# 臺灣介入性心臟血管醫學會

期

TAIWAN SOCIETY OF CARDIOVASCULAR INTERVENTIONS



108.8.10-11『2019 秋季會』

#### 學會活動預告:

108.11.02 Great Debate in Interventional Therapy



#### 臺灣介入性心臟血管醫學會(TSCI)

理 事 長 殷偉賢

常務理事 王志鴻 張其任

理 事 王光德 王怡智 吳道正 李文領

林宗憲 邱俊仁 施俊明 徐中和

高憲立 陳鴻毅 傅雲慶 黃偉春

鄭正一顧博明

常務監事謝宜璋

監 事 方慶章 洪大川 常敏之 趙庭興

秘 書 長 盧澤民

副秘書長 蔡政廷 陳盈憲 邱正安 陳業鵬

詹世鴻 賴志泓 郭風裕 宋思賢

劉俊廷 陳冠群 黃建龍 周柏青

任勗龍

秘 書 處 林佳慧 賴瑋儀 陳詠潔

#### 臺灣介入性心臟血管醫學會會訊(第七十期,Aug., 2019)

發行人 Publisher 殷偉賢 Wei-Hsian Yin

副主編 Deputy Editor-in-Chief 劉俊廷 Jun-Ting Liou

執行編輯 Executive Editor 蔡維哲 Wei-Che Tsai

林子喬 Tzu-Chiao Lin

曾國翔 Guo-Shiang Tseng

周琰璉 Yen-Lien Chou

陳詠潔 Yung-Chieh Chen

TO PLY TO

地址: 10041 台北市中正區忠孝西路一段 50 號 16 樓之 18

Address: 16F-18, No.50, Sec. 1, Zhongxiao W. Rd., Taipei 10041, Taiwan, R.O.C.

TEL:+886-2-2381-1698 FAX:+886-2-2381-5198

E-mail:tsci.med@msa.hinet.net Website:http://www.tscimd.org.tw/home.php

理事長的話	03
會務活動	
入會申請表	04
Great Debate in Interventional Therapy	06
會議記錄	
第七屆第五次教育訓練委員會	09
第七屆第四次週邊血管介入委員會	13
第七屆第四次編輯暨登錄委員會	15
「介入影像」專欄	
本期案例:三軍總醫院 劉俊廷醫師	17
上期解答:臺北榮總 蔡泉財醫師	
醫學新知	
Clinical Use of Intracoronary Imaging. Part 2: Acute Coronary Syndromes, Ambiguou Angiography Findings, and Guiding Interventional Decision-making: an Expert Document of the European Association of Percutaneous Cardiovascular Interventions 冠狀動脈血管內成像之臨床使用。 第 2 部分:急性冠心症,不明確的冠狀造影結果,和指導介入決策:歐洲經皮心血管介入協會的專家共識文件。編譯:三軍總醫院 心臟內科 蔡維哲醫師	Consensus · :動脈血管
Survival After Alcohol Septal Ablation in Patients With Hypertrophic Obstructive Cardion 肥厚型阻塞性心肌病變病患接受經皮穿刺酒精中隔心肌消融術後長期存活預編譯:三軍總醫院 心臟內科 林子喬醫師	後之研究
5-Year Outcomes According to FFR of Left Circumflex Coronary Artery After Le Crossover Stenting 左主冠狀動脈支架置放後之左迴旋冠狀動脈血流儲備分數數值 - 五年追蹤結編譯:國軍新竹地區醫院 心臟內科 曾國翔醫師	果分析
Drug-coated Balloon for Treatment of De-novo Coronary Artery Lesions in Par High Bleeding Risk (DEBUT): a Single-blind, Randomised, Non-inferiority Trial 在高出血風險的病人,藥物塗層氣球是否可以用於治療新發生的冠狀動脈病類單盲、隨機分配及非劣性試驗	±?
編譯:三軍總醫院 心臟內科 周琰璉醫師	
活動集錦	50
<b>雄詩投稿須知</b>	71

#### 敬愛的各位會員,大家好!

介入的領域日新月異,除了時時推陳出新的觀念、還加上突破創新各種新技術的挑戰。兩年來在 TTT 和平日的教育活動中,委員會都卯足全力設計最新的教育內容,相信大家都從精彩的內容中收益匪淺!此外,無遠弗屆的網路,更提供了新的會議型態和交流的平台和機會。未來的會議型態,勢必更快速,散布擴散得更廣!因此我們學習的腳步永不能停歇,這也是學會最核心的任務與責任。



為了永續發展,培養接班梯隊,支持年輕醫師勇往直前,是各醫院的 領頭羊和學會責無旁貸的義務,因為醫學原本就是「手把手」的專業,介入治療更是如此。另一方面, 也期望年輕醫師能夠飲水思源,「吃菓子,拜樹頭」,尊師重道,更要有團隊精神。就如「謝天」一文 所言:無論什麼事,不是需要先人的遺愛與遺產,即是需要眾人的支持與合作,還要等候機會的到來。 越是真正做過一點事,越是感覺自己的貢獻之渺小。於是,創業的人,都會自然而然的想到上天,而敗 家的人卻無時不想到自己。台灣不大,但團結力量大。願大家一起共同努力!

