

The United Mexico States
Republic of Colombia
Federative Republic of Brazil
The Argentine Republic

The United Mexico States, Republic of Colombia
Federative Republic of Brazil, The Argentine Republic

**Collaboration program with the Private
Sector for Disseminating Japanese
Technology for Training on Treating
Coronary Artery Diseases by Transradial
Intervention**

Final Report

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1. Back ground

Ischemic cardiac disease (CAD) is a critical heart disease which a coronary artery surrounding heart have occluded by any reason like blood clotting or narrowing the artery. Deteriorating disease will lose the heart function and may kill the patient in worst case. Although Coronary artery bypass graft (CABG) which is an open heart surgery to bypass the narrowed artery to supply blood to the distal part of the artery, had been a treatment for this disease for long time, Percutaneous coronary intervention (PCI), is has became a major selection of treatment. Interventional cardiologist deliver a balloon catheter or other device from the femoral artery up through blood vessels until they reach the stenotic lesion. At the stenotic lesion, balloon catheter is inflated to open the stenosis allowing blood to flow. In general, patient need to be in the hospital about 1months after CABG compare to about 3 days by PCI. The Trans Femoral Intervention (TFI) traditionally has been the primary approach for many operators, but the Trans Radial Intervention (TRI) became more popular method due to lower puncture site bleeding complication and better patient comfort and possible earlier hospital discharge after the procedure. In Japan, Dr.Shigeru Saito (Shonankamakura General Hospital) has started TRI from 1995 and been promoting this procedure not only in Japan but also overseas. Percentage of TRI among total PCI procedure is higher in Europe, Asia and Japan but lower in North, Latin Americas in general. It is considered due to lack of understanding of TRI benefits and education, training in those countries.

2. Overview of this project

The purpose of this project is to expand TRI procedure penetration in Mexico, Colombia, Brazil, Argentine where still low TRI rate followed by Terumo sales growth. To expand TRI ratio, giving an opportunities to interventional cardiologists of those countries to learn rationales, techniques and skills in Japan. Main trainer is Dr.Shigeru Saito/Shonan Kamakura General Hospital, the world famous TRI expert supported by Terumo utilizing our facilities, Ashitaka factory, Medical Pranex which is the medical training and education center of Terumo.

3. Actual condition and challenges for the objective countries. (Pre-project)

The statistics of mortality ratio by diseases, annual number of PCI cases, TRI ratio among the procedure was as follows. (Terumo data 2013)

3.1 Mortality ratio by diseases

Mexico	1: CAD (26%), 2: DM related (13%), 3: Tumor (13%)
Colombia	1: CAD (27%), 2: Tumor (17%), 3: Inflict injury (14%)
Brazil	1: CAD (33%), 2: Tumor (20%), 3: Respiratory disease (10%)
Argentina	1 : CAD (33%), 2: Tumor (16%), 3: Respiratory disease (6%)

*CAD : Coronary Artery Disease, DM; Diabetes

Diabetes is one of the risk factor of Coronary artery disease (CAD). CAD is increasing in those countries due the lifestyle westernization. Brazil and Mexico are within the top 10 worst countries of number of diabetic (No.4 12.4million and No.7 10.3million respectively) and expected to increase CAD continuously due to the increase of population.

3.2 PCI cases and TRI rate

Number of PCI procedures in Latin Americas are 224,400cases (2013). 4 objectives countries for this project have 83% of total procedures.

Country	PCI cases	Growth (%)	TRI rate (%)
Mexico	28,500	6.6	30
Colombia	16,000	6.6	15
Brazil	110,000	5.6	25
Argentina	32,000	6.5	10

3.3 Possibility of contribution to the objective countries' local community and the economic development.

Inequality of procedural quality between wealthy patient who can receive high level treatment in private hospital and worth level in public sector is existing. The famous private hospital has almost same equipments installed in the hospital and can receive better quality of treatment. On the other hands, more efficient procedural pathway management is demanded for the public hospital to clear many waiting patients of the diagnosis, treatment and operation. Budget of public hospital is controlled by government so that the hospital which has less budget need to limit both in and out patient resulted limited acceptance of patients. Since TRI possibly give hospital an opportunity to accept more patient thanks to it's safer, lower cost and shorter hospital stay compare to the traditional femoral approach, patients of those objective countries will have more chance to receive PCI procedure resulted better health care. Since medical tourism is one of the objective counties' governmental strategy, they can also expect trade balance surplus by welcoming patient from their outside countries by cost beneficial TRI.

