The Egyptian Journal of Hospital Medicine (July, 2012) Vol., 48: 368 – 382

The Current Status of Usage of Complementary Cardiovascular Devices in Cardiac Catheterization Laboratory in Queen Alia Heart Institute (QAHI)

Marwan AlNimri*, MD, JBM, JBC, FACC, FSCAI
* From Queen Alia Heart Institute/ Adult Cardiology Department.
Queen Alia Heart Institute/King Hussein Medical Center. POBox: 789 TAREQ, Amman Jordan. Zip code 11947.E-mail: mtnimri@hotmail.com

Abstract

Cardiac catheterization laboratories are experiencing phenomenal change, as their volume increases and cases become more complex. In the search for the perfect angiographic result, interventional cardiologists have explored numerous therapeutic complementary devices that are used in the cath labs to facilitate achieving this elusive prize.

Unfortunately, these adjunctive interventional devices are lacking in the majority of cath labs all around developing countries including those in Middle East /North Africa region (MENA region). In fact, most of coronary interventions here became restricted to implantation of bare metal stents or drug-eluted stents with or without simple balloon predilatation or post-dilatation. The limited adoption of complementary devices reflects concerns of the high costs for these devices, un-suitability for their re-sterilization, having their own learning curve with compelling continuous need for high level of training.

In this review, we will summarize the evidence base concerning most of the important therapeutic complementary cardio-vascular interventional devices and comment on challenges facing the more widespread adoption of their use in MENA region .Hopefully, this objective analysis would help fostering their further growth and penetration into the markets, making them part of daily practice.

Key words: Complementary Cardiovascular Devices, Cardiac Catheterization Laboratory

Introduction

Improvements in basic percutaneous coronary intervention (PCI) equipment have largely been bought by the availability of bare metal stents (BMSs) *(Fischman et al .,1994)* and drug-eluting stents (DESs). *(Stone et al., 2007)* Recent and ongoing progress will make bypass surgery largely obsolete within the next several years. *(Baim, 2004)*

In the search for the perfect angiographic result, interventional cardiologists have explored numerous therapeutic complementary devices that are used in the cardiac catheterization laboratories (cath labs) to facilitate achieving this elusive prize. Unfortunately, most of these devices are lacking in most cath labs all around the MENA region and generally all developing countries. Their limited adoption reflects concerns of the high costs for these devices, un-suitability for their re-sterilization, having their own learning curve with compelling continuous need for high level of training both for

operators and the rest of cath labs personnel.

In this review, we will summarize the evidence base concerning most of the important therapeutic complementary cardio-vascular interventional devices and comment on challenges facing the more widespread adoption of their use in MENA region.

Intravascular coronary ultrasound and pressure wires:

IVUS and /or FFR are currently used to overcome the problem of clinical decision making in patients with intermediate coronary artery stenosis *(Pills et al., 1995, Pills et al., 2000, Tobis et al., 2007, Magni et al., 2009 and Pills et al., 2008)* and in left main coronary artery disease. *(Sano et al 2007)* The merits of IVUS and /or FFR have been previously acknowledged by a number of investigators, as of its role in the coronary artery arena as well as peripheral vasculature. *(Cook et al., 2007 and Tonino et al., 2009)*

In fact, the occulostenotic reflex tends to vary among operators, where they tend to over-estimate or underestimate coronary lesions . In our daily practice, the use of IVUS or FFR can help deciding to stent an intermediate lesion and can prevent making a "full metal jacket" in a coronary artery that could affect flow, side branches, and have a negative influence on normal physiology. In addition, treating diffuse vessels with focal stenting guided by these two modalities could limit the expenses of multiple stent usage and avoid difficulties in future treatment by bypass surgery.

The recently published FAME trial reported that FFR-guided PCI reduced the risk of death, MI, or repeat revascularization by 30% and death or MI by 35%, compared with the current practice of using angiography to guide stenting decisions. *(Tonino et al., 2009)* Even though the recently published AVID trial (angiography versus intravascular ultrasound-directed bare-metal coronary stent placement) failed to demonstrate the same benefit with IVUS-directed bare-metal stenting , it remains unknown whether its results are valid in a contemporary population as this trial was conducted more than 10 years ago, and there have been several procedural and technological advances in PCI since then. *(Russo et al., 2009)*. Recently Chia-Pin Lin *et al.(2011)* stated that IVUS is a powerful imaging modality which can provide more information before, during and after PCI to facilitate the procedure. Therefore, it should be used more widely in order to improve clinical outcomes and quality of our interventions. *(Chia Pin Lin et al., 2011)*

Status of IVUS and pressure wires in QAHI and MENA region in comparison to developed countries:

Challenges that face the expanded use of IVUS and pressure wires are mainly related to their high initial costs beside the un-suitability of re-use, r eprocessing or re-sterilization and their steep learning curves .

To compare with what's happening in the United States of America (U.S), the market for IVUS catheters, is one of the fastest-growing segments in the U.S. market for interventional cardiology. Even though the U.S. penetration rate for IVUS catheters is expected to more than double by 2013, it is still considered a small increase when compared with penetration rates in Japan. *(Kamran et al., 2009)*

Furthermore, the new integrated systems that can now accommodate the three primary intravascular diagnostic tools in regular use by cardiologists today (high frequency rotational IVUS, fast and simple phased array IVUS, and pressure-based FFR guidewires) on a single platform, makes cath labs more user-friendly and efficacious.

