Allegato n° 1 alla determinazione
Serv. Provveditorato N° 328 del 25.06.2010
Composto di n° 12 fogli

Bianchi 24/6/10

SERVIZIO SANITARIO NAZIONALE – REGIONE SARDEGNA

Azienda U S L 5 - OSPEDALE S. MARTINO - ORISTANO

U. O. CARDIOLOGIA - UTIC

Primario: Dr. Sergio Mariano Marchi
Telefono: UTIC 0783 317295 Ambulatorio 0783 317209
E-mail: utic.oristano@anmco.it

Alla cortese attenzione della Responsabile Ufficcio Acquisti ASL5.

Oggetto: integrazione infungibili per l'Emodinamica S. Martino.

Si dichiara che è indispensabile l'inserimento nella lista infungibili del sostema del catetere Guideliner (codice VAS-5571, VAS 5572 e VAS 5573) che permette d'eseguire in sicurezza angioplastiche coronariche particolarmente complesse per la tortuosità del vaso e/o lo scarso supporto del catetere guida.
Tale sistema costituisce un prodotto unico ed insostituibile per cui si opta per la dichiarazione di scelta.
Tale prodotto è commercializzato direttamente dalla NGC quindi il prezzo è il più basso possibile e assolutamente proporzionato rispetto all'ordine di grandezza dei prezzi delle procedure d'Emodinamica (il prodotto è sterile e monouso per cui è necessario un pezzo per ogni procedura).
Si allega le relative offerta economica e documentazone scientifica.
Il consumo annuo prevosto è di circa 20 pezzi.
Porgendo cordiali saluti si resta a disposizione.

Oristano 22/06/10

In fede.
Il Responsabile della Struttura Semplice d'Emodinamica Dr. Stefano Naccarato

medical S.p.A.

Servizio Acquisti, S.T. e G.P.
AZIENDA U.S.L. N.5
Via Carducci 35
09170 ORISTANO

Novellara, 9 giugno 2010

Oggetto: contratto per la fornitura di un laboratorio di [illegible] presso il P.O. San Martino di Oristano.
Ns. offerta integrativa nr. NN/189/10

In relazione alla gestione in service in oggetto e ad integrazione della ns. offerta nr.NN/016/07 del 15/01/07, con la presente siamo lieti di sottoporvi la nostra migliore offerta per il seguente prodotto di Vs. interesse:

Materiali speciali o esclusivi per procedure interventistiche [illegible]

- Guideliner
  Produzione Vascular Solutions
  cod. VAS-5571 6 fr
  Prezzo unitario a Voi riservato .... € 400,00
  (quattrocento/00)
- Guideliner
  Produzione Vascular Solutions
  cod. VAS-5572 7 fr
  Prezzo unitario a Voi riservato .... € 400,00
  (quattrocento/00)
- Guideliner
  Produzione Vascular Solutions
  cod. VAS-5573 8 fr
  Prezzo unitario a Voi riservato .... € 400,00
  (quattrocento/00)

* * *

Condizioni di fornitura
- I.V.A. (20%) a Vs. carico
- Merce resa franco Vs. sede
- Consegna entro i termini da Voi stabiliti
- Validità offerta: per tutta la durata del contratto
- Pagamento 90 gg d.f.

Nella speranza che la presente venga favorevolmente accolta, ci è gradito porgerVi i nostri più cordiali saluti.

N.G.C. Medical S.p.A.
Il Legale Rappresentante
Dr. Paolo Cremascoli

N.G.C. Medical S.p.A.

Catheterization and Cardiovascular Interventions 00:000–000 (2010)

Case Report

Distal Stent Delivery With Guideliner Catheter: First in Man Experience

Mamas A. Mamas,[1,2] PhD, BM BCh, Farzin Fath-Ordoubadi,[1] MD, BM BChir, and Douglas G. Fraser,[1*] MD, BM BChir

Failure to deliver stents is one of the commonest causes of procedural failure in contemporary PCI practice. We describe successful use of the Guideliner Catheter, the first purpose designed FDA and CE marked device delivery catheter in 13 complex cases in native coronary vessels and bypass grafts performed via the radial route to enable distal stent delivery following failure of conventional techniques. We discuss how the Guideliner catheter may be used to facilitate difficult radial cases. © 2010 Wiley-Liss, Inc.

Key words: TRAD; transradial cath; PCI; percutaneous coronary intervention; ANGO; angiography; coronary

INTRODUCTION

Failure to deliver stents during percutaneous coronary interventions (PCI) is one of the major causes of procedural failure that may occur in up to 5% of cases in contemporary PCI practice [1,2]. We have previously described use of the Terumo 5F Heartrail II catheter within a standard 6F guiding catheter (so called "five-in-six" system) to aid stent delivery. Extra deep coronary intubation using this catheter increases backup support and bypasses proximal points of obstruction to enable distal stent delivery in both native coronary vessels and coronary artery bypass grafts [3,4].

The Terumo "five-in-six" Heartrail II system was developed for use in chronic total occlusion PCI cases in order to increase back-up support [5]. Conversely, the Guideliner catheter (Vascular Solutions, MN) that has now been both CE marked and FDA approved has been developed more specifically with device delivery in mind. The Guideliner "five-in-six" catheter (Vascular Solutions, MN) is essentially a rapid exchange or monorail equivalent of the "five-in-six" Heartrail II catheter that consists of a short guide catheter extension connected to an introducer rod, and so is potentially easier to use than the Heartrail II catheter. In this case series we describe our initial experience with the use of this catheter for stent delivery and backup support in a series of challenging cases performed transradially, and discuss its potential utility in complex radial PCI cases.

METHOD OF INTRODUCTION

The 5-in-6 Guideliner catheter is a 20 cm soft tipped 5F catheter with an internal diameter (ID) of 0.056″ connected via a metal collar to a 115 cm stainless steel shaft to a proximal positioning tab (Fig. 1A). At any time, following placement of the mother guide catheter and coronary wire in the target vessel, the 20 cm Guideliner catheter can be advanced over the wire through the haemostatic valve without the need to disconnect this from the mother guide. The catheter tip is then advanced beyond the tip of the mother guide into the coronary vessel by pushing on the proximal tab. The interventional procedure is performed in the usual manner through the haemostatic valve (Fig. 1B and C).