4. Project policy, Plan

Terumo have working not only device delivery as manufacturer but also keep development for better treatment, promotion of proper use, supportive work for continuous medical education based on our corporate mission "Contributing society through healthcare" TRI concept and it's related devices has not been introduced in objective countries yet by American medical manufactures because they has no TRI devices since TRI is not widely accepted in the US. Terumo has a long history in TRI segment and outstanding experience for the device development and support educational activities. We are planning to invite interventional cardiologist who like to learn TRI from objective countries to Japan and giving educational activities at Terumo Ashitaka factory, medical training center "Terumo Medical Pranex" and Shonankamakura general hospital and Sapporo Higashi Tokusyukai hospital coordinated and trained by Dr.Shigeru Saito.(In bound training) After few month, Dr.Saito will visit those objective countries to confirm, verify the trainees' improvement (follow-up training) TRI ratio of objective countries are still low. We set the quantative goal of TRI rate after the project as 50% in Mexico, 30% in Colombia, 40% in Brazil and 20% in Argentine.

5. Original schedule and the result

Original plan and the result is described below. All of milestones (in, out bound training) have been

completed although there were some schedule deviation.

Milestone	Original Schedule	Result
Start project	Jan. 2014	Jan. 2014
Selection of training hospitals in Japan and request cooperation. Scheduling.	~Feb.	Feb.
Selection of trainees for 1 st , 2 nd training.	~Feb.	Feb
The 1 st Training in Japan (Mexico, Colombia)	Apr.	May12~16
Follow up training (Colombia)	Oct.	Oct. 19~22
The 2 st Training in Japan (Brazil, Argentina)	Sep	Sep. 8~12
Follow up training (Brazil, Argentina)	Mar. 2015	Mar. 12~19, 2015
Selection of trainees for 3 rd , 4 th training.	Oct. 2014	Oct. 2014
The 3 rd Training in Japan (Mexico, Colombia)	Feb. 2015	Jan.26~30, 2015
Follow up training (Mexico, Colombia)	July	Aug. 17~21
The 4 th Training in Japan (Brazil, Argentina)	Jun	July 6~10
Follow up training (Brazil, Argentina)	Dec.	Nov. 23~27

6. Trainees and the affiliation

Total 39 physicians, 4 times training has been organized.

	Country	Name	Affiliation
1 st	Colombia	Dario Echeverri	Fundación Cardioinfantil
		Carlos Tenorio	Centro Médico Imbanaco
		Arturo Rodriguez	Clínica El Rosario
		Hector Hernandez	Instituto del corazón de Bucaramanga
		Jorge Mor	Fundación Santa Fé
	Mexico	Elías Vinicio Merlín González	HCMN IMSS SXXI
		José Luis Romero Ibarra	Instituto Nacional de Cardiología "Ignacio Chávez"
		Roberto Muratalla	Centro Médico "20 de Noviembre", ISSSTE
		Miguel Angel Ramírez Aldaraca	Hospital Militar. SEDENA
		Hector Manuel Alcaraz Álvarez	Hospital "Miguel Trejo Ochoa", ISSSTE Colima
2 nd	Argentine	Gustavo Andersen	Clínica Bazterriz, Clínica Santa Isabel , Sanatorio Franchin
		Laura Decandido	Hospital Posadas & Hospital Naval
		Alejandro Álvarez Iorio	Hospital Privado del Sur & Hospital Italiano, & Hospital Regional Espanol
		Juan Pablo Zimmerman	FLENI, Sanatorio Anchorena
		Pablo Pollono	Hospital del Cruce & Hospital Espanol de La plata
	Brazil	Igor Bienert	HC Marilia and Santa Casa Marilia
		Leonardo Guimaraes	Hospital Stella Maris and ABC Imagem
		Bruno Laurenti Janella	Hospital Santa Marcelina
		Higo Cunha Noronha	Hospital Regional do Vale do Paraíba
		Lourenço Teixeira Ligabó	Hospital Instituto Dante Pazzanese de Cardiologia