Unfortunately, both IVUS and FFR modalities are available only in a handful of cardiac cath labs in MENA region. Here, the penetration rates are remarkably small and access to these systems is too limited to drive broader acceptance. Hopefully the growing concerns over stent thrombosis in DES era as well as the emerging of new technological innovations that simplify the use of such devices could drive their use dramatically higher in the coming years. Education programs, hands-on system training, guided proficiency tools should be offered by companies to their customers, targeting the increase in IVUS and FFR awareness and building staff proficiency with these new integrated systems.

Novel devices, wires and techniques for chronic total occlusions:

Coronary chronic total occlusion (CTO) is one of the most challenging coronary lesions to be faced in the cath labs. Coronary (CTOs) causes ischemia when the distal myocardium is viable; yet, coronary collaterals are insufficient to provide adequate myocardial perfusion during stress. CTOs are found in up to 30% of patients undergoing diagnostic angiography and are often the determining factor in the triage of patients with multivessel CAD to CABG surgery. *(Olivari et al., 2003 and Sirnes et al., 1998)* Recanalization of CTOs improves angina, *(Yousef et al., 2002)* left ventricular function *(Sirnes et al., 1998 and Yousef et al., 2002)* and, potentially, late survival.*(Yousef et al., 2002, Suero et al., 2001, Hoye et al., 2005, Stone et al., 2005 part I and Stone et al., 2005 part II)* The major challenge relating to percutneous treatment of CTOs is the attainment of guide-wire positioning distal to the occlusion that is within the true coronary lumen. Because conventional wires are suitable for crossing only 60-70% of CTOs, *(Olivari et al., 2003, Sirnes et al., 1998 and Stone et al., 2005 part II)* a variety of newer,dedicated guidewires have been designed with stiffer and tapered (to 0.010") tips and also its hydrophilic-coating. *(Olivari et al., 2003, Sirnes et al., 1998 and Saito et al., 2003)*. The Excimer laser wire (Spectranetics, Colorado Springs, CO) was evaluated in a US-based registry *(Oesterle et al., 1998)* with excellent results (61% wire

success). In addition a number of novel devices have been developed as adjuncts to conventional wires to facilitate guidewire crossing into the distal coronary vessel using either microdissection techniques *(Orlic et al., 2005)* or guidance using optical coherence reflectometry coupled with radio-frequency ablation. *(Baim et al .,2004)*

The safety and efficacy of many of these devices have been demonstrated in many of recently conducted trials. The micro-dissecting FrontRunner catheter (Cordis Endovascular , Warren,NJ), *(Whitbourn et al., 2003)* the Safe-Cross radio-frequencym guidewire(Kensey,Nash,Exton,PA), *(Baim et al., 2004)* and the CROSSER catheter(Flow-Cardia,Sunnyvale,CA). *(Tiroch et al., 2008.)*

The retrograde approach via collateral channels is revolutionizing the treatment of CTOs. *(Ozawa, 2006 and Saito, 2008.)* This approach was developed to overcome the remarkable resistance of the proximal cap of the plaque to antegrade entry. Since the distal cap is oftentimes softer than the proximal cap, it frequently yields to retrograde penetration.

Once again, PCI for CTOs necessitates the presence of expensive equipments including wires, microcathetrs, dissecting catheters as well as a good experience in retrograde techniques. Using the number of diagnostic procedures as a reference, specialized CTO devices could be used in up to 75% of the cases in which guidewires have failed.

Acquisitions of coronary chronic total occlusion (CTO) crossers by larger players will result in significant growth as they become incorporated into the mainstream market. Unfortunately, in MENA region these devices and techniques are barely existent. They are costly and technically demanding and most patients are left for medical therapy or sent for open heart surgery in case of continuous angina.

Vascular closure devices:

VCDs were first developed in the mid-1990s, largely propelled by concerns of high rates of access site bleeding associated with PCI procedures. *(Sanborn et al., 1993.)* Since their introduction, the original devices have undergone multiple iterations while maintaining their core concept. *(Applegate et al., 2006, Ansel et al., 2006 and Hermiller et al., 2006.)* The learning curve for each device may be steep, and thus complication rates may have been higher in the mid-to-late 1990s related to slow improvement in operator proficiency. *(Applegate et al., 2006, Nikolsky et al., 2004, Dangas et al., 2001 and Tavris et al., 2001)*

Although most VCDs currently cost on the order of $150 to $200, given the large volume of both diagnostic angiograms and PCI procedures at many U.S. hospitals, *(Rickli et al., 2002, Resnic et al., 2007 and Kim, 2006)* even such a modest incremental cost has the potential to substantially impact cath labs and hospital budgets.

There are concerns that VCDs may cause increased rates of rare complications, primarily based upon

anecdotal case reports. Infections, femoral artery compromise, arterial laceration, uncontrolled bleeding, pseudoaneurysm, atrioventricular fistula, as well as device embolism and limb ischemia have all been reported after VCD utilization. *(Arora et al., 2007.)* These reports span all VCD types. Importantly, *Warren et al. (1999) and Balzer et al .(2001)* demonstrated that complication rates decrease with experience.

Closure failure with VCDs may be multifactorial. The use of glycoprotein IIb/IIIa inhibitors, advanced age, *(Piper et al., 2003)* multiple sticks and back wall sticks *(Hermiller et al., 2006)* all may contribute to closure failure.

