

Results of the first 5 patients with iliac artery lesions treated by placement of a platinum/iridium stent of mexican manufacture and literature review

Arturo Abundes Velasco,* Efraín Arizmendi Uribe,** Manuel Odin De los Ríos,***
Joel Estrada Gallegos,**** Germán Quintana Peña*****

ABSTRACT

Introduction: This article submits the results of the first five patients treated with a platinum stent designed and manufactured in Mexico by our working group. The stent has gold welded joints and it may be mounted on peripheral angioplasty conventional balloons. **Material and methods:** We submit a case and control report of four patients treated at the Cardiology Hospital of the National Medical Center (CMN) of the Mexican Social Security Institute (IMSS), and of one patient that was studied and treated at the Hospital General de Salubridad (General Health Hospital) of Culiacán, State of Sinaloa. All patients underwent the implantation of a platinum stent in six iliac segments. The stents used were 30 mm long and between 6 and 8 mm in diameter. **Results:** All treated patients exhibited angiographic and clinical success during hospitalization with no complications and blockage opening. **Conclusions:** The platinum stent manufactured in Mexico could become an efficient alternative to those currently available.

Key words: Platinum/iridium stent, iliac artery lesions, angiographic success.

RESUMEN

Introducción: Presentamos los resultados de los primeros cinco pacientes tratados mediante un stent de platino diseñado y fabricado en México por nuestro grupo de trabajo. Es un stent con soldadura de oro en sus uniones y que puede ser montado en balones convencionales de angioplastia periférica. **Material y métodos:** Hacemos un reporte de casos y controles de cuatro pacientes tratados en el Hospital de Cardiología CMN IMSS y uno estudiado y tratado en el Hospital General de Salubridad de Culiacán Sinaloa, a los que se les realizó la aplicación del stent de platino en seis segmentos iliacos. Los stents utilizados fueron de 30 mm de longitud y de 6 a 8 mm de diámetro. **Resultados:** Todos los pacientes tratados resultaron con éxito angiográfico y clínico durante su hospitalización y sin ninguna complicación, con resolución de la obstrucción. **Conclusiones:** Este stent de platino fabricado en México podría ser una alternativa eficaz a los disponibles actualmente.

Palabras clave: Stent de platino, lesiones de arteria iliaca, éxito angiográfico.

BACKGROUND INFORMATION

Atherosclerosis is a systemic disease that –in humans– may affect a single vascular territory or several at once through overlap (*Figure 1*). The CAPRIE¹ Study, which comprised 19,185 patients, showed that 25%

of them were diagnosed with coronary heart disease only; another 25% suffered cerebral vascular disease; 20% suffered peripheral vascular disease and in between 3 and 12%, more than two territories overlapped (*Figure 1*).

The increase in life expectancy has also raised the number of atherosclerosis cases and one of the causes of greater disability is the affectation of iliac arteries.

At present, surgical or endovascular procedures are indicated for this pathology,² depending on the severity and location of the blockages.

A comparison of surgical procedures vs. endovascular treatment shows that the latter, despite its inherent complications, is less invasive, has a faster recovery rate and therefore allows patients to return to their normal activities sooner.

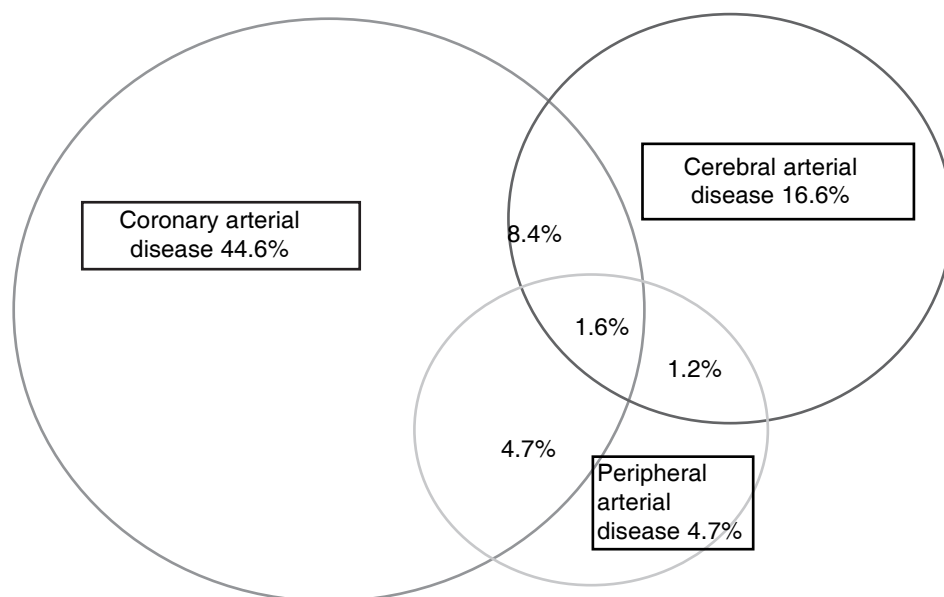
* Physicians ascribed to the Hemodynamics Service of the Cardiology Hospital Juarez SSA of México City.