	Country	Name	Affiliation
3 rd	Mexico	Carlos Alberto Merigo Azpiri	American British Cowdray Medical Center
		Oscar Sánchez Hurtado	Medical Center "Lic. Adolfo López Mateor"
		Luis Roberto Álvarez Contreras	American British Cowdray Medical Center
		Manuel Ben Adinoram Gaxiola Macías	National Institute of Cardiology "Ignacio Chávez"
	Colombia	Juan Andres Delgado	San Vicente de Paul
		Marcos Morales	Servicios especializados del corazón
		Federico Saaibi	Fundación Cardio Vascular
		Pedro Carreño	Clinica Reina Catalina
		Jhon Liévano	Hospital San Rafael
4 th	Brazil	Gustavo Affonso de Oliveira	Hospital São Paulo
		Camila Naomi Matsuda	Hospital Santa Marcelina
		Fabio Conejo	Hospital Sancta Maggiore
		Eduardo Szuster	Hospital Biocor
		Frederick Gusmão	Hospital Santa Catarina / Hospital Santa Virgínia
	Argentine	Raúl Solernó	1)Hospital El Cruce-Néstor Kirchner 2)Clínica Sagrada Familia 3)Instituto Médico Central Ituzaingó (IMC)
		Pablo Núñez	Hospital Italiano, La Plata
		Adolfo Lopez Campanher	Instituto de Cardiología de Corrientes Juana F.Cabral - FUNCACORR
		Juan Manuel Pereira	1)Hospital San Bernardo de Salta 2)Hospital Privado Tres Cerritos 3)Clínica Privada Sagrada Corazón
		Gerardo Nau	1)Instituto Cardiovascular Buenos Aires, ICBA 2)Sanatorio Anchorena

7. Training agenda

Following are the agenda of each in, out bound training.

<In bound training>

days	Venue	Contents
Day 1	Arrive Japan	
Day 2	JICA office. Move to Terumo Ashitaka factory	Opening, Orientation, Instruction for use, precaution training of TRI related devices.
Day 3	Terumo Medical Pranex	Hands on training using simulator, anatomy model (by physician from Shonankamakura general hospital, Sapporo higashi Tokusyukai hospital
Day 4	Shonankamakura general hospital	Lectures related TRI procedures, In cath labo observation of Dr.Saito's procedures. Hospital visit.
Day 5	Sapporo higashi Tokusyukai hospital	Lectures related TRI procedures, In cath labo observation of Dr.Saito's procedures. Hospital visit.
Day 6	JICA office	Closing, review of training, Giving certificate.
Day 7	Leave Japan	

<Out bound training (Follow-up) >

Follow-up of trainee's TRI technical skill progress after 6 months of in-bound

- Visiting trainee's hospital and observe their growth of technique, knowledge of TRI.
- Debriefing meeting of post in-bound training presented their TRI penetration, technical progress by each trainees.

8. Impact of training program

8.1 TRI rate in their total procedure.

TRI rate in trainee's total procedures has significantly increased even over the original target. There are some report from trainees that they started TRI for more complex procedure than before.