While one-third of patients in 2001 received a VCD in the American College of Cardiology-National Cardiovascular Data Registry *(Anderson et al., 2002)* in MENA region, VCD use is almost negligible. Manual compression offers a much cheaper way to deal with arteriotomies in the presence of cheap man-power. By and large, manually compressing 30 arteriotomies may cost 20 U.S $ (< 1 dollar for each) per day whereas it may cost more than 6000-9000 $ if VCDs are to be used. The challenge for expanded VCD use in our countries is substantial and could only be lessened by providing them at very less affordable prices or as a part of stent or diagnostic cath package.

Rotational atherectomy:

Rotational atherectomy (RA) was developed by Dr. David C. Auth and was first introduced in the late 1980s as a method of tackling the rock-hard, calcified atheromatous plaques.*(Hansen et al., 1988, Brent et al., 2011, OnTopaz et al., 2009 and Prevosti et al., 1988.)* It is currently available as the Rotablator System (Boston Scientific, Scimed) .

The enthusiasm for the use of RA has decreased greatly since its introduction because of established lack of benefit in preventing restenosis in native vessels *(Gracia et al., 2012, Dill et al., 2000, Mauri et al., 2003 and Buchbinder et al., 2000)* and controversial efficacy in restenotic vessels. *(Vom et al., 2002 and Sharma et al., 2004.)* The robust data confirming the efficacy of drug –eluting stents in the treatment of *de-novo* simple and complex CAD as well as in-stent restenotic lesions *(Stone et al., 2006, Holmes et al., 2006 and Stone et al., 2007)* has resurged recently the role of RA in these situations. However, RA still accounts for less than 5% of all interventional cases. *(Rubartelli et al., 2004).* Today in a group of high surgical risk patients, RA on severely calcified left main stenosis is feasible and, in spite of high mortality rates, could pose the only possible effective treatment. *(Gracia et al .,2012)*

RA maintains its role in the facilitation of stenting, particularly DES, in fibrocalcific lesions that are not dilatable or to enable stent delivery. *(Henneke et al .,1999)* The benefit of RA has also been proposed to prevent less plaque shifting

(snow plowing) while treating bifurcation lesions. *(Chia Pin Lin et al., 2011).* In TAXUS ıv trial , failure to deliver DESs and BMSs was reported in 8.2% of patients (5.8% and 2.4% respectively) in calcific lesions versus only 1.8% in noncalcified ones. *(Moussa et al., 2005)*

RA prevents vigorous manipulation of DES through calcified lesions that can result in the disruption of the polymer coating and decrease its effectiveness in preventing restenosis. RA can prevent suboptimal deployment of stents and malopposition which may increase the rate of stent thrombosis. In addition, RA can prevent inadequate diffusion of the drug to the subintima through extensive calcium arcs that could contribute to the ineffectiveness of DES when implanted into such lesions.

Challenges facing RA use in our region.

As in all parts of the world, the efficacy of this device is highly operator dependent compared with other devices and its learning curve is very steep.

Furthermore, performing RA mandates usually the availability of several costly equipments; different sizes of burrs, the RotaWire Guide Wire family, and Rotaglide lubricate. There is no approved method for the resterilization of any of these equipments.

The cost of one burr attached to the advancer is approximately $1100. By using the same advancer throughout the entire procedure and exchanging only the burr, one can save about $200 a burr. The Rotablator Advancer costs about $200; each Rotablator Burr costs approximately $900. Costs vary from institution to institution, depending on contract pricing.

For the various reasons mentioned above, RA use in MENA region is almost non-existing. Furthermore, the coronary market for atherectomy devices is limited by the efficiency of drug-eluting stents, which are usually placed directly in the lesion without plaque debulking. This clinical practice is expected to persist during the forecast period.

Thrombus aspiration of thrombotic lesions and the use of embolic protection devices in degenerated saphenous vein graft "SVGs".

Adjunctive devices which remove thrombus from coronary arteries (thrombectomy devices) or protect from distal embolisation of thrombus (embolic protection devices) are increasingly used in primary PCI. *(Burzotta et al., 2008)*

The use of thrombectomy devices in randomised and multicentre trials in patients undergoing PCI during STEMI is associated with a significant benefit in a number of markers of myocardial perfusion including MBG (myocardial blush grade), ST segment resolution and improvement of distal embolisation, and significant reduction in 30-day mortality. *(De Luca et al., 2008)*

There are several systems for intracoronary thrombectomy that differ considerably in construction, principles of operation and management. Most of these

systems have reported efficacies for epicardial flow restoration similar to aspiration devices. *(Burzotta et al., 2008, De Luca et al., 2008, Murakami et al., 1998 and Wang et al .,2002)*

Among patients who presented within 12 hours of a STEMI, Svilaas T and his colleagues *(Svilaas et al., 2008)* demonstrated that a strategy of thrombus aspiration and stent implantation was superior to balloon predilatation and stent implantation. Brent Rochon *et al*.(2011) based on current evidence, consider thrombus aspiration to be an important maneuver during STEMI PCI, even in the absence of visible angiographic thrombus, and recommend it whenever the presence of thrombus is likely *(Brent et al., 2011)* .Recent studies have demonstrated that thrombus aspiration is applicable and safe in a large majority of patients with STEMI, resulting in better reperfusion and clinical outcomes than standard PCI. *(On Topaz et al., 2009)*