** Physicians ascribed to the Hemodynamics Service of the Cardiology Hospital of the Centro Médico Nacional Siglo XXI. (HC CMN).

*** Head of the Hemodynamics Service of the Regional Hospital of Culiacán, State of Sinaloa.

**** Head of the Hemodynamics of the Cardiology Hospital of the Centro Médico Nacional Siglo XXI. (HC CMN).

***** Expert in Metal Handling.



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Figure 1. Arterial disease overlap of the various territories.

Our working group has developed and tested a coronary platinum/iridium stent, obtaining similar results to those reported with other conventional stents.^{3,4} We have designed and developed other models to be applied in renal and iliac arteries as well as the aortic model for the repair of coarctation of the aorta.

MATERIAL AND METHODS

We submit a the report of four patients treated at the Cardiology Hospital of the *Siglo XXI* National Medical Center (CMN) of the Mexican Social Security Institute (IMSS), and of one patient whose iliac arteries were treated on separate days at the General Hospital in Culiacán, State of Sinaloa.

Design and manufacturing of the iliac artery stent

The stent is manufactured using a 0.08 inch diameter platinum wire (90% platinum and 10% iridium).

The platinum wire is shaped into a sinusoidal strut with smooth and even-length handles by means of a template. Said structure is then heated lengthwise to a red-hot temperature (annealed) by direct application of a gas welding torch flame. It is then wound into a helicoidal shape around a metallic axis having 2 mm in diameter and annealed once again.

Pure gold soldering is then applied to the joints. A microscope with appropriate magnifying capabilities is used to verify the structure's welding points and edges, after which an electropolishing process is applied for 20 minutes in order to remove any burrs and achieve a smooth metallic surface. This process is followed by centrifugal washing with alcohol and once this has been completed, the stent is handled exclusively with instruments in order to dry it and place it in an appropriate sterile container. It is then packaged and gas sterilized. It is manufactured so as to be mounted on any peripheral angioplasty balloon catheter and attain lengths of 12, 16, 20, 30 and 40 mm, and to be mounted on any peripheral angioplasty balloon catheter to attain diameters of 5, 6, 8, 10 and 12 mm.

Compared with the steel stents, the platinum/iridium stent has a lower radial force which is, nonetheless, sufficient for atherosclerosis obstruction treatment and which provides the following advantages: greater malleability, better adjustment to the treated arterial structures and higher biocompatibility.

The procedure's success was defined as a decrease of the peak-to-peak gradient of less than 10 mg Hg.

As regards statistical analysis, no central trend measurements or dispersion are applicable given the number of patients involved. The results submitted are considered as the mean.

RESULTS

The present article reports on the results of 5 patients and 6 iliac arteries treated with the stent. Four patients were treated at the Cardiology Hospital and another one at the Mexican Ministry of Health's General Hospital of Culiacán, State of Sinaloa. The right iliac artery of the latter was treated first, followed by the subsequent intervention of the left iliac artery.

The average age was 67 (age range between 60 and 78).

There were four men and one woman.

Out of the five patients, three had a history of diabetes mellitus; four had a history of smoking and two of hypercholesterolemia.

Two patients had evidence of previous myocardial infarctions and one had a history of previous surgical myocardial revascularization.