	TRI rate in total procedures	
	Original target	TRI rate after the training (by country average)
Mexico	50%	77%
Colombia	30%	66%
Brazil	40%	62%
Argentina	20%	54%

Change by hospital

	Country	Physician	Affiliate hospital	TRI rate	
				Before	After
1 st	Colombia	Dario Echeverri	Fundación Cardioinfantil	30%	60%
		Carlos Tenorio	Centro Médico Imbanaco	0%	15%
		Arturo Rodriguez	Clínica El Rosario	30%	50%
		Hector Hernandez	Instituto del corazón de Bucaramanga	5%	30%
		Jorge Mor	Fundación Santa Fé	10%	35%
	Mexico	Elías Vinicio Merlín González	HCMN IMSS SXXI	30%	70%
		José Luis Romero Ibarra	Instituto Nacional de Cardiología "Ignacio Chávez"	35%	75%
		Roberto Muratalla	Centro Médico "20 de Noviembre", ISSSTE	25%	65%
		Miguel Angel Ramírez Aldaraca	Hospital Militar. SEDENA	15%	65%
		Hector Manuel Alcaraz Álvarez	Hospital "Miguel Trejo Ochoa", ISSSTE Colima	20%	80%

	Country	Physician	Affiliate hospital	TRI rate	
				Before	After
2nd	Argentina	Gustavo Andersen	Clínica Bazterriz, Clínica Santa Isabel , Sanatorio Franchin	15%	35%
		Laura Decandido	Hospital Posadas & Hospital Naval	15%	35%
		Alejandro Álvarez Iorio	Hospital Privado del Sur & Hospital Italiano, & Hospital Regional Espanol	15%	50%
		Juan Pablo Zimmerman	FLENI, Sanatorio Anchorena	15%	30%
		Pablo Pollono	Hospital del Cruce & Hospital Espanol de La plata	15%	40%
	Brazil	Igor Bienert	HC Marilia and Santa Casa Marilia	90%	95%
		Leonardo Guimaraes	Hospital Stella Maris and ABC Imagem	10%	30%
		Bruno Laurenti Janella	Hospital Santa Marcelina	30%	50%
		Higo Cunha Noronha	Hospital Regional do Vale do Paraíba	30%	70%
		Lourenço Teixeira Ligabó	Hospital Instituto Dante Pazzanese de Cardiologia	30%	40%

	Country	Physician	Affiliate hospital	TRI rate	
				Before	After
3rd	Mexico	Carlos Alberto Merigo Azpiri	American British Cowdray Medical Center	60%	85%
		Oscar Sánchez Hurtado	Medical Center "Lic. Adolfo López Mateor"	50%	80%
		Luis Roberto Álvarez Contreras	American British Cowdray Medical Center	85%	95%
		Manuel Ben Adinoram Gaxiola Macías	National Institute of Cardiology "Ignacio Chávez"	43%	75%
	Colombia	Juan Andres Delgado	San Vicente de Paul	30%	90%
		Marcos Morales	Servicios especializados del corazón	35%	95%
		Federico Saaibi	Fundación Cardio Vascular	30%	95%
		Pedro Carreño	Clinica Reina Catalina	40%	95%
		Jhon Liévano	Hospital San Rafael	20%	90%

	Country	Physician	Affiliate hospital	TRI rate	
				Before	After
4 th	Brazil	Gustavo Affonso de Oliveira	Hospital São Paulo	30%	90%
		Camila Naomi Matsuda	Hospital Santa Marcelina	50%	70%
		Fabio Conejo	Hospital Sancta Maggiore	79%	84%
		Eduardo Szuster	Hospital Biocor	1%	40%
		Frederick Gusmão	Hospital Santa Catarina / Hospital Santa Virgínia	10%	50%
	Argentina	Raúl Solernó	1)Hospital El Cruce-Néstor Kirchner 2)Clínica Sagrada Familia 3)Instituto Médico Central Ituzaingó (IMC)	10%	40%
		Pablo Núñez	Hospital Italiano, La Plata	10%	80%
		Adolfo Lopez Campanher	Instituto de Cardiología de Corrientes Juana F.Cabral – FUNCACORR	25%	80%
		Juan Manuel Pereira	1)Hospital San Bernardo de Salta 2)Hospital Privado Tres Cerritos 3)Clínica Privada Sagrada Corazón	25%	60%
		Gerardo Nau	1)Instituto Cardiovascular Buenos Aires, ICBA 2)Sanatorio Anchorena	30%	90%

8.2 Business growth of Terumo branches after the program

Although there seems various negative economical impact by counties and hospital financial conditions, sales of each branches have been increased as follows. We speculates it result of TRI penetration and the related device market growth and/or Terumo brand recognition.