[1]Manchester Heart Centre, Manchester Royal Infirmary, Biomedical Research Centre, Manchester, United Kingdom
[2]Manchester Academic Health Science Centre, University of Manchester, Manchester, United Kingdom

Conflict of interest: Nothing to report.

*Correspondence to: Dr. Douglas G. Fraser, Manchester Heart Centre, Manchester Royal Infirmary, Biomedical Research Centre, Manchester, M13 9WL, United Kingdom. E-mail: Douglas.Fraser@cmft.nhs.uk

Received 3 December 2009; Revision accepted 5 January 2010

DOI 10.1002/ccd.22458
Published online in Wiley InterScience (www.interscience.wiley.com)

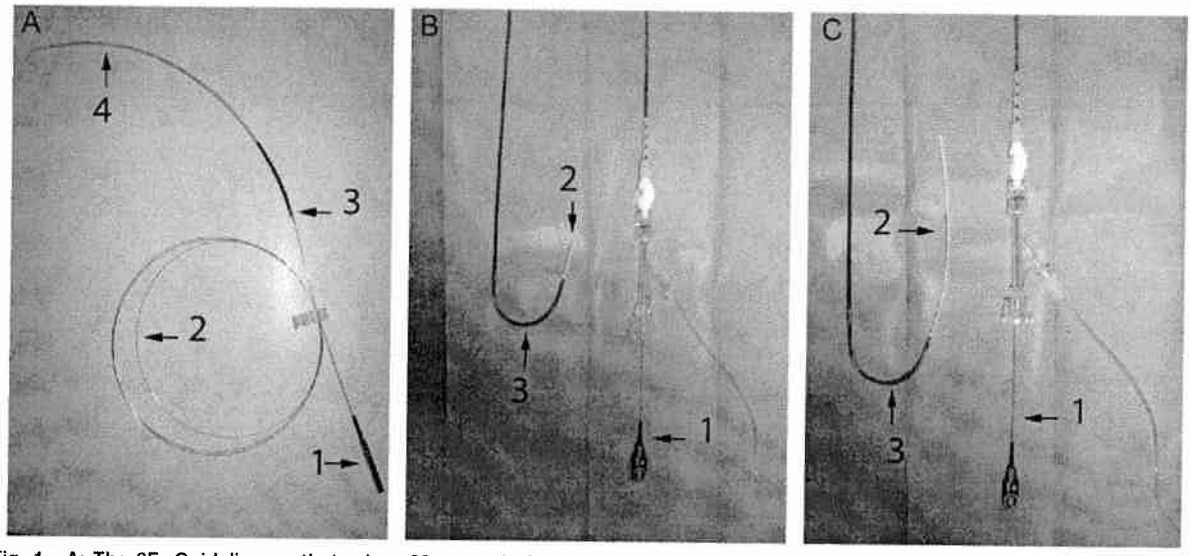

Fig. 1. A: The 6Fr Guideliner catheter is a 20 cm soft tipped catheter (Arrow 4) connected via a metal collar (Arrow 3) to a 115 cm stainless steel shaft (Arrow 2) with a large proximal tab (Arrow 1) for accurate positioning of the device within the coronary system. B: Guideliner catheter setup. The Guideliner is passed through the haemostatic valve over a guidewire. The proximal tab (Arrow 1) is attached to the 115 cm stainless steel shaft that attaches to the 20 cm soft tipped catheter (Arrow 2) seen to extend from the guide catheter (Arrow 3). The proximal tab can be used to position the 20 cm soft tip catheter more distally into the vessel (C).

Frequently, placement would follow predilation of the target vessel and prior attempts at stent placement.

Conversely, introduction of the much longer 120 cm Heartrail II catheter requires removal of the haemostatic valve followed by advancement over the coronary wire into and through the mother guide, with subsequent reconnection of the haemostatic valve to the proximal end of the Heartrail catheter [3,4,6]. Again, this is frequently performed following predilation and prior attempts at stent placement. When complete removal of the Heartrail catheter is required, the haemostatic valve needs to be removed and reconnected to the mother guide, and may dislodge the coronary wires if these are not docked. Conversely, removal of the Guideliner catheter can be performed without repositioning of the haemostatic valve or docking the wires in a similar fashion to removal of a monorail balloon. Consequently, advancement, positioning, and removal of the Guideliner catheter is potentially greatly simplified in comparison to the Heartrail catheter.

Case 1

A 48-year-old female with significant exertional angina and good left ventricular function underwent attempted recanalisaton of a chronically occluded LAD artery (Fig. 2A). Access was from the right radial artery with a 6F Cordis extra backup guiding catheter. Wire crossing was rapidly achieved using a whisper wire to negotiate a visible microchannel connecting the proximal and distal lumens (Fig. 2B). However, subsequent passage of either a Finecross microcatheter or a low profile 1.25-mm balloon (Riujn, Terumo) was unsuccessful due to marked resistance at the entry to the microchannel. A Guideliner catheter was therefore introduced over the coronary wire, through the guiding catheter. This was advanced 4 cm beyond the tip of the guide catheter into the LAD, up to the point of occlusion. Subsequent passage of a Quickcross microcatheter across the occlusion was achieved (Fig. 2C), and the Whisper wire was exchanged for a super support Mailman wire. Subsequent introduction of a 1.25 mm balloon allowed expansion of the microchannel, with successful further balloon dilation and finally stenting using a 2.5 × 38 mm Xience (Fig. 2D) and 3 × 28 mm Promus stents. These stents were further expanded with 2.75 and 3 mm balloons to high pressure with an excellent angiographic result (Fig. 2E).