Thrombus aspiration also produced trends toward reduction in death and reinfarction at 30 days, which became significant by 1 year. Thrombus aspiration was feasible in most patients (approximately 90%) without any signal of procedural-related complications. *(Vlaar et al., 2008)*

While it is shown that there does not appear to be strong evidence for the use of EPDs in the setting of primary PCI in native coronary arteries, *(Burzotta et al., 2008, and Mamas et al., 2008)* ,evidence provided by SAFER trial investigators and Filter Wire EX randomized investigators would make a strong case for their use in SVG interventions. *(Baim et al., 2002 and Stone et al., 2003.)*

In 2006, the U.S. market for coronary thrombectomy devices increased at a rate of 14% over 2005. Physicians' awareness and increasing familiarity with the procedure are the main driving forces of this market. From 2006 to 2013, the U.S. market for coronary thrombectomy devices is estimated to grow at a compound annual growth rate (CAGR) of 6.4%. In terms of penetration rates, EPDs are currently used in almost 4% of all conventional angioplasty procedures. This rate is expected to undergo a slight increase during the forecast period. *(Kamran et al., 2009)*

In MENA region, EPDs and thrombectomy devices are rarely used in coronary interventions due to their high cost. Selective filter EPD strategy in SVGs may help reduce the costs by 50% compared to their routine use *(Senter et al., 2006)* but this percentage looks still too small in view of the extremely limited health care resources. Most operators here are adopting the strategy of direct stenting while avoiding high pressure inflations in treating degenerated SVGs *(Lozano et al., 2005)* and in case of primary PCIs, stents are deployed in situ after squeezing the thrombus with multiple balloon inflations and milking the deflated balloon back and forth in the coronary artery so that the thrombus would reside as much distal as possible in the coronary circulation. Such practice is

definitely associated with a great amount of endothelial injury and higher chance for no-reflow phenomenon.

Conclusion

Despite those dramatic changes that have occurred in the health sector in MENA region, still many modern adjunctive cardiology interventions have not been effectively and homogeneously introduced and disseminated similar to what is observed in western countries. Governments are requested here to use all their bargaining power to help lowering the cost of these devices through negotiation with the providing companies. Contractual agreements, capitated procedures, and major hospital buying groups could bring the costs of these devices down with a potential for significant savings if cardiologists start to incorporate them in their interventional procedures. New generations of well-trained cardiologists and professionals who take advantage of continued medical education programes will be ready to face the challenge and be able to perform procedures that are becoming more complex than was seen 10 years ago , in a more timely manner and with better outcomes.

The industrial companies are asked to take the lead and access the MENA region market by offering education programs, hands-on system training and guided proficiency tools, targeting more awareness to these devices and building staff proficiency .They are asked to continue refining their products for the cath labs on an individual basis, as well as collaboratively, in the future so that these devices become more user-friendly and available at much less prices.

References

-**Anderson HV, Shaw RE, Brindis RG, Hewitt K, Krone RJ, Block PC, McKay CR, Weintraub WS (2002):** A contemporary overview of percutaneous coronary interventions. The American College of Cardiology-National Cardiovascular Data Registry (ACC-NCDR)**.** *Am Coll Cardiol; 39: 1096-1103.*

-**Ansel G, Yakubov S, Neilsen C, Allie D, Stoler R, Hall P, Fail P, Sanborn T, Caputo RP (2006):** Safety and efficacy of staple-mediated femoral arteriotomy closure: results from a randomized multicenter study**.** *Catheter Cardiovasc Interv; 67: 546-553.*

-**Applegate RJ, Sacrinty M, Kutcher MA,Gandhi SK, Baki TT, Santos RM, Little WC (2006**): Vascular complications with newer generations of angioseal vascular closure devices**.** *J Interv Cardiol; 19: 67-74.*

- **Arora N, Matheny ME, Sepke C, Resnic FS (2007):** A propensity analysis of the risk of vascular complications after cardiac catheterization procedures with the use of vascular closure devices**.** *Am Heart J; 153:606-611*

-**Baim DS (2004):** New devices for percutaneous coronary intervention are rapidly making bypass surgery obsolete. *Curr Opin Cardiol; 19:593-597.*

- Baim DS, Braden G, Heuser R, Popma JJ, Cutlip DE, Massaro JM, Marulkar S, Arvay LJ, Kuntz RE (2004): Guided Radio Frequency Energy Ablation of Total Occlusions Registry Study. Utility of the Safe-Cross-guided radiofrequency total occlusion crossing system in chronic coronary total occlusions (results from the Guided Radio Frequency Energy Ablation of Total Occlusions Registry Study). *Am J Cardiol; 94: 853-858.*

- Baim DS, Wahr D, George B, Leon MB, Greenberg J, Cutlip DE, Kaya U, Popma JJ, Ho KK, Kuntz RE (2002): Randomized trial of a distal embolic protection device during percutaneous intervention of saphenous vein aorto- coronary bypass grafts**.** *Circulation; 105: 1285 - 1290.*

-Balzer JO, Scheinert D, Diebold T, Haufe M, Vogl TJ, Biamino G (2001): Postinterventional transcutaneous suture of femoral artery access sites in patients with peripheral arterial occlusive disease: a study of 930 patients. *Catheter Cardiovasc Interv; 53:174-181.*