	Sales growth (vs year before this project 2013)
Mexico	16%
Colombia	52%
Brazil	47%
Argentine	14%
Consolidate	31%

**8.3 Contribution to the society and economical development of objective countries.
(Advance of health, energizing of economy)**

We summarized the qualitative contribution to each societies as follows.

Mexico	Safety and efficacy of TRI are promoting in the country through the medical society and can expect the advancement of health by the trainees who are belong to the national cardiovascular center in Mexico and it's influence to the medical society.
Colombia	More higher quality of medical care is providing to the patients especially by the trainees who participated to this training program. Day care service after PCI have also started by some of the hospital and contributing to shorten hospital stay to lead economical benefit. Penetration growth of TRI are also leading introduction of high quality Japanese medical devices rapidly resulted sales growth of Terumo branch.
Brazil	TRI is rapidly growing because of the very good reputation and effectiveness of this training program to the trainees. Positive effect to medical ependiture in Brazil are expected by shortening hospital stay, lowering of hospital staff workload by safer, lower cost TRI growth.
Argentina	This program is very well accepted by doctors, nurses because no other companies have been supporting them to learn TRI. The clinical, economical benefit was initiated to the Ministry of public health during follow-up training seminar organized with dr.Saito and expect further communication with those public domain.

8.4 Reputation of TRI procedure in the hospital

Reputation of TRI procedure and its penetration in the hospital is as follows. (feed back from the trainees)

Mexico	JICA trainees have successfully shown and applied their TRI skills at the hospitals they work at. It is a major benefit that three of them work at school hospitals (INC, IMSSsigroXXI, ISSSTE 20 de Noviembre), where they can also spread the acquired knowledge to physicians who are currently at their fellowship, that after they finish, will take the learned technique to other hospitals. TRI is providing improvement of interventional procedures by the risk reduction of access complications, post procedure care and so on.
Colombia	TRI provides more opportunity to the hospital which can discharge patient their early discharge from the hospital and accept more patient to treat. This benefit clinical, economical benefits are gradually recognizing not only physicians, but also hospital management. Nurses are able to work for safer efficient patient care thanks to the reduction of post PCI care and additional workload by complication.
Brazil	Hospitals which dispatch trainees are trying to provide day care service and the economical benefits followed by have been gradually recognizing by hospital management.
Argentina	TRI rate of trainees' hospitals are rapidly growing not only their selves but also spreading to their colleagues working together.

8.5 Spreading TRI to the country

Interest of TRI in the other hospitals are increasing.

Mexico	Many of trainees are working not only their affiliation but also other hospital so that they are shareing their knowledge and skills to the subordinates.
Colombia	Trainees are giving presentation of TRI knowledge or techniques, data at the presentation at the scientific meeting resulted area, country.
Brazil	TRI training and promotion can be expected by the affiliate of the trainees such as Hospital São Paulo、Hospital Dante Pazzanese de Cardiologia as they are accepting many fellows and are famous antenna hospital in Brazil.
Argentine	TRI are well accepting and focusing to stat TRI even in the low penetration country, Argentine because physicians are understanding it's clinical benefit.

9. Summary

All of the program is completed in December 2015 with total 4 group for each in bound, out bound training in each Mexico, Colombia, Brazil, and Argentine. Instruction for use and precaution of TRI products were trained to the physicians in the 1st day. Trainer physicians from ShonanKamakura hospital and Sapporo higashi Tokusyukai hospital gave a technical training of TRI using TRI simulator and artery models at Terumo Medical Pranex. The artery model in Pranex is special specification which beating heart as of human body reflecting real clinical practice and the program could provide good training to the physicians from the objective countries even they could not do real clinical procedure in Japan. The day in Ashitaka factory was valuable for both physicians and Ashitaka engineers because they discussed about how to use devices, precautions and competitive devices listen to the real field voices. Factory visit which was orgnised at Ashitaka factory was also important opportunity to let physicians understand Terumo history, corporate vision, products and our quality management philosophy.