Case 2

A 79-year-old lady with good resting left ventricular function was admitted with an NSTEMI associated with critical single vessel disease of a large RCA. The RCA was heavily calcified with 95% stenoses of the mid vessel and distal vessel at the crux extending into PDA and PLV branches with TIMI 2 flow (Fig. 3A). Access was from the right radial artery using a JR4 guiding catheter. Two Choice floppy wires (Boston Scientific) were advanced into the PDA and PLV

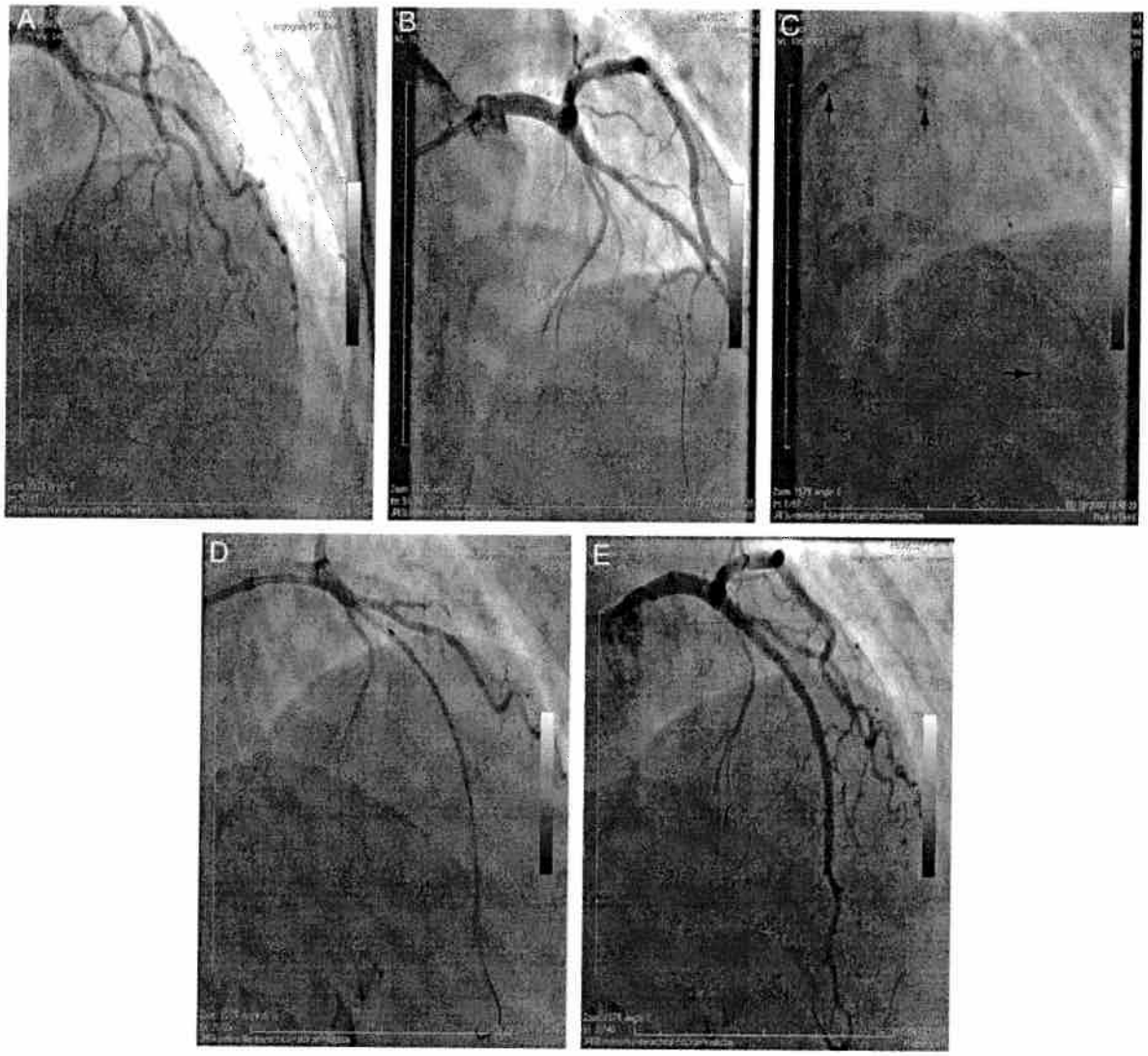

Fig. 2. Chronically occluded LAD (A) and subsequent crossing of the lesion with whisper wire (B). (C) illustrates positioning of the Guideliner catheter into the LAD (second vertical arrow) and the position of the guide catheter is shown by the first arrow. The horizontal arrow illustrates the Quickcross microcatheter used to exchange the whisper wire for a more supportive mailman wire. (D) positioning of xience stent and final result (E).

branches respectively and both lesions were predilated with 2.5-mm compliant and 3-mm angiosculpt balloons (Pyromed). However, stent delivery across the proximal lesion was not possible due to significant calcification and resistance to stent passage hence a Guideliner catheter was advanced into the RCA. To aid deep intubation of the catheter a 2.5-mm balloon was inflated in the distal RCA lesion and a combination of gentle traction on inflated balloon and push on the Guideliner catheter allowed passage of the Guideliner beyond the midvessel lesion. A 4 × 23-cm Biomatrix stent was then advanced without resistance through the midvessel lesion within the Guideliner catheter and on into the distal vessel (Fig. 3B). The Guideliner was then brought back into the proximal vessel and the stent was brought back into the mid vessel stenosis were it was inflated with good strut expansion. Again, using an inflated balloon in the distal lesion as an anchor, the Guideliner was advanced through the deployed stent into the distal vessel. A Triton bifurcation stent was then advanced to the distal vessel through the Guideliner catheter and was deployed across the crux into