-Brent Rochon, Youssef Chami, Rajesh Sachdeva, Joe K Bissett, Nick Willis, and Barry F Uretsky (2011): Manual aspiration thrombectomy in acute ST elevation myocardial infarction: New gold standard. *World Journal of cardiology 26; 3(2):43-47.*

-Buchbinder M, Fortuna R, Sharma SK (2000): Debulking prior to stenting improves acute outcomes: early results from the SPORT trial**.** *J Am Coll Cardiol; 35(Suppl A):9A.*

- Burzotta F, Testa L, Giannico F, Biondi-Zoccai GG, Trani C, Romagnoli E, Mazzari M, Mongiardo R, Siviglia M, Niccoli G, De Vita M, Porto I, Schiavoni G, Crea F (2008): Adjunctive devices in primary or rescue PCI: a meta-analysis of randomized trials**.** *Int J Cardiol; 123: 313-321*

- Chia-Pin Lin, Junko Honye, Chi-Jen Chang and Chi-Tai Kuo (2011): Clinical Application of Intravascular Ultrasound in Coronary Artery Disease: An Update. *Acta Cardiol Sin; 27:1-13.*

-Cook S, Wenaweser P, Togni M, Billinger M, Morger C, Seiler C, Vogel R, Hess O, Meier B, Windecker S (2007): Incomplete stent apposition and very late stent thrombosis after drug-eluting stent implantation. *Circulation; 115:2426-2434.*

-Dangas G, Mehran R, Kokolis S, Feldman D, Satler LF, Pichard AD, Kent KM, Lansky AJ, Stone GW, Leon MB (2001): Vascular complications after percutaneous coronary interventions following hemostasis with manual compression versus arteriotomy closure devices. *J Am Coll Cardiol; 38:638-641.*

-De Luca G, Dudek D, Sardella G, Marino P, Chevalier B, Zijlstra F (2008): Adjunctive manual thrombectomy improves myocardial perfusion and mortality in patients undergoing primary percutaneous coronary intervention for ST-elevation myocardial infarction: a meta-analysis of randomized trials**.** *Eur Heart J; 29: 3002-3010.*

-Dill T, Dietz U, Hamm CW, Küchler R, Rupprecht HJ, Haude M, Cyran J, Ozbek C, Kuck KH, Berger J, Erbel R (2000): A randomized comparison of balloon angioplasty versus rotational atherectomy in complex coronary lesions (COBRA study)**.** *Eur Heart J; 21: 1759-1766.*

-Fischman D L, Leon M B, Baim D S, Schatz RA, Savage MP, Penn I, Detre K, Veltri L, Ricci D, Nobuyoshi M (1994): A randomized comparison of coronary-stent placement and balloon angioplasty in the treatment of coronary artery disease**.** *N Engl J Med.*, 331:496–501.

-Garcia-Lara,J., Pinar,E., Valdesuso, R., Lacunza, J., Gimeno,J. R., Hurtado, J. A.and Valdes-Chavarri, M (2012): Percutaneous coronary intervention with rotational atherectomy for severely calcified unprotected left main: Immediate and two-years follow-up results**.** *Cathet Cardiovasc.Intervent..doi:10./1002/ccd.23419.*

- Hansen DD, Auth DC, Vracko R, Ritchie JL (1988): Rotational atherectomy in atherosclerotic rabbit iliac arteries**.** *Am Heart J. 115: 160-165.*

-Henneke KH, Regar E, König A, Werner F, Klauss V, Metz J, Theisen K, Mudra H (1999): Impact of target lesion calcification on coronary stent expansion after rotational atherectomy. *Am Heart J; 137: 93-99.*

-Hermiller JB, Simonton C, Hinohara T, Lee D, Cannon L, Mooney M, O'Shaughnessy C, Carlson H, Fortuna R, Zapien M, Fletcher DR, DiDonato K, Chou TM (2006): The StarClose vascular closure system: interventional results from the CLIP study**.** *Catheter Cardiovasc Interv; 68: 677-683.*

- Holmes DR Jr, Teirstein P, Satler L, Sketch M, O'Malley J, Popma JJ, Kuntz RE, Fitzgerald PJ, Wang H, Caramanica E, Cohen SA (2006): Sirolimus-eluting stents vs vascular brachytherapy for in-stent restenosis within bare-metal stents: the SISR randomized trial.SISR Investigators. *JAMA; 295:1264-1273.*

- Hoye A, van Domburg RT, Sonnenschein K, Serruys PW (2005): Percutaneous coronary intervention for chronic total occlusions: the Thoraxcenter experience 1992-2002**.** *Eur Heart J; 26: 2630-2636.*

-Kamran Zamanian and Milton Tosto Jr (2009): Turmoil in the Interventional Cardiology Market. *http://www.devicelink.com/mx/archive/07/11/market.html.*

-Kim M (2006): Vascular closure devices**.** *Cardiol Clin; 24:277–286.*

-Lozano I, Lopez-Palop R, Pinar E, D, Fuertes J, Rondán J, Suárez E, Valdés M, Morís C (2005): Direct stenting in saphenous vein grafts. Immediate and long-term results**.** *Rev ESP Cardiol; 58: 270-277.*

-Magni V, Chieffo A, Colombo A (2009): Evaluation of intermediate coronary stenosis with intravascular ultrasound and fractional flow reserve: Its use and abuse**.** *Catheter Cardiovasc Interv.73: 441- 448.*