理事長



2019.08

# 會務活動 - 入會申請書

# 臺灣介入性心臟血管醫學會 入會申請書

填表日期: 年 月 日

姓名		性 別	□男 [	□女		
		身分證				貼相片處
英文姓名		號碼				(實貼一張)
				省(市)		
出生日期	年 月 日	出生地				
				縣(市)		
最高學歷			學校			科系(所)
現任醫院			單位/職務			/
户籍地址					O: 電 H:	
12 to 11. 11	□同戶籍地址				M:1.	
通訊地址	□通訊地址				(必 2.	
E-mail(必填)	@				填) Fax:	
	(1) 醫院:		期間:	_ 年	_ 月至	年 月
	醫師主管姓名:		列目	印後主管	簽名:	
最近一年	(2) 醫院:		期間:	_ 年	_ 月至	年 月
介 入 性 工作經歷	醫師主管姓名:		列日	印後主管	簽名:	
工作經歷	(3) 醫院:		期間:	_ 年	_ 月至	年 月
	醫師主管姓名:		列日	印後主管	簽名:	
推薦會員	姓 名:		推薦會員	性	名:	
(1)	列印後簽名:		(2)	刊印後簽>	名:	
審查結果 (此欄由審	□ 同意入會       □ 不同意入會	會 [	<ul><li>」普通會員</li><li>□ 準會員</li></ul>	會員	證	
查人員填		類 [	] 名譽會員	號		
寫)	審查人員:	別 [	] 贊助會員			

本人茲遵照 貴會章程之規定,申請加入 貴會為會員,遵守 貴會一切章程、簡則、決議等,謹此檢具各項證件,敬希 鑒核准予入會。

此致 臺灣介入性心臟血管醫學會

申請人: (簽章)

中華民國 年 月 日

#### 繳驗資料:

- □1. 入會申請表一份(共兩面)
- □2. 本人二吋照片共三張
- □3. 身分證正反面影本一份
- □4. 最高學歷畢業證書影本一份
- □5. 醫師會員一心臟專科醫師證書影本一份(若無,請附醫師證書影本一份) 醫事會員一師級醫事人員資格證書(護理師或放射師或醫檢師)影本一份
- □6. 服務(在職)證明正本一份

#### 注意事項

- 一、準會員申覆為普通會員:
  - 1. 請在入會申請書左上角自行加註「準會員申覆普通會員 | 字樣。
  - 2. 證明從事介入性心臟血管醫學實務工作滿一年,須由現職主管簽章。
- 二、列印入會申請表格,填寫完整後,將紙本資料備齊全,郵寄至學會進行甄審。
- 三、介入性工作經歷
  - 1. 醫師準會員真正從事介入性工作日起算,醫師普通會員指取得心臟專科證書起算。
  - 2. 醫事人員指真正從事介入相關工作日起算。
- 四、醫師申請入會之兩位推薦會員,必須為本會之普通會員。
- 五、介入性工作經歷須由現職之醫師主管在「最近一年介入性工作經歷」欄位親自簽名。

臺灣介入性心臟血管醫學會 秘書處

地址:10041 台北市中正區忠孝西路一段 50 號 16 樓之 18

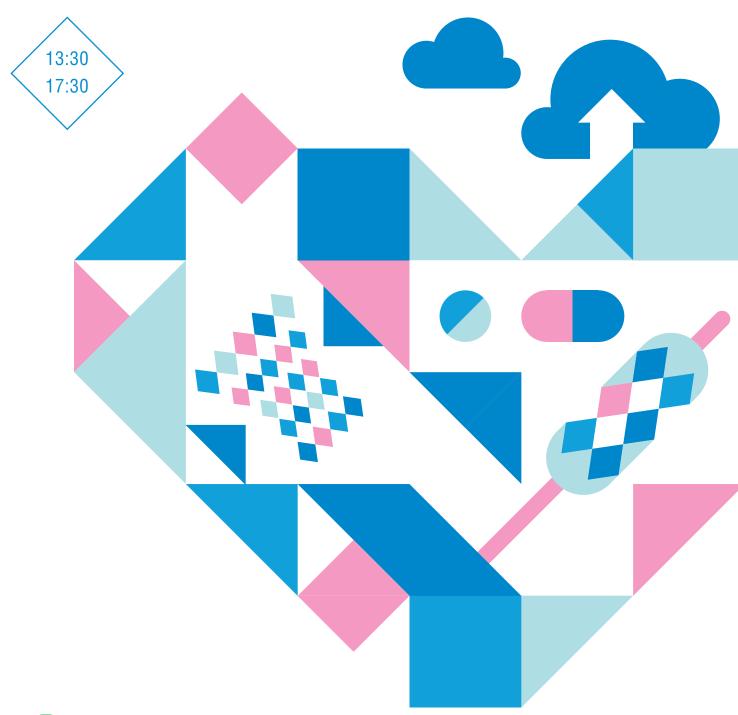
TEL: 02-23813098 FAX: 02-23815198

E-mail: tsci1.med@msa.hinet.net

# Great Debate in Interventional Therapy

2019 Nov. 2

財團法人張榮發基金會802講堂 (台北市中山南路11號)





# **Great Debate in Interventional Therapy**

日期:108年11月2日(週六)13:30-17:30

地點:財團法人張榮發基金會 802 講堂 (台北市中山南路 11 號)

贊助單位: 頡安實業有限公司/美敦力醫療產品股份有限公司/台灣愛德華生命科學股份有限公司

時間	講題	講師	座長				
13:30	OPENING	殷偉賢	理事長				
Debate 1	L: 南北大戰 Multi-vessel PCI in STEMI and Shock						
13:35	Vote						
13:37	I Don't Care What the Data Says, This Maybe the Patient's Only Chance!	何明昀	王怡智				
13:47	Let's Pause and Review the Data Before We Change the Approach to Reperfusion Therapy for STEMI	郭風裕	王光德				
13:57	Rebuttal (3 min each)						
14:03	03 Vote & Discussion						
Debate 2	Debate 2: CTO 大戰 Remnant Non-LAD CTO with High JCTO Score 需要 Revascularization 嗎?						
14:08	Vote						
14:10	Optimal Medical Treatment Will Be First Choice	王駿丞	徐中和				
14:20	Revascularization Whatever Any CTO?						
14:30	Rebuttal (3 min each)						
14:36	Vote & Discussion						
Debate 3	B: 氣球大戰 Significant Small Vessel Disease 的 DEB vs. DES 比較						
14:41	Vote						
14:43	DEB Is a First Choice in Significant Small Vessel Disease!	朱俊源	方慶章				
14:53	DES Is Always Better Than DEB						
15:03	Rebuttal (3 min each)						
15:09	Vote & Discussion						
15:15	Coffee Break						