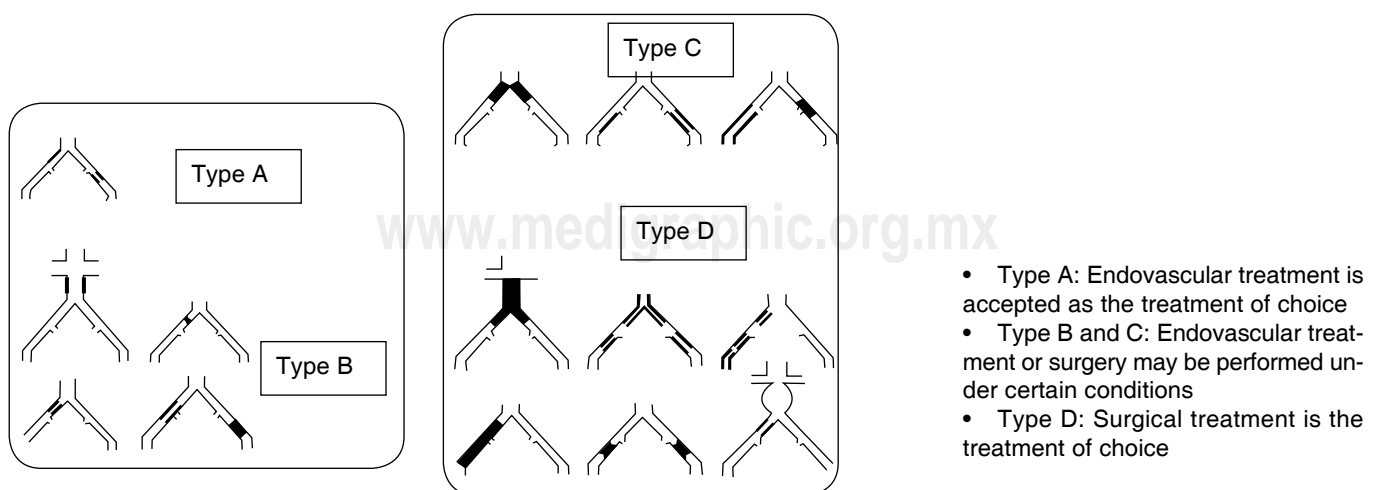
On three out of the four patients that were treated at the Cardiology Hospital a coronariography was indicated since they exhibited ischemic cardiopathy. Suspicion of peripheral arterial disease was clinically established and the existence of atherosclerosis in the common iliac artery was corroborated through an angiography. The other patient exhibited an acquired aortic stenosis and during the diagnostic catheterism suffered an accidental severe dissection of the common iliac artery. The patient treated at the General Hospital in Culiacán suffered from a severe disabling claudication and tissue loss in the right foot due to ischemia. The right iliac artery was treated first and, one week later, the left iliac artery was treated with the stent.

According to Rutherford's⁵ classification, patients were rated as follows: one patient in class 0, category 0; one patient in class 0, category I; two patients in class I and one in class III category 5 (Table I). Ac-

Table I. Rutherford classification: Stratification of chronic ischemia in lower limbs.

Grade	Category	Clinical manifestation	Clinical criterion
0	0	Asymptomatic	Normal PE
	1	Mild claudication	Complete PE; Post-Stress TA > 50 mmHg but ≤ 20 mmHg lower than value at rest
I	2	Moderate claudication	Between categories 1 and 3
	3	Severe claudication	Without completing PE and TA < 50 mmHg
II	4	Ischemic rest pain	TA at rest < 40 mmHg; flat PVR; TP < 30 mmHg
III	5	Minor tissue loss	TA at rest < 60 mmHg; flat PVR; TP < 40 mmHg
	6	Major tissue loss, non-salvageable limb	Same as 5

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Figure 2. Classification of iliac artery lesions according to TASC II.

cording to TASC classification (*Figure 2*), 4 of the 6 iliac arteries treated were type A and two were type B. 0.

Out of the four right common iliac arteries treated, three had lesions located in the mid third and one affected the aortic ostium. The mid third of one left common iliac artery was treated. As concerns the accidental dissection, said dissection was located in the internal iliac artery, immediately below the bifurcation.

Three of the atherosclerotic obstructive lesions were rated at 75% and two at 90%. In all cases 30 mm long stents were used; 8 mm diameter stents were used in four cases and 6 mm diameter stents were used in two cases.