- Mamas MA, Fraser D, Fath-Ordoubadi F (2008): The role of thrombectomy and distal protection devices during percutaneous coronary interventions. *EuroIntervention.; 4: 115-123.*

-Mauri L, Reisman M, Buchbinder M, Popma JJ, Sharma SK, Cutlip DE, Ho KK, Prpic R, Zimetbaum PJ, Kuntz RE (2003): Comparison of rotational atherectomy with conventional balloon angioplasty in the prevention of restenosis of small coronary arteries: results of the Dilatation vs Ablation Revascularization Trial Targeting Restenosis (DART). *Am Heart J; 145: 847-854.*

- **Moussa I, Ellis SG, Jones M, Kereiakes DJ, McMartin D, Rutherford B, Mehran R, Collins M, Leon MB, Popma JJ, Russell ME, Stone GW (2005):** Impact of coronary culprit lesion calcium in patients undergoing paclitaxel-eluting stent implantation (a TAXUS-IV sub study). *Am J Cardiol; 96: 1242-1247*.

-**Murakami T, Mizuno S, Takahashi Y, Ohsato K, Moriuchi I, Arai Y, Mifune J, Shimizu M, Ohnaka M (1998):** Intracoronary aspiration thrombectomy for acute myocardial infarction**.** *Am J Cardiol*; 82: 839–844.

- **Nikolsky E, Mehran R, Halkin A, Aymong ED, Mintz GS, Lasic Z, Negoita M, Fahy M, Krieger S, Moussa I, Moses JW, Stone GW, Leon MB, Pocock SJ, Dangas G (2004):** Vascular complications associated with arteriotomy closure devices in patients undergoing percutaneous coronary procedures: a meta-analysis. *J Am Coll Cardiol; 44:1200-1209.*

-Oesterle SN, Bittl JA, Leon MB, Hamburger J, Tcheng JE, Litvack F, Margolis J, Gilmore P, Madsen R, Holmes D, Moses J, Cohen H, King S 3rd, Brinker J, Hale T, Geraci DJ, Kerker WJ, Popma J (1998): Laser wire for crossing chronic total occlusions: "learning phase" results from the U.S. TOTAL trial. Total Occlusion Trial with Angioplasty by Using a Laser Wire. Cathet Cardiovasc Diagn*; 44:235-43.*

-Olivari Z, Rubartelli P, Piscione F, Ettori F, Fontanelli A, Salemme L, Giachero C, Di Mario C, Gabrielli G, Spedicato L, Bedogni F (2003): Immediate results and one-year clinical outcome after percutaneous coronary interventions in chronic total occlusions: data from a multicenter, prospective, observational study (TOAST-GISE)**.** *J Am Coll Cardiol; 41:1672- 1678.*

-On Topaz, Allyne Topaz, Pritam R Polkampally (2009): Thrombectomy in acute myocardial infarction. *International Cardiology; 4(1):86-91*

-Orlic D, Stankovic G, Sangiorgi G, Airoldi F, Chieffo A, Michev I, Montorfano M, Carlino M, Corvaja N, Finci L, Colombo A (2005): Preliminary experience with the Frontrunner coronary catheter: novel device dedicated to mechanical revascularization of chronic total occlusions. *Catheter Cardiovasc Interv; 64:146-152.*

-Ozawa N (2006): A new understanding of chronic total occlusion from a novel PCI technique that involves a retrograde approach to the right coronary artery via a septal branch and passing of the guidewire to a guiding catheter on the other side of the lesion. *Catheter Cardiovasc Interv; 68: 907-913.*

-Pills NH, De Bruyne B, Bech GJ, Liistro F, Heyndrickx GR, Bonnier HJ, Koolen JJ (2000): Coronary pressure measurement to assess the hemodynamic significance of serial stenoses within one coronary artery: validation in humans. *Circulation. 102:2371-2377.*

- **Pills NH, Van Gelder B, Van der Voort P, Peels K, Bracke FA, Bonnier HJ, el Gamal MI (1995):** Fractional flow reserve. A useful index to evaluate the influence of an epicardial coronary stenosis on myocardial blood flow. *Circulation. 92:3183- 3193.*

-Pills NH, van Schaardenburgh P, Manoharan G (2008): Percutaneous coronary intervention of functionally

nonsignificant stenosis: 5-year follow-up of the DEFER Study**.** *J Am Coll Cardiol. 51:1123-1129.*

-Piper WD, Malenka DJ, Ryan Jr. TJ, Shubrooks SJ Jr, O'Connor GT, Robb JF, Farrell KL, Corliss MS, Hearne MJ, Kellett MA Jr, Watkins MW, Bradley WA, Hettleman BD, Silver TM, McGrath PD, O'Mears JR, Wennberg DE (2003): Predicting vascular complications in percutaneous coronary interventions. *Am Heart J; 145: 1022-1029.*

- Prevosti LG, Cook JA, Unger EF (1988): Particulate debris from rotational atherectomy: size distribution and physiological effects. *Circulation; 82(suppl II): II-83.*

- Resnic F, Arora N, Matheny M, Reynolds MR (2007): A cost minimization analysis of the Angioseal vascular closure device following percutaneous coronary intervention**.** *Am J Cardiol; 99: 766–770.*