時間	講題	講師	座長	
Debate 4	:地鐵大戰 IABP in Cardiogenic Shock			
15:45	Vote			
15:47	Management of Cardiogenic Shock: IABP Is Still Gold Standard	陳冠任	邱俊仁	
15:57	Management of Cardiogenic shock: IABP Is an Old Fashion. PCPS Is New 藍偉仁 洪大)			
16:07	Rebuttal (3 min each)			
16:13	Vote & Discussion			
Debates	5: 取栓大戰 Stroke Routine IA or Not			
16:18	Vote			
16:20	Wait! IA therapy Is Only for Bail-out Choice for Thrombolytic Therapy	嚴寶勝	陳威良	
16:30	Door to IA Time! All Stroke Patients Should Receive IA Therapy	謝慕揚	陳盈憲	
16:40	Rebuttal (3 min each)			
16:46	Vote & Discussion			
Debates	6: 內外大戰 Asymptomatic Low Risk AS: TAVR or SAVR?			
16:51	Vote			
16:53	Asymptomatic Low Risk Severe Aortic Stenosis: TAVR Is a Good Option	柯呈諭	李政翰	
17:03	Asymptomatic Low Risk Severe Aortic Stenosis: SAVR Is a Gold Standard	李永在	曹殿萍	
17:13	Rebuttal (3 min each)			
17:19	Vote & Discussion			
17:25	TAKE HOME MESSAGE	王光德	副主委	

# 第七屆第五次教育訓練委員會

#### 臺灣介入性心臟血管醫學會 第七屆五次教育訓練委員會會議記錄

一、時 間:108年8月26日(星期一)18:30

二、地 點:視訊會議

三、出席人員:主 委:謝宜璋

副主委:王光德

委 員:王怡智、曹殿萍、鄭書孟、李文領、朱俊源、黃偉春、邱俊仁、

蔡政廷

四、請假人員:委員:方慶章、羅秉漢、吳卓鍇

五、列席人員:殷偉賢理事長

秘書處:盧澤民秘書長,秘書:林佳慧、賴瑋儀、陳詠潔(記錄)

六、報告事項:

七、議 程:

提案一:『Special Skills in Rare Cases』節目策劃相關內容。

說明:1. 策劃人: 蔡政廷委員

2. 時 間:108年9月7日(六)

3. 地 點:台大醫學院

4. 相關建議 topic:

- Coronary aneurysm 的治療策略
- Coronary AV fistula
- Alcohol septal ablation
- The extravasation of periphery artery during coronary interventions
- Unexpanded stent
- Paravalvular leakage
- Tx of Pericardial effusion
- Home made cover stent
- Tx of pseudo aneurysm
- How to implant stent in Ostia lesion precisely?
- Cath-related stroke
- Celiac artery or other unusual artery stenting
- The use of filter wire in STEMI
- Tx of pulmonary stenosis
- 5. 節目表 (參閱 P.3)

決議: 節目表無異議,依節目規劃執行。

## 第七屆第五次教育訓練委員會

提案二:『Great Debate in Interventional Guideline』節目策劃相關內容。

說明: 1. 策劃人: 黃偉春委員

2. 時 間:108年11月2日(六)

3. 地 點:張榮發基金會

4. 避開以下 TTT Debate 主題:

Multivessel Disease with Intermediate SYNTAX Score

Management of Patients with Severe Functional Mitral Regurgitation

**TAVI** 

相關建議 topic 有:

- CAD:
- ①治療 ISR 的 DEB 及 DES 比較
- ②治療 Small Vessel 的 DEB 及 DES 比較
- ③ Multiple CTO's with High JCTO Score 需要 Complete Revascularization 嗎?
- ④如何處理 Multiple CTO with Prior CABG
- AMI:
- ①需要 Thrombus Aspiration 嗎?
- ②需要 IABP 嗎?
- ③ STEMI Cardiogenic Shock 在 index procedure 只做 Culprit Lesions 嗎?
- VALVE:
- ① Asymptomatic Low Risk Severe Aortic Stenosis 做 TAVR or SAVR?
- ② Management of Surgical Aortic Valve Degenerative Bio Prosthesis in an Intermediate

Risk Patient at High Risk for Coronary Occlusion

- 1 Prevention of Leaflet Thrombosis after TAVR
- ② Cerebral Protection during TAVR
- 5. 新增:Acute Stroke 治療相關 topic
- 6. 節目表 (參閱 P.4-5)

決議:1.節目時間調整,lecture 每段增至10min,詳如P.4-5節目表。

2. Vote 事先進行網路調查,請秘書處佳慧設計 Google 問卷。若實際執行情形 未如預期,則改由座長進行現場調查。

八、臨時動議

九、散會

# **GreatDebate in Interventional Therapy**

日期:108年11月2日(週六)13:30-17:30

地點:財團法人張榮發基金會 802 講堂 (台北市中山南路 11 號)

贊助單位: 頡安實業有限公司/美敦力醫療產品股份有限公司/台灣愛德華生命科學股份有限公司

講題	講師	座長			
OPENING	殷偉賢	理事長			
: 南北大戰 Multi-vessel PCI in STEMI and Shock					
VOTE					
I Don't Care What the Data Says, This Maybe the Patient's Only Chance!	何明昀	王怡智			
Let's Pause and Review the Data Before We Change the Approach to Reperfusion Therapy for STEMI	郭風裕	王光德			
Rebuttal (3 min each)					
Vote & Discussion					
2: CTO 大戰 Remnant Non-LAD CTO with High JCTO Score 需要 Revascu	llarization 嗎?				
VOTE					
Optimal Medical Treatment Will be First Choice	王駿丞	徐中和			
Revascularization Whatever Any CTO?	宋思賢	盧澤民			
Rebuttal (3 min each)					
Vote & Discussion					
: 氣球大戰 Significant Small Vessel Disease 的 DEB vs. DES 比較					
VOTE					
DEB is a First Choice in Significant Small Vessel Disease!	朱俊源	方慶章			
DES is Always Better than DEB	林俊呈	鄭書孟			
Rebuttal (3 min each)					
Vote & Discussion					
Coffee Break					
	DPENING  DPENING  DEBLISH Multi-vessel PCI in STEMI and Shock  VOTE  I Don't Care What the Data Says, This Maybe the Patient's Only Chance! Let's Pause and Review the Data Before We Change the Approach to Reperfusion Therapy for STEMI Rebuttal (3 min each)  Vote & Discussion  CTO 大戦 Remnant Non-LAD CTO with High JCTO Score 需要 RevascuvoTE  Optimal Medical Treatment Will be First Choice Revascularization Whatever Any CTO? Rebuttal (3 min each)  Vote & Discussion  CREVAN Significant Small Vessel Disease 的 DEB vs. DES 比較  VOTE  DEB is a First Choice in Significant Small Vessel Disease!  DES is Always Better than DEB  Rebuttal (3 min each)  Vote & Discussion	DPENING  DP			