In hospital training has been done in Shonankamakura general hospital and Sapporo higashi Tokusyukai hospital in 3rd and 4th days. It was a great opportunity for the trainees since they could observe Dr.Shigeru Saito, the world famous interventional cardiologist and could close communication with him in the cath labo in front of the patients. The one of the reason not to

increase TRI is due to the difficulty of the TRI cases facing unusual procedures or complex cases. This cath labo training could clarify their daily questions and believed they can try those cases once trainees back to their hospital and increase TRI rate.

This hospital training were organized at both Shonankamakura General Hospital and Sapporo Higashi Tokusyukai hospital which have geographical distance. Although it took time to move to the other place, organizing training in those 2 hospitals were valuable to know the different clinical path way of each hospital and patient management. Both hospitals are working for medical tourism and no problem for the practices. It was a good opportunity for the hospital staff to understand different culture.

After the 2nd in bound training, we asked JICA representatives to give opening and closing address in JICA office. Even this training program is the commissioned project undertaken by Terumo, this official opportunity was important to let participants feel the royalty as this public-private partnership program even short time. Trainees could feel the system, cleanliness and hospitality of Japan during their stay.

Dr.Saito visited objective countries after 6months of inbound training to confirm, verify their progress. In hospital observation and debriefing meeting clearly gave the progress of technique and the ratio of TRI procedure in each trainee. They seem to try increase radial approach even for the complex case which had not proceeded before the inbound training. This new approach was well accepted by nurses or technicians in the cath labo since it's reduce their patient care work. TRI procedure of in global hospital is expected to be increase once the trainees colleagues starts TRI. Future impact of patients increase, economical benefit need to be follow-up for long term.

We started to invite fellows, person in charge from department of health, Ambassador, JICA personals, and key opinion leaders of each country and share our work so that they could understand the benefits of TRI. This project has been now closed but hope to keep promotion of TRI by trainees to their countries and would contribute to the society through health care as of Terumo mission.

10. Possibility of Terumo business followed by

Increase of TRI penetration of the trainees affiliate hospitals has been confirmed. Our business is growing in Latin American countries year by year even some variance. Colombia is leading high growth because there is leading key opinion leader in this country. This can give us a very good impact thanks to this leading physicians' initiative for the follow up training and gave us an opportunity for device promotion other than TRI. On the other hands, Arzentine is unique by various factors and can expect further growth. Our business opportunity will expand with spreading TRI procedures in the country. We keep contribute for this expansion to support scientific work for the interventional field.

11. Possibility of further collaboration with ODA

There are several requests from some of the country to continue this program after finishing this project. Continuous technical support from Japan are also expected. It is ideal that the trainees of this program will lead the future TRI expansion in each country. Further communication through this kind of continuous program may also effect to the regulatory authorization to shorten approval of Japanese medical devises in their country. This will give strong impact for Japanese medical manufacturer to introduce and contribute to the local procedural improvement and Japanese industrial development.

The project which has been organized in Mexico previously this project with JICA gave an positive impression to the Mexican and Japanese government and the new TRI training project leading by the Mexican public sectors to establish training center in National Cardiovascular Center under the official support of JICA. This project can further provide opportunity to the Mexican physicians to learn TRI by some of the trainees which participated in this project. TRI expansion if it's became the authorized procedure in the country can provide better health care improvement and by less complication and shortning hospital stay. This training center project is rational to grow the procedure and beneficial for both country and may approcable for other development countries in the future.

Finally, we acknowledge Dr.Shigeru Saito, Shonankamakura General Hospital and the staffs, Staffs of JICA, Ambassador of Japan in Foregin countries of sincere thanks to support this project.

References ;

¹ Sanjit S Jolly et.al ; DOI:10.1016/S0140-6736(11)60404-2

¹ Amit.P.Amin et.al ; J Am Coll Cardiol Intv 2013;6:827-34