- Rickli H, Unterweger M, Sütsch G, Brunner-La Rocca HP, Sagmeister M, Ammann P, Amann FW (2002): Comparison of costs and safety of a suture-mediated closure device with conventional manual compression after coronary artery interventions. *Catheter Cardiovasc Interv; 57: 297–302.*

- Rubartelli P, Niccoli L, Alberti A, Giachero C, Ettori F, Missiroli B, Bernardi G, Maiello L, Reimers B, Cernigliaro C, Sardella G, Bramucci E (2004): Coronary rotational atherectomy in current practice: acute and mid-term results in high- and low-volume centers. *Catheter Cardiovasc Interv; 61: 463-471.*

-Russo RJ, Silva PD, Teirstein PS (2009): A randomized controlled trial of angiography versus intravascular ultrasound-directed bare-metal coronary stent placement (The AVID Trial). *Circ Cardiovasc Intervent; 2:113-23.*

-Saito S (2008): Different strategies of retrograde approach in coronary angioplasty for chronic total occlusion. *Catheter Cardiovasc Interv; 71: 8-19.*

-Saito S, Tanaka S, Hiroe Y, Miyashita Y, Takahashi S, Satake S, Tanaka K (2003): Angioplasty for chronic total occlusion by using tapered-tip guidewires. *Catheter Cardiovasc Interv; 59: 305-311.*

-Sanborn TA, Gibbs HH, Brinker JA, Knopf WD, Kosinski EJ, Roubin GS (1993): A multicenter randomized trial comparing a percutaneous collagen hemostasis device with conventional manual compression after diagnostic angiography and angioplasty. *J Am Coll Cardiol; 22:1273-1279.*

- Sano K, Mintz GS, Carlier SG, de Ribamar Costa J Jr, Qian J, Missel E, Shan S, Franklin-Bond T, Boland P, Weisz G, Moussa I, Dangas GD, Mehran R, Lansky AJ, Kreps EM, Collins MB, Stone GW, Leon MB, Moses JW (2007): Assessing intermediate left main coronary lesions using intravascular ultrasound. *Am Heart J. 154:983-988.*

-Senter SR, Nathan S, Gupta A, Klein LW (2006): Clinical and economic outcomes of embolic complications and strategies for distal embolic protection during percutaaneous coronary intervention in saphenous vein grafts**.** *J Invasive Cardiol; 18: 49-53.*

- Sharma SK, Kini A, Mehran R, Lansky A, Kobayashi Y, Marmur JD (2004):

Randomized trial of Rotational Atherectomy Versus Balloon Angioplasty for Diffuse In-stent Restenosis (ROSTER). *Am Heart J; 147: 16-22.*

-Sirnes PA, Myreng Y, Mølstad P, Bonarjee V, Golf S (1998): Improvement in left ventricular ejection fraction and wall motion after successful recanalization of chronic coronary occlusions**.** *Eur Heart J; 19: 273-281.*

-Stone GW, Ellis SG, O'Shaughnessy CD, Martin SL, Satler L, McGarry T, Turco MA, Kereiakes DJ, Kelley L, Popma JJ, Russell ME (2006): Paclitaxel-eluting stents vs vascular brachytherapy for in-stent restenosis within bare-metal stents: the TAXUS V ISR randomized trial. TAXUS V ISR Investigators. *JAMA; 295:1253-1263.*

-Stone GW, Kandzari DE, Mehran R, Colombo A, Schwartz RS, Bailey S, Moussa I, Teirstein PS, Dangas G, Baim DS, Selmon M, Strauss BH, Tamai H, Suzuki T, Mitsudo K, Katoh O, Cox DA, Hoye A, Mintz GS, Grube E, Cannon LA, Reifart NJ, Reisman M, Abizaid A, Moses JW, Leon MB, Serruys PW (2005): Percutaneous recanalization of chronically occluded coronary arteries: a consensus document: part I. *Circulation; 112: 2364-2372*

-Stone GW, Moses JW, Ellis SG, Schofer J, Dawkins KD, Morice MC, Colombo A, Schampaert E, Grube E, Kirtane AJ, Cutlip DE, Fahy M, Pocock SJ, Mehran R, Leon MB (2007): Safety and efficacy of sirolimus-and paclitaxel-eluting stents. *N Engl J Med; 356: 998-1008.*

-Stone GW, Reifart NJ, Moussa I, Hoye A, Cox DA, Colombo A, Baim DS, Teirstein PS, Strauss BH, Selmon M, Mintz GS, Katoh O, Mitsudo K, Suzuki T, Tamai H, Grube E, Cannon LA, Kandzari DE, Reisman M, Schwartz RS, Bailey S, Dangas G, Mehran R, Abizaid A, Moses JW, Leon MB, Serruys PW (2005): Percutaneous recanalization of chronically occluded coronary arteries: a consensus document: part II. *Circulation; 112: 2530-2537.*

-Stone GW, Rogers C, Hermiller J, Feldman R, Hall P, Haber R, Masud A, Cambier P, Caputo RP, Turco M, Kovach R, Brodie B, Herrmann HC, Kuntz RE, Popma JJ, Ramee S, Cox DA (2003): Randomized comparison of distal protection with a filter-based catheter and a balloon occlusion and aspiration system during percutaneous intervention of diseased saphenous vein aorto-coronary bypass grafts**.** *Circulation; 108: 548 - 553.*