The stents were released and fixed at an average pressure of 6 atmospheres. The final gradient in the four cases treated at the Cardiology Hospital turned out to be 0 mm Hg. All cases evidenced angiographic and clinical success throughout the procedure and hospital stay. There were no complications during the procedure or during hospitalization in all cases.

DISCUSSION

We are submitting the initial experience regarding the percutaneous intervention treatment of the iliac artery disease using the platinum/iridium stent manufactured in Mexico.

Previous experiences with Platinum- Iridium Alloy Stents:

The international literature⁶ makes reference to a platinum stent that was later put on the market for routine use.

The satisfactory results on the use of platinum/iridium stents manufactured in Mexico and designed for coronary atherosclerotic disease treatment have been reported in Mexico concerning *in vivo* and *in vitro* results on laboratory animals.³ A human protocol was later developed and the coronary platinum/iridium stent was implanted on 169 patients with coronary disease, obtaining excellent immediate results and a restenosis similar to the one obtained with the stainless steel stents.⁴

The prevalence of Peripheral Vascular Disease (PVD) varies according to the criterion used to diagnose it. In the United States and in the European Union 6.3 million patients have been diagnosed with symptomatic PVD. The actual prevalence is estimated at 20 million (equal to 9.5% of the patients over 50 years of age).

One easy and inexpensive way of identifying atherosclerotic disease in lower limbs is by using the

Ankle/Arm blood pressure index (AAI), which correlates appropriately with the angiographic findings. An AAI of <0.9 is a marker of significant obstructive atherosclerosis in lower limbs.^{7,8}

The incidence and prevalence of intermittent claudication in men under 50 is of 1%, while in those over 50 it is 3.5%. In general, at a younger age, it is up to three times more prevalent in men, but this situation tends to even out as both sexes grow older, being practically the same by age 70.

Five percent of the population over age 55 suffers from intermittent claudication and progress is stable in most of them (73%); only 16% get worse and 7% will require surgery or angioplasty and 4% amputation. We must also take into account that 5-year mortality is 30% and that its origin is cardiac in 75% of the cases.⁹

Several therapeutic options may be used in the treatment of peripheral vascular disease. Medical treatment resorts to the use of antithrombotic and anticoagulant agents, as well as of new agents such as Cilostazol and Propionyl-L-Carnitine. Physical exercise is of the utmost importance in order to try to stimulate collateral blood circulation, but modifying risk factors constitutes the most important element of them all.

One alternative is invasive management through endovascular, surgical or hybrid revascularization.

The decision making process must take into consideration the natural history of intermittent claudication.

The treatment goals are as follows: limb salvage; improving the quality of life; identifying and treating atherosclerosis in other territories so as to prolong survival and reducing the progress of the disease by thoroughly modifying the risk factors.

(*Table II*. Revascularization methods).

Endovascular treatment offers several advantages: it is safe and less invasive; it has few undesirable effects; improvement is similar to the one attained through surgery; it requires a shorter hospital stay and it is less expensive.

Iliac artery occlusion treatment is currently based on the TASC II recommendations published in 2007,² which clearly establish the procedures for type A lesions. These are short lesions that do not affect the origin of the internal iliac artery. Revascularization may be either endovascular or surgical in the case of type B and C lesions, which are longer or circumscribed total occlusions. In the case of type D lesions, which are diffuse, multiple or long total occlusions, surgical treatment should be preferred as an alternative to endovascular therapy.

Table II. Revascularization methods

1. Surgical revascularization
• Endarterectomy
• By-passes and grafts
2. Revascularization through angioplasty with or without stent
• Balloon angioplasty
• Stents
• Arterectomy devices
• Blood clot aspiration devices
• Stent-grafts
• Brachytherapy
• Medicated stents
3. Hybrid revascularization:
• Iliac artery stent and femoropopliteal by-pass