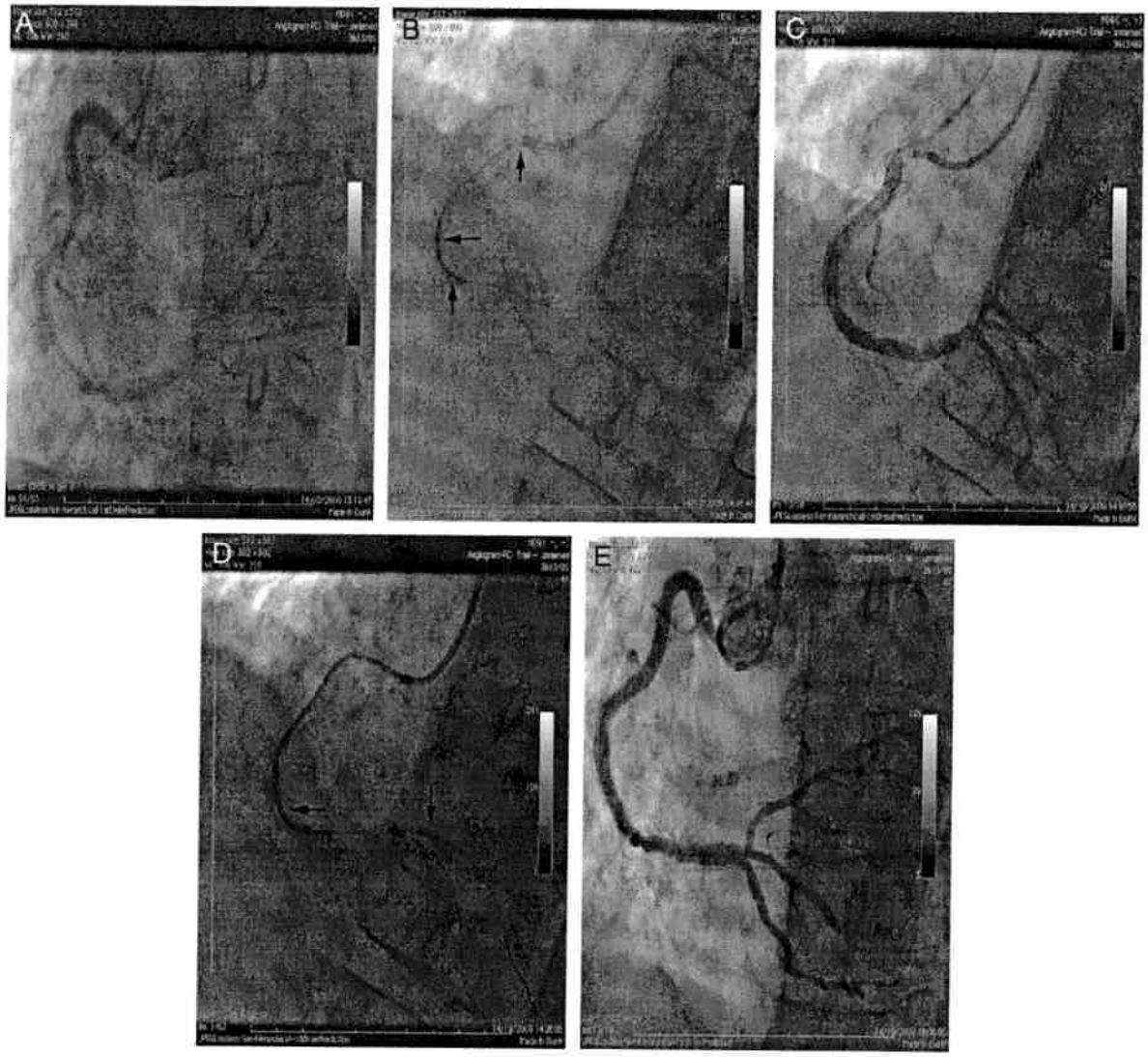

Fig. 3. A: RCA at start of case. B: Guideliner catheter (Horizontal arrow) used to bypass proximal point of obstruction enabling delivery of biomatrix stent (Vertical arrow). The guide catheter is illustrated by vertical arrow at top of figure. C: opacification of RCA following stenting of proximal and mid RCA. D: Triton bifurcation stent (Vertical arrow) delivered into PLV branch of RCA through Guideliner catheter (Horizontal arrow) passed through previously deployed proximal stents. E: Final result.

the PLV branch. Further stents were then placed in the PLV branch distal to the crux and from the distal RCA into the PDA. A final kissing balloon from the distal RCA into the PDA and PLV branches completed the procedure with an excellent angiographic result.

Case 3

A 76-year-old male with good left ventricular function and previous CABG was scheduled for PCI of the native RCA due to ongoing ischaemia at rest in this territory that had no graft supply. The RCA was diffusely diseased from the proximal to the distal vessel with heavy calcification, marked tortuousity and subtotal occlusion of the midvessel (Fig. 4A). We proceeded from the right radial artery using a 6F JR4 catheter and successfully crossed into the distal vessel using a Whisper wire. The mid and proximal RCA was dilated with 1.5, 2.5, and 2.75 mm balloons (Maverick, Boston), however stent passage was unsuccessful due to