n-t- 88	****	<b>***</b> * <b>T</b>	÷=
時間	講題	講師	座長
Debate 4	I:地鐵大戰 IABP in Cardiogenic Shock		
15:45	VOTE		
15:47	Management of Cardiogenic Shock: IABP is Still Gold Standard	陳冠任	邱俊仁
15:57	Management of Cardiogenic shock: IABP Is an Old Fashion. PCPS is New Gold Standard	藍偉仁	洪大川
16:07	Rebuttal (3 min each)		
16:13	Vote & Discussion		
Debates	5: 取栓大戰 Stroke Routine IA or Not		
16:18	VOTE		
16:20	Wait! IA Therapy is Only for Bail-out Choice for Thrombolytic Therapy	嚴寶勝	陳威良
16:30	Door to IA Time! All Stroke Patients Should Receive IA Therapy	謝慕揚	陳盈憲
16:40	Rebuttal (3 min each)		
16:46	Vote & Discussion		
Debates	6: 內外大戰 Asymptomatic Low Risk AS: TAVR or SAVR?		
16:51	VOTE		
16:53	Asymptomatic Low Risk Severe Aortic Stenosis: TAVR is a Good Option	柯呈諭	李政翰
17:03	Asymptomatic Low Risk Severe Aortic Stenosis: SAVR is a Gold Standard	李永在	曹殿萍
17:13	Rebuttal (3 min each)		
17:19	Vote & Discussion		
17:25	TAKE HOME MESSAGE	王光德	副主委

## 第七屆第四次週邊伽管介入委員會

# 臺灣介入性心臟血管醫學會第七屆第四次週邊血管介入委員會會議記錄

一、時 間:108年8月30日(星期五)18:30

二、地 點:視訊會議

三、出席人員:主 委:陳俊吉

副主委:徐中和

委 員:黃玄禮、謝慕揚、張偉俊、許栢超、薛書凱

四、請假人員:委員:黃柏勳、李政翰、李任光、吳敘平、曾維功、陳怡芝

五、列席人員:殷偉賢理事長

秘書:林佳慧、賴瑋儀(請假)、陳詠潔(記錄)

六、報告事項:

七、議 程:

提案一:討論策劃『TTT』節目相關內容。

說明:1.時間:109年1月5日(日)下午3:00-4:30。

2. 地點:台大醫院國際會議中心

決議: 節目表由陳主委擬定並確認人選後放置 Line 群組 (詳如 P.2)。

八、臨時動議

九、散會

# **Critical Issues for Peripheral Intervention in 2020**

Sunday (W7), January 5, 2020

15:00PM - 16:30PM

**Room 301** 

Time	Speaker	Торіс	Moderator			
15:00	15:00 Opening 陳俊吉 主委					
15:05	李任光	The Safety & Efficacy of Drug-Eluting Device	黄玄禮			
15:25	子仕九	Q & A	<b>男</b> 幺 位			
15:30	許柏超	Medication for arterial & venous intervention update	前份计			
15:50	<b>计</b> 相程	Q & A	曾維功			
15:55	吳典育	DVT Intervention Update 2020	徐中和			
16:20	<del>大兴</del> 月	Q & A	徐十和			
16:25	16:25 Closing Remark 徐中和 副主委					

## 第七屆第四次編輯暨登錄委員會

#### 臺灣介入性心臟血管醫學會 第七屆第四次編輯暨登錄委員會會議記錄

一、時 間:108年8月26日(星期一)PM7:00

二、地 點:視訊會議

三、出席人員:主 委:林宗憲

副主委: 黃偉春

委 員:張其任、徐國基、黃慶昌、陳郁志、王宇澄

四、請假人員:劉俊廷、呂信邦、林肇鋒、詹世鴻、辛和宗、鍾政達

五、列席人員:殷偉賢理事長

秘書處:盧澤民秘書長,秘書:林佳慧、陳詠潔、賴瑋儀

六、報告事項:

七、議 程:

提案一:學會各項登錄計畫、網路登錄系統之進度。

說明:1.CHIP計畫進度說明

2.ROTA 計畫進度說明

3. 登錄費用每件 2000 元整

決議: 1. CHIP 計畫請黃建龍醫師 9/5 前提供 IRB 學會版, 9 月底前完成網頁登錄系統, 預計 10/1 啟用。請黃建龍醫師與張其任醫師再討論 CRF 必填欄位。

