article was published in 1990, they had attempted this technique five times. Four of the five cases were accessed by cutdown and arteriotomy of the accessed artery. They successfully accessed and treated through the posterior tibial artery four times and the anterior tibial artery once.[11]

Since its beginning, tibiopedal access has progressively developed into a technique facilitating crossing and treating complex lower extremity atherosclerotic disease. The sheathless technique was initially used most often because the complications associated with pedal access were related to the large-bore sheaths that were available at that time. The sheathless technique had the hypothetical advantage of creating a smaller arteriotomy. Operators would secure a long wire in the vessels via the Seldinger technique, then support the wire with either a low-profile balloon or catheter directly through the skin. The drawbacks associated with this are potential risk of losing access during device exchange and lack of a port to be used for administering medications (eg, intraarterial vasodilatory cocktails) or injecting contrast to obtain angiographic control images.[12-14] In addition, it has been the authors' experience that the sheathless, or "bareback," approach[13] with its repeated movement at the access site can create intimal injuries and dissections. This approach may result in endothelial trauma and even thrombosis of the access vessel. The advancements in sheath technology have made sheaths easier to insert from a pedal approach and have improved safety and efficiency for treatment of CLI patients. The new pedal sheath technology available allows for wire escalation and support catheter exchanges which facilitate CTO crossing. Other advantages of new technology sheaths include access large enough to utilize a wider range of atherectomy devices, balloons (including DCB), and stent devices. Distal embolectomy devices can also be introduced through these newer sheaths. Additionally, a tibiopedal sheath may also offer the advantage of avoidance of arteriotomy site trauma related to device exchanges.

For some interventionalists, retrograde pedal access presents difficulties and should be performed with additional training and

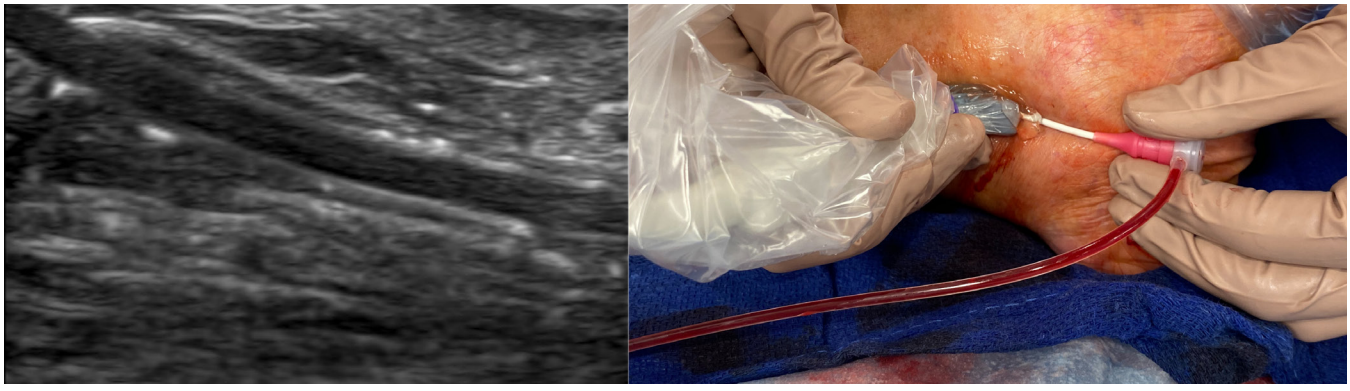

Figure 3. Extravascular ultrasound (EVUS) image (left) showing the sheath withdrawing from the access vessel while the sonographer (right) evaluates the removal in live time for accurate arteriotomy identification and to ensure appropriate pressure for patent hemostasis.

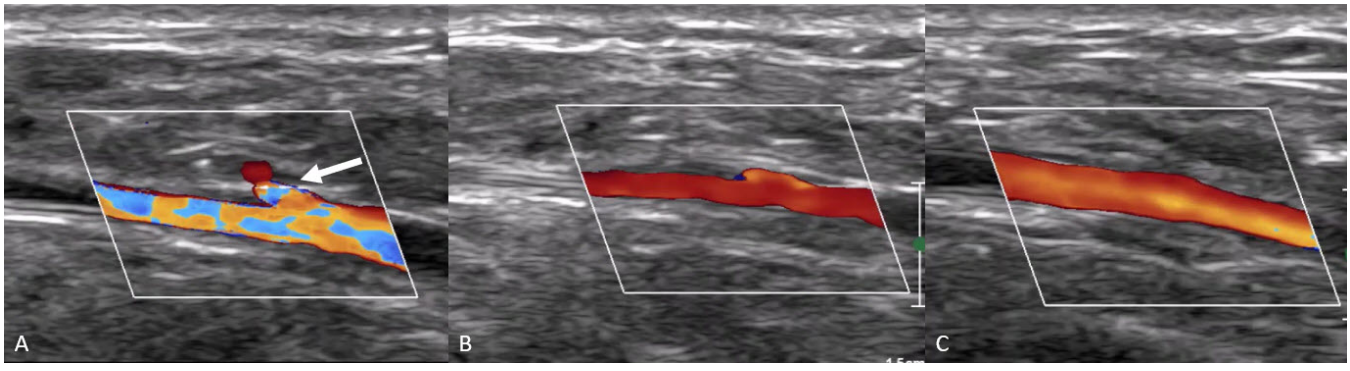

Figure 4. (A) Extravascular ultrasound (EVUS) assessment of the tibial artery after sheath removal using color doppler to identify the location of the arteriotomy. **(B)** EVUS-guided pressure is held while maintaining patency of the artery. **(C)** Evaluation of the tibial artery post pressure confirming successful EVUS-guided patent hemostasis.

proficiency. It has been reported that 20% of tibial lesions cannot be crossed with an antegrade technique,[15] hence incorporating retrograde access facilitates crossing. Long-term outcomes utilizing retrograde access with endovascular intervention of the tibial, superficial femoral, and popliteal arteries are unknown.[9] With continued information gathering and progressive technical advancements in technology, as well as improving individual skill levels, the retrograde pedal approach may become more common in the future. The quality and safety of any device is in its ability to repeatedly perform as expected and to deliver according to interventional expectations.

The authors would like to mention that after this analysis was performed, an institutional EVUS-guided closure protocol of the pedal arteriotomy site was implemented. The protocol includes utilizing EVUS guidance during removal of the tibiopedal sheath with ultrasound-mediated pressure applied to obtain hemostasis while maintaining flow through the vessel. EVUS-mediated pressure is utilized for a duration of 5-10 minutes and successful hemostasis is confirmed with EVUS. The impact of access vessel closure should be evaluated utilizing patent hemostasis techniques in the future **(Figures 3 and 4)**.

There were several limitations of the study that warrant discussion. The study included data collected from 4 operators at 2 different locations. Additional multicenter studies are recommended to determine whether the results presented here are generalizable to techniques used in a broader range of patient characteristics and user experiences. The specific types of atherectomy, balloon, and stent technology were not evaluated for this study. Complication data were not available for four of the patients in the TAMI cohort and were excluded from the analysis. This was a retrospective study and, therefore, the potential for bias and confounding must be acknowledged.

Conclusion

Tibiopedal access is an ever-evolving technique that has grown in popularity and use for treatment of CLI patients. The use of the Glidesheath Slender in tibiopedal access represents a safe and effective technique for achieving successful access that allows for many treatment modalities and provides successful procedure outcomes.

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