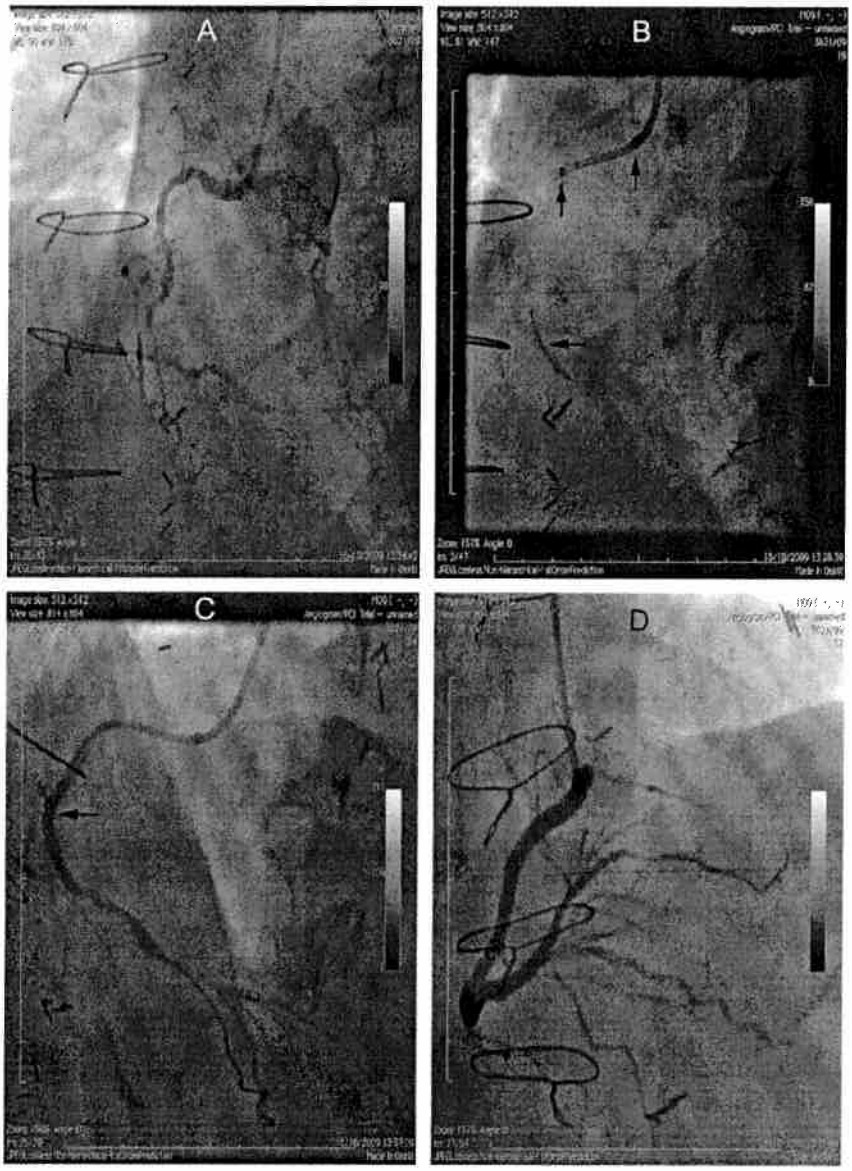

Fig. 4. A: Angiographic appearance of RCA at start of case. B: Positioning of initial Promus stent (Horizontal arrow). The Guideliner catheter and guide catheter are shown by vertical arrows. C: Passage of Guideliner catheter through the proximally deployed stents and opacification of the distal vessel demonstrating further disease. Distal end of Guideliner highlighted by horizontal arrow. D: Final result.

heavy calcification and tortuosity. The Guideliner catheter was then advanced 3.5 cm into the proximal RCA, enabling deployment of a 2.5 by 18 mm Promus stent to the site of subtotal occlusion in the mid RCA (Fig. 4B). Again with the aid of deep intubation an overlapping 3 × 28 mm Promus stent could then placed proximally extending from the first stent to the proximal RCA. This allowed visualization of the distal RCA that had two further severe stenoses together with a severe stenosis of the proximal PDA. To treat these lesions a 2.5-mm balloon was inflated in the distal RCA and the Guideliner catheter advanced through the stented segments into the distal RCA (Fig. 4C). Following predilation this allowed easy passage of a 2.25 × 23 mm Promus stent that extended from the RCA into the PLV and a further 3 × 28 mm Promus stent that