STENTS

Several types of stents have been used in this territory, such as the self-expandable and balloon expandable ones, as well as stents made out of different metals such as stainless steel and nitinol.¹⁰ However, the experience with platinum is quite limited. The reports on the different types of models and materials do not establish significant differences between them. Okka, for instance, reports on the results obtained with a self-expandable nitinol stent (Jostent-SelfX). Said stent was evaluated in 27 patients and yielded very satisfactory results such as a 94% rate of technical success and a 6-month permeability of 85%. In a recent multicentric European report on the evaluation of a modular stainless steel stent, Gaines¹¹ reported satisfactory immediate results and a 30-day permeability of 94%. After 6 months, permeability was 83% and in 86% of the cases there had been clinical improvement. Ponc¹² performed a randomized study comparing a nitinol self-expandable stent vs. a stainless steel one. The study comprised 100 patients for each model and provided similar immediate and long-term results with a 1-year restenosis of 2.7% and 3.5%, respectively.

APPROACH

Both the distal disease and the multiple lesions of the iliac artery have been regarded as adverse situations in maintaining the permeability of the iliac stent. On this subject, Lau¹³ reported an interesting approach on patients with multi-level peripheral occlusive lesions. The iliac artery lesion was treated with a stent in a transoperative manner and by performing a simultaneous femoropopliteal by-pass surgery, thus

obtaining an immediate success of 93% and a 1-year stent permeability of 100%. Powel¹⁴ reported the results obtained with patients having multiple lesions in the iliac arteries who were treated with endovascular treatment and stents. Out of 115 iliac arteries, he treated 210 different segments. His results showed a satisfactory permeability range, but a higher probability of future reintervention. The only significant adverse marker he found was the existence of significant stenosis of the external iliac artery.

Some conditions are adverse to surgery, such as having a previous history of vascular surgery in the affected location. Derom et al.¹⁵ reported excellent results in patients with restenosis due to previous surgical endarterectomy, which was successfully resolved through angioplasty and stenting, with an initial success rate of 100% and a long-term permeability of 96% after 1 year, and 76% after 3 years. A new surgical procedure in this specific group of patients constitutes a significant challenge that is generally resolved through by-pass implantation through grafts, taking into account the risks inherent to surgery and the potential infections it entails.

DIAGNOSIS

Upon following up on patients that have received an iliac stent implant it is important to consider the clinical aspects so as to identify reocclusion (due to restenosis) or the manifestation of new lesions unrelated to the location that was treated with a stent.

Pulse exploration, the color and temperature of the treated limb, the condition of the more distal tissues, ulcer cicatrization and AAI, are essential clinical data. Uberoi¹⁶ validated the use of Duplex in 75 patients treated with a stent. This method was used to follow up on this group of patients for a whole year and, when correlated with angiography, provided sensitivity, specificity and certainty levels of 100, 93 and 96%, respectively. Nonetheless, in an extremely well-performed study aimed at validating the non-invasive methods based on Bernoulli's formula compared with intra-arterial pressure measurement in order to assess the optimal or sub-optimal results (gradient higher or lower than 10 mm Hg) following angioplasty or stenting, Smet¹⁷ showed a deficient correlation between these methods in identifying immediate results. Therefore, their effectiveness in moderate and light gradient changes due to restenosis could be questionable.

GENERAL OBSERVATIONS

Timaran's¹⁸ study exemplifies most of the published works. He reported that in his center 65% of the patients who had been treated with an iliac artery stent had received such a treatment due to claudication; 33% due to limb salvage and 2% due to blue foot syndrome.

Stenting had been the first choice in 42% of his cases and it had been used as backup after a failed angioplasty in 43% of the cases. Patients with external iliac artery disease evidenced more diffuse disease, reduced blood flow, longer lesions and smaller vessels. This is how he discovered that the application of a stent in the external iliac artery in women was associated with a lower probability of long-term permeability.

PROGNOSIS MARKERS

We have listed some factors that are associated with reocclusion and poor results such as age, gender (female) and decreased distal arterial flow. No one had, however, analyzed whether there was a difference in treating the common iliac artery and the external iliac artery through stenting. Lee¹⁹ carried out a retrospective study with such purpose and found no difference regarding reocclusion or restenosis between both treated areas.

Timaran²⁰ identified the female gender as a bad prognosis marker in maintaining the permeability of iliac stents. This probably has to do with the smaller iliac artery diameters in females. He also found that kidney failure and severe ischemia of the limbs were bad prognosis markers as well.