2. ROTA 登錄網頁小幅修改後請秘書長協助確認,等網頁內容確認完成後再提供 IRB 申請學會版。

提案二:第七屆雜誌稿件第九期邀稿對象及交稿時間。

說明:1. 第八期雜誌4月出版

2. 第九期雜誌 ---- 進度說明

決議: 1. 第九期雜誌目前已收 9 篇,預訂於 2020 TTT 出刊。

# 第七屆第四次編輯暨登錄委員會

提案三:學會網站進度。

說明: 官網完成

決議:1.雜誌開放非會員可閱讀

2. 學會雜誌與相關連結互換位置 3. 雜誌文章可以被搜尋引擎找到

提案四:討論本年度預訂召開會議次數、下次召開會議日期及委員們方便出席會議之週

間時間。

說明:參閱會議當天委員方便出席會議週間時間之調查彙整。

決議:預計11/25晚上6:30 開會

八、臨時動議

說明:下次會議再詳細討論。

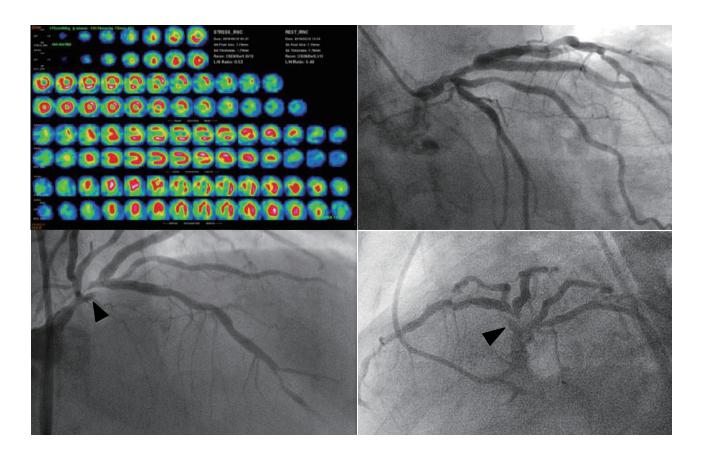
提案:可搜尋學會醫師會員

九、散會

#### 本期案例

#### 【案例】

69 歲吸菸男性,罹患高血壓、糖尿病、高血脂約十年,有運動呼吸困難及典型狹心症約三個月,心臟超音波檢查無明顯異常,鉈-201 心肌灌流掃描影像顯示左心室前壁及下壁可逆性灌流缺損。第一次心導管冠狀動脈攝影如下圖。



#### 【試問】

- 1. 左前降支開口狹窄,箭頭所指,類似殘端處,為何病灶?
- 2. 何血管內影像檢查工具可用來評估此種病灶?
- 3. 若病患拒絕開刀,對左前降支開口病變建議如何處置?

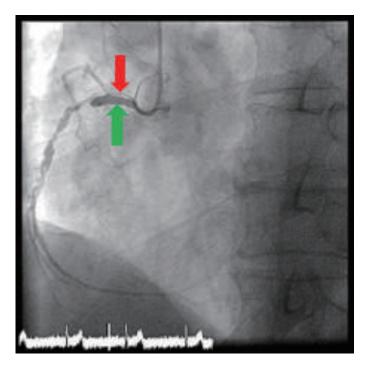
三軍總醫院心臟內科 劉俊廷 醫師

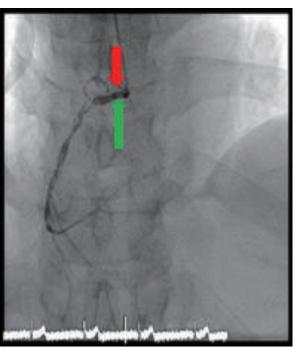
# 「介入影像」專欄

### 上期解答

#### 【案例】

56-years old man, a smoker, had hepatitis B. He received percutaneous coronary intervention in another hospital one month ago. Revascularization of left circumflex artery was performed at that time. Right coronary artery was also attempted. However, ostial dissection happened due to deep seating of guiding catheter (AL). Procedure was stopped and he was referred to tertiary medical center thereafter. Angiography in tertiary center was showed below. What is true lumen of right coronary artery? Which guiding catheter may be considered for PCI?

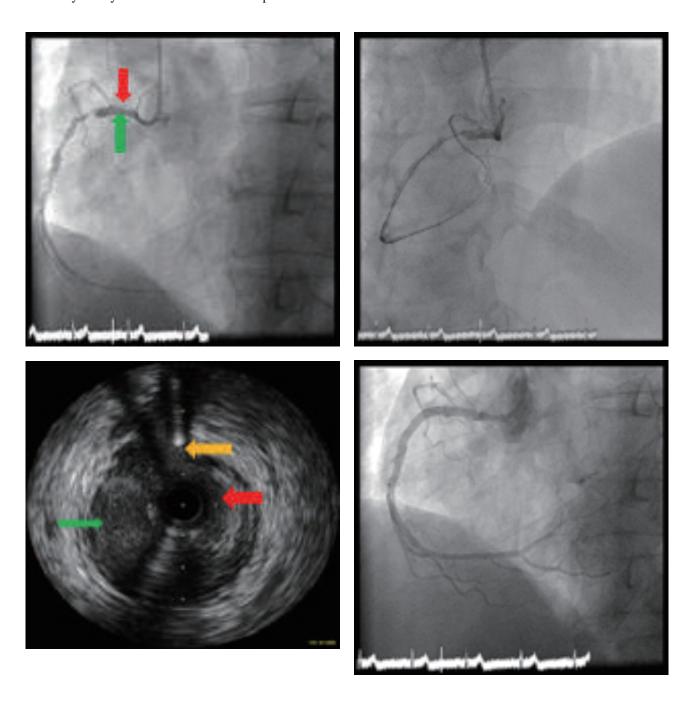




台北榮民總醫院 心臟內科 蔡泉財 醫師

#### 【答案】

Judkins right guiding catheter (GC) was selected first. There was poor backup. Short Amplatz Left 0.75/6 Fr GC engaged right coronary artery instead. True lumen was found to be smaller caliber (red arrow) and false lumen was larger caliber (green arrow). This was confirmed by intravascular ultrasound that showed side branch (yellow arrow), true lumen (red arrow), false lumen (green arrow). Final result of right coronary artery was shown below with preservation of side branches.



Clinical Use of Intracoronary Imaging. Part 2: Acute Coronary Syndromes, Ambiguous Coronary Angiography Findings, and Guiding Interventional Decision-making: an Expert Consensus Document of the European Association of Percutaneous Cardiovascular Interventions.

Thomas W. Johnson, et al. European Heart Journal 2019 Aug 14;40(31):2566-2584.