-Suero JA, Marso SP, Jones PG, Laster SB, Huber KC, Giorgi LV, Johnson WL, Rutherford BD (2001): Procedural outcomes and long-term survival among patients undergoing percutaneous coronary intervention of a chronic total occlusion in native coronary arteries: a 20-year experience. *J Am Coll Cardiol; 38: 409-414.*

-Svilaas T, Vlaar PJ, van der Horst IC, Diercks GF, de Smet BJ, van den Heuvel AF, Anthonio RL, Jessurun GA, Tan ES, Suurmeijer AJ, Zijlstra F (2008): Thrombus aspiration during primary percutaneous coronary intervention. *N Engl J Med; 358: 557-67.*

-Tavris D, Gross T, Gallauresi B, Kessler L (2001): Arteriotomy closure devices—the

FDA perspective. *J Am Coll Cardiol; 38:642-644.*

-Tiroch K, Cannon L, Reisman M, Caputo R, Caulfield T, Heuser R, Braden G, Low R, Stone G, Almonacid A, Popma JJ (2008): High-frequency vibration for the recanalization of guidewire refractory chronic total coronary occlusions. *Catheter Cardiovasc Interv; 72: 771-780.*

-Tobis J, Azarbal B, Slavin L (2007): Assessment of intermediate severity coronary lesions in the catheterization laboratory. *J Am Coll Cardiol. 49:839-848.*

-Tonino PAL, De Bruyne B, Pijls NH, Siebert U, Ikeno F, van' t Veer M, Klauss V, Manoharan G, Engstrøm T, Oldroyd KG, Ver Lee PN, MacCarthy PA, Fearon WF (2009): Fractional flow reserve versus angiography for guiding percutaneous coronary angiography. *N Engl J Med; 360: 213-224.*

-Vlaar PJ, Svilaas T, van der Horst IC, Diercks GF, Fokkema ML, de Smet BJ, van den Heuvel AF, Anthonio RL, Jessurun GA, Tan ES, Suurmeijer AJ, Zijlstra F (2008): Cardiac death and reinfarction after 1 year in the Thrombus Aspiration during Percutaneous coronary intervention in Acute myocardial infarction Study (TAPAS): a 1-year follow-up study. *Lancet*; 371:1915-1920.

-Vom Dahl J, Dietz U, Haager PK, Silber S, Niccoli L, Buettner HJ, Schiele F, Thomas M, Commeau P, Ramsdale DR, Garcia E, Hamm CW, Hoffmann R, Reineke T, Klues HG (2002): Rotational atherectomy does not reduce recurrent in-stent restenosis: results of the angioplasty versus rotational atherectomy for treatment of diffuse in-stent restenosis trial (ARTIST). *Circulation; 105: 583-588.*

-Wang H J, Kao H L, Liau C S, Lee YT (2002): Export aspiration catheter thrombosuction before actual angioplasty in primary coronary intervention for acute myocardial infarction. *Catheter Cardiovasc Interv*; 57:332–339.

- Warren BS, Warren SG, Miller SD (1999): Predictors of complications and learning curve using the Angio-Seal closure device following interventional and diagnostic catheterization**.** *Catheter Cardiovasc Interv; 48:162-166.*

-Whitbourn RJ, Cincotta M, Mossop P, Selmon M (2003): Intraluminal blunt microdissection for angioplasty of coronary chronic total occlusions. *Catheter Cardiovasc Interv; 58: 194-198.*

-Yousef ZR, Redwood SR, Bucknall CA, Sulke AN, Marber MS (2002): Late intervention after anterior myocardial infarction: effects on left ventricular size, function, quality of life, and exercise tolerance: results of the Open Artery Trial (TOAT Study). *J Am Coll Cardiol; 40: 869-876.*

استخدام الادوات و الأجهزة الشريانية المكملة في قسطرة القلب في مركز الملكة علياء لأمراض و جراحة القلب

د. مــروان أديب فـرح النمـري

خلاصة:

ان قسطرة القلب تشهد تغيراً واسعاً في الخبرات نتيجة لإزدياد حجم العمل و كذلك وجود حالات أكثر تعقيدا

يستخدم أطباء القلب في العالم العديد من الأدوات والأجهزة الشريانية القلبية وذلك لتحقيق النتيجة المثالية ، ولكن على الرغم من التقدم الكبير الذي حصل في القطاع الطبي في منطقة الشرق الاوسط وشمال افريقيا، الا ان الوسائل الحديثة المتطوره في عالم التداخلات القلبيه لا زالت لم تفعل بالشكل الصحيح ولم يتم استخدامها بطريقة واسعة كما هو الحال في الدول الغربية.

قد يكون السبب في عدم توفرها دائما في العديد من مختبرات القسطره هو ارتفاع كلفتها المادية وعدم قابليتها للتعقيم واعادة الاستخدام.

في هذه المراجعة ، نقوم بتلخيص الأدلة على أهمية استخدام هذه الأدوات و الأجهزة في التدخلات القلبية والشريانيه ، وكذلك التحديات التي تواجه توفرها في منطقة الشرق الأوسط و شمال افريقيا ، املين من الشركات الصانعه ان تاخذ زمام المبادره للدخول بشكل اوسع في اسواق الشرق لاوسط وشمال افريقيا ضمن برنامج التعليم الطبي المستمر حتى تصبح هذه الادوات اسهل اسخداماً واكثر شيوعاً باسعار مناسبه تحقيقاً للهدف المرجو وهو منفعة المريض.

.