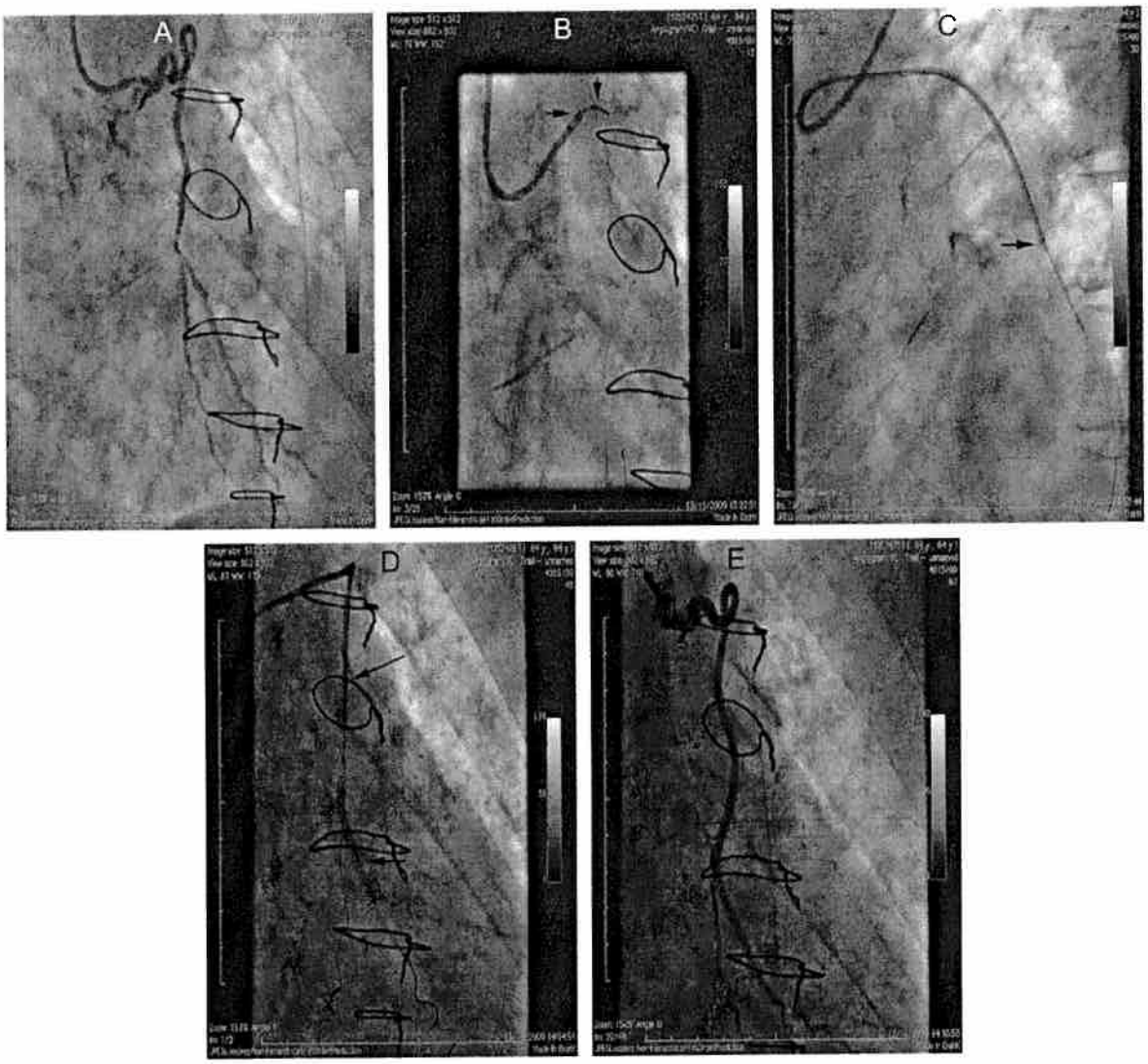

Fig. 5. A: Angiographic appearance of SVG at the start of case. B: Guideliner catheter (Horizontal arrow) used to increase backup support to enable proximal stent delivery (Vertical arrow). C: Guideliner (Horizontal arrow) used to deeply intubate SVG. D: Deployment of distal Promus stent (Horizontal arrow). The position of Guideliner catheter is illustrated by oblique arrow. E: Final result.

overlapped this stent and the first stent placed. Following post dilation of the RCA stents to 3 mm and stenting of the proximal RCA with two 3.5 × 8 mm Promus stents, an excellent angiographic result was achieved (Fig. 4D).

Case 4

A 64-year-old male with Re-do CABG and aortic and mitral valve replacement was admitted for elective PCI due to significant limiting angina to an OM_1 graft with two proximal hair pin loops with a severe lesion at the apex of the first loop and a more distal lesion at the distal end of the graft with further disease within the native vessel (Fig. 5A). We proceeded from the left radial artery using an AL-1 guide. The graft was wired using a whisper wire, however due to the severe tortuosity of the graft we were unable to deliver a balloon for predilation. The Guideliner catheter was therefore advanced into the asending limb of the hair pin loop to increase backup support and a 3-mm balloon was passed relatively easily into the lesion to allow

predilation. The proximal lesion was stented with a 3.5 × 8 mm Promus stent (Fig. 5B) overlapping with a 3 × 15 mm Promus stent. Because of severe tortuosity and the proximally deployed stents, we were unable to pass further stents/balloons distally to treat the vein graft/native vessel disease. The Guideliner catheter was therefore used to bypass this area of extreme tortuosity with the previously deployed stents achieving extra deep intubation of the vein graft (7 cm) allowing distal balloon/stent delivery (Fig. 5C). The distal vein graft lesion was predilated and stented using a 2.75 × 23 mm Promus stent proximally (Fig. 5D) and a 2.25 × 23 mm stent distally into the native vessel. The stents were post dilated at high pressure and an excellent angiographic result was obtained (Fig. 5E). The patient remains angina free at one-month follow up.

A further 10 cases were performed (total of 13 cases) and these are summarized in Table I. All cases were performed via the radial route using conventional 6F guiding catheters.

DISCUSSION

To the best of our knowledge, for the first time in the literature we report the successful use of the Guideliner catheter for distal stent delivery in a series of 13 highly complex cases, with a mean stent length of more than 44 mm (range, 15–105 mm) and either severe tortuosity and/or calcification, or chronic occlusion in every case. The Guideliner catheter was used for stent delivery following prior failure using conventional techniques or upfront use due to anticipated failure (cases 9 and 10). Balloon and stent delivery was successfully achieved in all cases and the device was simple both to deploy and remove and was not associated with a procedural complication in any case. This was achieved using the Guideliner catheter by both increasing backup support and crossing proximal points of obstruction. The catheter can cross points of proximal obstruction where a stent gets stuck due to the greater flexibility and smoother surface of the catheter than a stent. In addition, distal balloon anchoring to deliver the Guideliner is more readily achieved than distal balloon anchoring to deliver a stent within a 6F guiding catheter. The main limitation of the device that we have observed was stent damage due to trauma entering the catheter portion of the device at the metal collar occurring in two cases (two of the 32 stents delivered; 6.2%) and failure to pass a 4-mm stent due to resistance at this point in 1 case (1 stent out of 32; 3.1%).

In most cases the Guideliner catheter was advanced over a coronary wire into the distal vessel. In some cases, additional techniques were used to aid Guideliner and then stent delivery in this series. In cases 2 and 3 advancement of the Guideliner catheter was associated with initial resistance. This was overcome by anchoring a balloon catheter in the distal vessel by inflating it within a distal target lesion followed by with gentle traction on the balloon during advancement of the Guideliner catheter (anchor balloon technique). In case 2, a severe proximal stenosis that had been predilated could not be crossed with a stent but was crossed with the Guideliner catheter enabling a stent to be delivered distal to the lesion within the catheter and then drawn back proximally into the lesion. In this case, crossing of the lesion with the Guideliner catheter was possible due to a good result from predilation; failure to cross the lesion directly with a stent was due to calcification and tortuousity at the lesion site. In cases 2, 3, 4, and 13 severe distal disease was stented following stenting of severe proximal disease. As well as facilitating proximal stenting in several of these cases, the Guideliner was deeply intubated through the stented proximal disease to gain direct access to the distal vessel to facilitate stenting of the distal disease.

Anchor balloon techniques using a conventional guide catheter have been used to facilitate stent delivery as well as wire and balloon passage in CTO lesions [7]. These techniques include both sidebranch anchor and distal main vessel anchor techniques. Whilst successful, these techniques usually require use of a 7F or larger guide, as smaller guides will not accommodate a stent with a conventional balloon catheter already in place. Placing the stent in the proximal vessel first could overcome this but would be technically demanding. This limits the applicability of these techniques to radial access when a 6F guide will be used in most cases. Conversely, using a distal anchor balloon to deliver the Guideliner catheter can easily be performed using a 6F guide. We have previously described this technique to aid delivery of the Heartrail 5-in-6 catheter [4]. We have always deployed the anchor balloon at a distal lesion site that we intend to stent, both to help to lock the balloon more successfully and to avoid trauma to an undiseased coronary segment.