#### **ABSTRACT**

This consensus document is the second of two reports summarizing the views of an expert panel organized by the European Association of Percutaneous Cardiovascular Interventions (EAPCI) on the clinical use of intracoronary imaging including intravascular ultrasound (IVUS), optical coherence tomography (OCT), and near infrared spectroscopy (NIRS)-IVUS. Beyond guidance of stent selection and optimization of deployment, invasive imaging facilitates angiographic interpretation and may guide treatment in acute coronary syndrome. Intravascular imaging can provide additional important diagnostic information when confronted with angiographically ambiguous lesions and allows assessment of plaque morphology enabling identification of vulnerability characteristics. This second document focuses on useful imaging features to identify culprit and vulnerable coronary plaque, which offers the interventional cardiologist guidance on when to adopt an intracoronary imaging-guided approach to the treatment of coronary artery disease and provides an appraisal of intravascular imaging-derived metrics to define the haemodynamic significance of coronary lesions.

Indications and clinical value of intravascular imaging in acute coronary syndromes

- Thrombus detection facilitates identification of an ACS culprit lesion.
- OCT is the current gold standard for thrombus detection.
- Intravascular imaging facilitates delineation of underlying plaque etiology in ACS and may guide tailoring of therapy.
- When a culprit lesion, attributable to a NSTEACS presentation, is not evident angiographically, an intravascular imaging-based assessment to guide appropriate management should be considered.
- Invasive imaging evaluation in suspected SCAD should be reserved for cases where angiographic assessment is unclear (usually Types 3 and 4 or if clinical/hemodynamic instability).
- Consider intravascular imaging where there is no evidence of significant CAD, in order to characterize MINOCA.

Role of imaging in vulnerable plaque detection and risk stratification

- IVUS-defined plaque burden >60–70% is predictive of subsequent MACE.
- Lipid-rich plaque (LCBI4mm> 400) is a predictor of plaque vulnerability and associated with a higher incidence of MACE.
- OCT and IVUS derived plaque characteristics enable identification of high-risk patients.
- Invasive plaque characterization provides superior positive predictive value of future events than CTCA.
- Identification of presumable high-risk plaque characteristics using IVUS, OCT, or NIRS-IVUS can be considered to identify high-risk patients who would benefit from an increased intensity of risk factor modification and emerging therapies targeting atherosclerosis. Prospective validation of this strategy requires confirmation.

冠狀動脈血管內成像之臨床使用。第2部分:急性冠心症,不明確的冠狀動脈血管造影結果,和指導介入決策:歐洲經皮心血管介入協會的專家共識文件。

編譯:三軍總醫院 心臟內科 蔡維哲醫師

該共識文件是兩份報告中的第二份,總結了由歐洲經皮心血管介入協會(EAPCI)組織的專家小組的觀點,此小組著重於討論冠狀動脈內成像的臨床應用,包括血管內超聲(IVUS),光學同調斷層掃描(OCT)和 近紅外光譜(NIRS)-IVUS。本共識提供了血管內影像 (intravascular imaging) 運用於急性冠心症 (acute coronary syndromes),不明確的冠狀動脈血管造影結果 (ambiguous coronary angiographic findings) 以及介入策略的臨床運用建議。

#### 以下是此篇文章的重點內容:

- ●血栓的偵測 (thrombus detection) 可以加速分辨急性冠心症的禍首病灶 (culprit lesion), 而 OCT 是目前偵測 血栓的黃金標準 (gold standard)
  - 當血管攝影並無法提供禍首病灶 (culprit lesion) 的證據,尤其是無明顯狹窄的冠狀動脈疾病時,這類目前被稱之為「MINOCA (MI No Obstructive Coronary Atherosclerosis—new term)」,應該根據血管內影像的輔助來制定適切的治療。
- OCT 所偵測的斑塊型態 (plaque characteristics),可以分辨出高風險的病患族群 從 OCT 下所分辨出的高風險斑塊 (high risk plaque),被認為可以分別出高風險且能受惠於高強度風險治療 (increased intensity of risk factor modification) 的病人。
- ●依據功能性壓力評估 (Pressure-derived haemodynamic assessment) 的結果,可以做為在非左主冠狀動脈病灶 (non-LMCA) 且為穩定性冠心症中,是否不需血路重建 (deferring revascularisation) 的黃金標準。

#### 前言

血管內影像來改善冠狀動脈介入的結果,已在 part 1 的文章中闡述,特別是病人的選擇以及支架最佳化的條件。此次的共識最近被歐洲指引所強化,並將 OCT 運用於支架選擇最佳化 (optimization) 的建議列為Class IIa。此外,IVUS 指引 (IVUS-guided) 與血管攝影指引 (angio-guided) 介入治療比較的研究中,都確認了IVUS 指引的介入治療可以降低 12 個月的 target vessel failure; 並且在最新的分析研究中也指出改善死亡率的優勢。對於血管內影像的使用,則從介入治療時延伸為介入治療前的冠狀血紋評估 (pre-PCI assessment of the coronary vasculature)。Part 2 的文章將著重在血管內影像在急性冠心症病人的使用,以及血管內影像用來分辨動脈硬化斑塊 (composition of atherosclerotic plaque) 的組成,特別是偵測禍首病灶 (culprit lesions) 以及斑塊脆弱性的標誌 (markers of vulnerability)。除此之外,本篇文章還強調血管內影像的角色,特別是在血管攝影中界定不明顯或非阻塞性的病灶,以及評估功能性狹窄 (stenosis haemodynamic significance) 的潛力。冠狀動脈影像的這些擴展益處將為介入醫師及其患者提供相當大的價值;然而,這些領域缺乏大規模及完整的數據,這也強化了此共識的重要性,並對臨床醫生提供關於血管內影像應用的指引。以下我們將針對本篇文章內容作重點摘要:

#### 急性冠心症

影響冠狀動脈介入治療最大的是治療急性冠心症。這些病人和慢性冠心症的病人比較起來,有著最高的心血管事件風險 (major adverse cardiovascular events (MACE)。冠狀動脈血管攝影先天上的盲點就在於準確的評估血管及管腔的幾何形狀 (geometry),而且對於斑塊的組成 (plaque components) 以及精準的偵測血栓 (presence of thrombus) 是無法執行的 - 更多的資訊需要血管內影像來提供。當在急性冠心症的診斷或存在血管攝影的結果有著不確定性,我們建議運用血管內影像來幫助診斷以及治療。(Figure 1)

#### 血管內影像運用於危險分級的角色

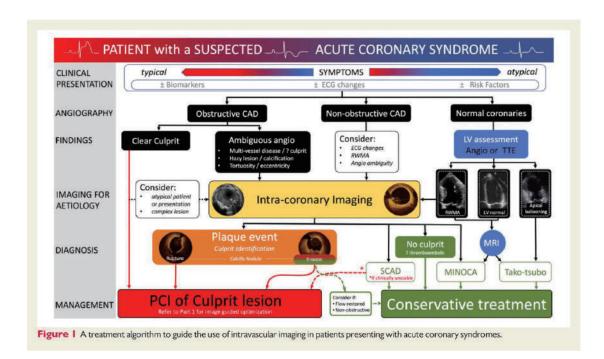
四個前瞻性的研究顯示,血管內影像有助於尋找出高風險的族群。在 ATHEROREMOIVUS 中所納入的 591 病人,比較血管攝影以及 VH-IVUS 影像,若病人血管病灶有 TCFA 型態 (thin-cap fibroatheroma, TCFA phenotype) 且高斑塊比例 (increased plaque burden >70%)) 者,在一年的追蹤中有著較高的 MACE。然而,在這項研究中,事件發生率很低,因此無法證實 VH-IVUS 是否可以提供比現有已知的危險因子更多的癒後的資訊。除此之外,LRP 研究和 ATHEROREMO-NIRS 次分析中顯示斑塊成分,特別是 LCBI(lipid core burden index) 升高與預後不良有關。最後,在 CLIMA study 中所收入的 1003 病人,針對冠狀動脈血管攝影以及 OCT影像,在非病灶性近端左前降支作研究分析,有 TCFA 型態 (thin-cap fibroatheroma, TCFA phenotype),lipid arc 大於 180 度,最小管腔面積 (minimum lumen area) 小於 3.5mm²,巨噬細胞聚集 (macrophages accumulation)的病人,相較於沒有這些高風險特徵的病人在 cardiac death 以及 target vessel MI 有 7.5 倍差異 (18.9% vs. 3.0%)。雖然高風險斑塊的非侵入性評估,對於減少心導管風險有著明顯的優勢,同時也有絕佳的陰性預測值 (negative predictive value),然而冠狀動脈電腦斷層 (computed tomography (CT) coronary angiography) 的陽性預測率 (positive predictive value) 不佳,因而侷限了預測急性冠心症事件的角色。(Figure 2)

#### 最小管腔面積是左主冠狀動脈病灶缺血的預測因子

#### 結論:

自從 Part 1 的專家共識發表後,ESC 指引委員會根據 OCT,血管攝影以及 IVUS 指引 (IVUS-guided) 介入治療的比較研究結果,利用 OCT 對於支架的最佳化 (stent optimization) 的選擇,建議從 Class IIb 提升至 Class IIa。

此外,全面性地 IVUS 與血管攝影指引介入治療的比較,顯示出利用影像指引 (imaging-guided) 的方式有著臨床上的優勢。隨著病人共病 (co-morbidity) 以及冠心症的複雜度增加,且使用經皮介入治療,血管內影像對於介入治療的最佳化有著指引的角色,對於長期預後的改善也會持續增加。Part 2 則指出血管內影像的其他適應症,像是克服某些血管攝影的盲點。迄今為止,專門的臨床試驗缺乏支持這些潛在用途的證據,但影像專家們認為血管內影像,將有助於針對高冠心症事件復發 (recurrent events) 的族群及支架再阻塞 (stent failure) 的高風險患者,指引介入治療的方法。隨著技術的不斷進步,更高的分辨率,更快的圖像採集時間,組合 OCT/IVUS 導管,以及更複雜的核心註冊圖像分析 (sophisticated coregistered image analysis),將讓血管內影像有更廣泛的使用。



Study	Modality	Variables	Endpoint	Follow-up	PPV	NPV
PROSPECT (n=697)	IVUS & VH-IVUS	PB≥70% &MLA<4mm² &VH-IVUS TCFA	MACE (CD, cardiac arrest, MI, rehospitalization due to AP)	3 years	17%	98%
ATHEROREMO IVUS (n=581)	IVUS & VH-IVUS	PB≥70% & MLA<4mm² & VH-IVUS TCFA	MACE (Non-CL related or Indeterminate death, ACS, unplanned revascularization)	1 year	23%	93%
PREDICTION (n=506)	IVUS & ESS	PB≥58% & Low ESS<1.0Pa	PCI	1 year	41%	92%
ATHROREMO NIRS (n=203)	NIRS	maxLCBI <sub>4mm</sub> >43	MACE (All-cause death, ACS, stroke, unplanned revascularisation, exclusive of event related to culprit lesion)	1 year	17%	96%
CLIMA (n=1003)	ост	MLA<3.5mm <sup>2</sup> & TCFA & Lipid arc >180° & Macrophage	MACE (CD and TV-MI)	1 year	19%	97%
PROMISE (n=4415)	СТА	High-risk plaque	MACE (All-cause death, MI, UAP)	2 years	6%	98%
PROMISE (n=4209)	CACS	CACS>300	MACE (All-cause death, MI, UAP)	2 years	6%	98%

Figure 5 A comparison of the positive and negative predictive values of intravascular and non-invasive imaging modalities. Summary of the positive and negative predictive values of coronary imaging-derived variables for prediction of clinical outcomes in the PROSPECT, ATHEROREMO-IVUS, PREDICTION, ATHEROREMO-NIRS, CLIMA, and PROMISE studies. AP, angina pectoris; CACS, CT angiography calcium score; CD, cardiac death; CTA, computed tomography angiography; ESS, endothelial shear stress; LCBI, lipid-core burden index; MACE, major adverse cardiac events; MI, myocardial infarction; MLA, minimal lumen area; PB, plaque burden; PCI, percutaneous coronary interventions; TCFA, thin-cap fibroatheroma; TV-MI, target vessel-MI. Adapted from Koskinas et al.<sup>71</sup>

# Survival After Alcohol Septal Ablation in Patients With Hypertrophic Obstructive Cardiomyopathy

Batzner et al. JACC Volume 72, Issue 24, 18 December 2018, Pages 3087-3094

#### **OBJECTIVES**

This study sought to report on long-term survival after echo-guided alcohol septal ablation (percutaneous transluminal septal myocardial ablation [PTSMA]) in symptomatic patients with HOCM.