It is a well known fact that the decreased distal flow to the iliac stent is an important predictor of its reocclusion. However, it was not known whether infrainguinal arterial reconstruction modified this result. Timaran²¹ reported 68 iliac stent cases in 62 patients. Half of them underwent infrainguinal arterial reconstruction. This group was older and had more diffuse lesions. After a five-year follow up, no improvement in this group's stent permeability was achieved; this led Timaran to conclude that infrainguinal arterial reconstruction does not affect the evolution of patients with deficient distal flow (runoff).

RESULTS

Nawas²² reported good results in a group of over 100 patients treated with iliac stents. Said group had a

95% immediate success rate and a 95% satisfactory clinical evolution after one year. Patients who did not take aspirin and those who had a translesion gradient of more than 10 mm Hg were considered as poor evolution factors.

In a multicentric study with clinic and paraclinic 12-month follow-up through application of the modular balloon expandable stent in patients previously treated with balloon angioplasty and residual lesion with a gradient of less than 10 mm Hg, Reekers²³ reported a stenosis decrease from 79 to 4% and a decrease of the final average gradient of 3 mm Hg, showing a clinical success of 88 and 86% after 6 and 12 months, respectively.

However, upon follow-up, approximately 40% of the patients still experienced intermittent claudication. This proved there was poor correlation between angiographic success and stent permeability. The probable cause may be the presence of disease in other arterial levels of the treated limb.

TYPE OF LESIONS

Scheinert²⁴ reported the results of 212 patients suffering from total chronic iliac artery occlusions after Excimer laser-assisted and stent-supported recanalization. The excellent immediate results show a 90% success rate; a significant clinical improvement in half of the patients and moderate in one third of them; a 1-year permeability of 84% and a 4-year permeability of 76%. This led him to conclude that this procedure entails less morbidity than surgery, but affords lower long-term permeability.

Timaran²⁵ compares the results obtained with iliac artery stent placement (135) vs surgery (52) in type B and C TASC lesions, in which the correct procedure is not well defined, showing that by-pass implantation surgery has a higher long-term permeability percentage and that the bad prognosis factors are: female gender, distal flow decrease and external iliac artery stenosis.

KISSING STENT TECHNIQUE

Greiner²⁶ reported on the results obtained with patients suffering from bilateral aortoiliac disease treated with stents placed with the Kissing Stent technique, and showed that despite the successful immediate results, the reintervention and reocclusion rates turned out to be higher than the ones reported with surgery. Therefore, this technique is recommended only for high-risk patients or for those who have a very limited life expectancy.

IVUS GUIDANCE

In a retrospective study, Buckley²⁷ evaluates the immediate results in patients treated with stent placement by comparing 36 angiography and IVUS-guided patients *vs* 16 patients guided only through angiography. He showed that almost 40% of the patients in the IVUS group had a poor fixation of the stent, which resulted in a change of method in order to optimize the result through redilatations.

Said optimization resulted in a 3- and 6-year permeability of 100%, compared with the group that had not been IVUS-guided, which obtained results of 84 and 67%, respectively.

This proved that the right choice of diameter and stent release pressure is a predictor of the success attained through IVUS guidance.

Most likely, the technological improvement of stents (materials, medicated stents, etc.), the better understanding of the disease and the occasional support of intravascular ultrasound, will lead to better results and to the substitution of surgery in most cases.

COST-BENEFIT ANALYSIS

A cost-effectiveness analysis performed in the United States by Bosch²⁸ evidenced a higher benefit in iliac artery stenosis management through angioplasty and stent placement than with angioplasty only, due to the higher efficiency of the stent strategy.

Our country needs to promote the development of technologies that may be manufactured and exploited in Mexico. The alternative that we propose for this pathology—demonstrated *in vitro* and *ex vivo* sections—has provided satisfactory results in the first patients with iliac artery disease.

CONCLUSIONS

Despite the reduced number of patients involved in this study, the results are most encouraging. The platinum/iridium stent manufactured in Mexico may become an effective alternative to the conventional steel stents used in iliac artery disease treatment.

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Correspondence:

Dr. Arturo Abundes Velasco,
Queretaro # 504-109 Colonia Roma 06760
Telephone and Fax 55741637.
E-mail: aabundes@att.net.mx