Conventional stenting is performed from distal to proximal vessel in most cases, mainly due to the potential difficulty of crossing a deployed stent in the proximal vessel in the setting of vessel tortuousity. However, use of the Guideliner catheter overcomes this restriction because of the ease with which the Guideliner catheter will pass through even very tortuous stented segments (in some cases aided by a distal balloon anchor). In the four cases using this technique in this series, passage of the Guideliner catheter into the distal vessel through stented proximal disease was performed without complication and greatly facilitated distal stent delivery. We believe this technique of

TABLE I. Summary of Cases Performed Using Guideliner Catheter

Case	Age	Access Site	Vessel	Obstruction	Mechanism	Indication	Intubation depth (cm)	Stents deployed (lengths in mm)	Stent damage/Failure to deliver stent
1	43	Radial	LAD	CTO lesion	Backup	Balloon and stent delivery	3 cm	2.5 × 38 Xience 3 × 28 Promus	
2	79	Radial	RCA	Tortuous calcified	Backup Cross obstruction	Stent delivery	6 cm	4.0 × 18 Biomatrix 2.5/3.5 ×19 Tryton 3.0 × 24 Biomatrix 2.5 × 18 Biomatrix 2.5 × 18 Biomatrix	4 × 23 Biomatrix Damaged
3	76	Radial	RCA	Tortuous calcified	Backup Cross obstruction	Stent delivery	6 cm	2.5 × 18 Promus 3 × 28 Promus 2.25 × 23 Promus 3 × 28 Promus 3.5 × 8 Promus	
4	64	Radial	OM VG	Extreme tortuousity	Backup Cross obstruction	Stent delivery	7 cm	2.5 × 28 Promus 3 × 28 Promus	
5	61	Radial	LAD	Tortuous calcified	Backup	Stent delivery	3 cm	2.5 × 28 Nobori 3 × 28 Nobori	2.5 × 28 Nobori Damaged
6	87	Radial	RCA	Tortuous calcified	Backup Cross obstruction	Stent delivery	6 cm	3.5 × 33 Xience 3.5 × 15 mm Promus	4 × 28 mm Biomatrix would not enter
7	50	Radial	RCA	Tortuous calcified	Backup Cross obstruction	Stent delivery	6 cm	3.5 × 20 Promus 3.0 × 16 Promus	
8	71	Radial	OM	Tortuous calcified	Backup	Stent delivery	4 cm	2.75 × 28 Promus	
9	74	Radial	Left PDA	Tortuous	Backup	Stent delivery (anticipated)	10 cm	2.75 × 28 Promus	
10	76	Radial	LAD	calcified	Backup	Stent delivery (anticipated)	3 cm	2.5/3.5 ×19 Tryton 3.5 × 28 Nobori	
11	60	Radial	PLV	Tortuous	Backup	Stent delivery	10 cm	3.5 × 20 Promus	
12	72	Radial	Cx	Tortuous calcified	Backup Cross obstruction	Stent delivery	3 cm	3.0 × 15 Promus	
13	55	Radial	RCA	Tortuous calcified CTO case	Backup Cross obstruction	Stent delivery	8 cm	3.5 × 38 Xience 3.0 × 38 Xience 3.5 × 18 Promus	

Catheterization and Cardiovascular Interventions DOI 10.1002/ccd.
Published on behalf of The Society for Cardiovascular Angiography and Interventions (SCAI).

proximal to distal stenting using the Guideliner catheter is an important new technique in the setting of highly complex proximal and distal disease.

In the treatment of tortuous and calcified disease it is failure to deliver a stent to the target lesion that remains one of the major causes of procedural failure. Improvements in stent design over time have been matched by increasing case complexity. Failure to deliver a stent occurs in up to 5% of cases in contemporary PCI practice [1,2] and is associated with in-hospital MACE rates of up to 19% [8]. Conventional techniques previously described to overcome problems of stent delivery include use of buddy wires and support wires to reduce tortuosity [9,10], use of rotational atherectemy or balloon dilation in calcified vessels to reduce friction [11], use of smaller sized stents [12] or increased backup support by deep intubation of the guide catheter, use of the anchor balloon techniques or exchange to a larger sized guide catheter [7]. In this series, stent delivery had failed in cases 1 to 8 and cases 11–13 despite predilation and the use of either support or buddy wires. We have demonstrated that successful stent delivery using the Heartrail catheter may be achieved in up to 90% of cases in which stent delivery had failed using conventional techniques [4]. More recently others have also adapted the Proxis proximal embolic protection catheter to facilitate distal stent delivery by deep intubation [13]. In the former series stent delivery was achieved in all cases when intubation depth of the Heartrail catheter exceeded 2 cm. However, stent delivery into very proximal lesions was not successful due to failure to intubate the device sufficiently. In this series, intubation depth exceeded 2 cm in all cases, and stent delivery was achieved in all cases.

Large bore guides provide greater passive backup support and permit a greater range of interventional techniques [7]. However, these may be poorly tolerated via the radial artery. For example, in a study of 250 patients, Saito et al. [14] demonstrated that the radial artery diameter was smaller than the outer diameter of a 7F Terumo (Terumo Co, Tokyo, Japan) introducer sheath in 28.5% of males and 59.7% of females. This may therefore contribute to procedural failure in complex cases performed through the transradial route, for example in a recent series of 2100 transradial PCI procedures, 36% of procedural failures were due to inadequate guide catheter support [15]. Use of Sheathless guide catheters may in part address this problem in the future [16] although their use is not currently widespread and they are still an evolving technology [17].

All of our cases were performed successfully despite highly complex disease via the radial artery using 6F guides with back-up support augmented using deep intubation of the Guideliner catheter. Deep intubation using such a system increases backup support dramatically. Using an arterial model Takahashi et al. [5] demonstrated that 5mm of intubation using a Heartrail catheter within a 6F guide produced 20% greater backup support than a 7 Fr guide catheter and 20-mm intubation produced greater back-up support approaching that of an 8Fr guide catheter. In this series, the mean intubation depth was 57.7 mm (range, 30–100 mm) therefore the additional support provided by the Guideliner catheter is likely to have been substantial. Consequently in transradial cases in which backup support is likely to be important such as CTO cases, or during cases where backup support is inadequate, the Guideliner catheter can be used upfront or as a bale out device. Backup support may be particularly poor using conventional guiding catheters for the treatment of vein graft lesions [15]. Backup using a Guideliner catheter to achieve deep graft intubation, as in case 4, may therefore be very useful also in transradial vein graft PCI.

The Guideliner was developed with stent delivery in mind and is able to deliver stents with similar effectiveness to the Heartrail catheter, although is easier to use but associated with a small but significant risk of stent damage. Advantages of the Guideliner include not needing to remove and reconnect the Y connector, less risk of air embolism, easier control of the mother catheter, easier advancement and removal, and ability to advance a stent further distal beyond the catheter tip.

Limitations of the Technique

Stent damage occurred in a total of two out of 32 stents used (6.3%) within the 6F mother guides. This occurred exclusively with the use of the bulkier Nobori (1/4 stents used) or Biomatrix stents (1/6 stents used) rather than lower profile Xience/Promus stents (0/20 stents used). It was also related to stent size with failure to pass 2/3 4 mm or larger Biomatrix or Nobori stents. In some cases it was clear that guide wire wrap around the Guideliner stainless steel introducer shaft had caused the stent to catch at the collar resulting in significant resistance to stent passage and damage.

CONCLUSION

The Guideliner is an easy to use guide catheter extension that greatly facilitates backup support and stent delivery, significantly extending the scope of coronary intervention possible within a 6F mother guide catheter. It should be considered either to increase backup support or enable stent delivery when problems are encountered using conventional techniques, or

upfront in the setting of very complex disease. Performance is similar to the 5-in-6 Heartrail II catheter, whilst ease of use is significantly improved. The main limitation however is that there is a small risk that large/bulky stents can get damaged entering the metal collar, and caution should be exercised particularly when resistance to the passage of a stent is felt whilst within the Guideliner catheter since excess force may not only lead to damage of the stent but also to potential stent loss. We would currently recommend the use of low profile stents with this system since this appears to limit the potential for stent damage in our series and would caution the Guideliner for stent delivery of stents $\geq$4 mm in diameter. Future catheter design modifications, particularly at the steel collar may reduce the small risk of stent damage that we have observed. This device will be useful for both transfemoral and transradial procedures in which backup support and stent delivery difficulties are encountered, and may be of especial interest to radial interventionalists taking on complex disease. Early or upfront use in highly complex cases should be considered.

REFERENCES

1. Morice MC, Colombo A, Meier B, Serruys P, Tamburino C, Guagliumi G, Sousa E, Stoll HP; REALITY Trial Investigators. Sirolimus – vs Paclitaxel eluting stents in de novo coronary artery lesions. JAMA 2006;295:895–904.
2. Nikolsky E, Gruberg L, Pechersky S, Kapeliovich M, Grenadier E, Amikam S, Boulos M, Suleiman M, Markiewicz W, Beyar R. Stent deployment failure: reasons, implications, and short- and long-term outcomes. Catheter Cardiovasc Interv 2003;59:324–328.
3. Mamas MA, Fath-Ordoubadi F, Fraser D. Successful use of the Heartrail III catheter as a stent delivery catheter following failure of conventional techniques. Catheter Cardiovasc Interv 2008;71:358–363.
4. Mamas MA, Eichhöfer J, Hendry C, El-Omar M, Clarke B, Neyses L, Fath-Ordoubadi F, Fraser D. Use of the Heartrail II catheter as a distal stent delivery device; an extended case series. EuroIntervention 2009;5:265–271.
5. Takahashi S, Saito S, Tanaka S, Miyashita Y, Shiono T, Arai F, Domae H, Satake S, Itoh T. New method to increase a backup support of a 6 French guiding coronary catheter. Catheter Cardiovasc Interv 2004;63:452–456.
6. Mamas MA, Fath-Ordoubadi F, Fraser D. Telescoping catheter technique; Looking towards the kidneys. Cardiovasc Revasc Med. In Press.
7. Di Mario C, Ramasami N. Techniques to enhance guide catheter support. Catheter Cardiovasc Interv 2008;72:505–512.
8. Cantor WJ, Lazzam C, Cohen EA, Bowman KA, Dolman S, Mackie K, Natarajan MK, Strauss BH. Failed coronary stent deployment. Am Heart J 1998;136:1088–1095.
9. Jafary FH. When one won't do it, use two-double "buddy" wiring to facilitate stent advancement across a highly calcified artery. Catheter Cardiovasc Interv 2006;67:721–723.
10. Vijayvergiya R, Swamy AJ, Grover A. Buddy wire technique: A simple technique for treating calcified lesion during percutaneous coronary intervention: A case report. J Invasive Cardiol 2006;18:E129–E130.
11. Cavusoglu E, Kini AS, Marmur JD, Sharma SK. Current status of rotational atherectomy. Catheter Cardiovasc Interv 2004; 62:485–498.
12. Feldman T. Tricks for overcoming difficult stent delivery. Catheter Cardiovasc Interv 1999;48:285–286.
13. Brilakis ES, Banerjee S. Novel uses of the Proxis embolic protection catheter. Catheter Cardiovasc Interv 2009;74:438–445.
14. Saito S, Ikei H, Hosokawa G, Tanaka S. Influence of the ratio between radial artery inner diameter and sheath outer diameter on radial artery flow after transradial coronary intervention. Catheter Cardiovasc Interv 1999;46:173–178.
15. Dehghani P, Mohammad A, Bajaj R, Hong T, Suen CM, Sharieff W, Chisholm RJ, Kutryk MJ, Fam NP, Cheema AN. Mechanism and predictors of failed transradial approach for percutaneous coronary interventions. JACC Cardiovasc Interv 2009;2: 1057–1064.
16. Mamas MA, Fath-Ordoubadi F, Fraser DG. Atraumatic complex transradial intervention using large bore sheathless guide catheter. Catheter Cardiovasc Interv 2008;72:357–364.
17. Mamas MA, D'Souza S, Hendry C, Ali R, Iles-Smith H, Palmer K, El-Omar M, Fath-Ordoubadi F, Neyses L, Fraser DG. Use of the sheathless guide catheter during routine transradial percutaneous coronary intervention: A feasibility study Catheter Cardiovasc Interv 2010;74:596–602.