#### **METHODS**

Between May 2000 and June 2017, PTSMA with alcohol injection was performed in 952 patients (age 55.7  $\pm$  14.9 years; 59.2% men; 73.3% New York Heart Association functional class III or IV; 50.3% syncope; 10.3% sudden cardiac death in family). Clinical follow-up after 6.0  $\pm$  5.0 years was achieved in all patients.

#### **RESULTS**

We injected  $2.1 \pm 0.4$  cc of alcohol. Maximal creatine kinase rise was  $872 \pm 489$  U/l. Two (0.21%) patients died 3 and 33 days after ablation. Permanent pacemaker was implanted in  $100 \ (10.50\%)$  patients. Echo gradients were acutely reduced from  $63.9 \pm 38.2$  mm Hg to  $33.6 \pm 29.8$  mm Hg at rest and from  $104.6 \pm 44.0$  mm Hg to  $56.5 \pm 41.0$  mm Hg at Valsalva (p<0.0001, each). During follow-up,  $164 \ (17.2\%)$  patients underwent reablation due to the planned staged procedure,  $18 \ (1.9\%)$  patients underwent surgical myectomy, and 49(5.10%) patients underwent cardioverter-defibrillator implantation. Seventy patients died: causes of death were identified as noncardiovascular in 50, stroke related in 6, and cardiac in 14 patients. Estimated 5-year survival was 95.8%, estimated 5-year survival free of cardiovascular events was 98.6%, and an estimated 5-year survival free of cardiac events was 98.9%. Corresponding values at 10 years were 88.3%, 96.5%, and 97.0%, and at 15 years were 79.7%, 92.3%, and 96.5%.

#### CONCLUSIONS

In this study, PTSMA could be proofed as a safe procedure with ongoing symptomatic improvement and excellent long-term survival. Therefore, PTSMA is a reasonable alternative to surgical myectomy in HOCM.

# 肥厚型阻塞性心肌病變病患接受經皮穿刺酒精中隔心肌 消融術後長期存活預後之研究

編譯:三軍總醫院 心臟內科 林子喬醫師

#### 緣由

肥厚型阻塞性心肌病變 (Hypertrophic Obstructive Cardiomyopathy, HOCM) 屬於肥厚型心肌病變 (HCM) 的一種;左心室中隔增生的肌肉,肥厚病變至一個程度會阻塞左心室出口,稱為肥厚型阻塞性心肌病變。

「超音波導引酒精中隔消融術」 (echo-guided alcohol septal ablation) ,也統稱「經皮穿刺腔內間隔心肌消融術」 (Percutaneous Trasluminal Septal Myocardial ablation; PTSMA),是其中一種介入治療方式,於 1995 年由 Sigwart 發表第一例迄今,已經超過 20 年。

根據先前研究指出,經皮穿刺酒精間膈心肌消融術可用來治療有症狀之肥厚型阻塞性心肌病變,但與傳統心室中隔心肌切除術(septal myectomy)比較,此治療方式後續追蹤發現可能有較高的死亡率。本研究想藉由長時間追蹤,來證實此治療方式之長期預後及安全性。

#### 方法

2000 年 5 月至 2017 年 6 月期間,共 952 人次接受酒精注射 PTSMA。其中病患平均年齡 55.7 ± 14.9 歲;59.2% 為男性;73.3% 為紐約心臟協會心衰竭第 3 或 4 級;50.3% 有暈厥症狀;10.3% 有家族猝死病史。所有病患術後追蹤  $6.0 \pm 5.0$  年。

#### 結果

平均每位病患接受  $2.1\pm0.4$  cc 酒精注射。其中 2 位病患 ( 6.21%) 分別在接受此治療後 3 天及 6.21% 天及 6.21% 分別在接受此治療後 6.21% 分別在接受此治療後 6.21% 分別在接受此治療後 6.21% 大人性心臟節律器置放。經心臟超音波證實,於休息時可使壓力差由 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219 6.219

追蹤過程中共 164 位病患 (佔 17.2%) 接受再次間隔心肌消融術。(皆為已計劃好分階段執行之手術)。 有 18 位病患 (佔 1.9%) 接受心室中隔心肌切除術 (septal myectomy)。有 49 位病患 (佔 5.10%) 接受植入式心臟整流去顫器植入術。

70 位病患最後死亡,其中 50 位死於非心血管相關成因,6 位死因為中風相關,14 位病患死因為心因性相關。估算平均 5 年總存活率為 95.8%, 平均 5 年無心血管事件存活率為 98.6%,平均 5 年無心臟事件存活率為 98.9%。而 10 年相關存活率為 88.3%,96.5% 及 97.0%,15 年相關存活率為 79.7%,92.3% 及 96.5%。

#### 結論

由此研究可證實經皮穿刺腔內間隔心肌消融術 (Percutaneous Trasluminal Septal Myocardial ablation; PTSMA) 為一安全且有效的處置方法,不只緩解病患症狀,且長期預後相當優異。

故在肥厚型阻塞性心肌病變治療上,除了心室中隔心肌切除術 (septal myectomy ) 外,PTSMA 是一個合理的替代方式。

#### 補充

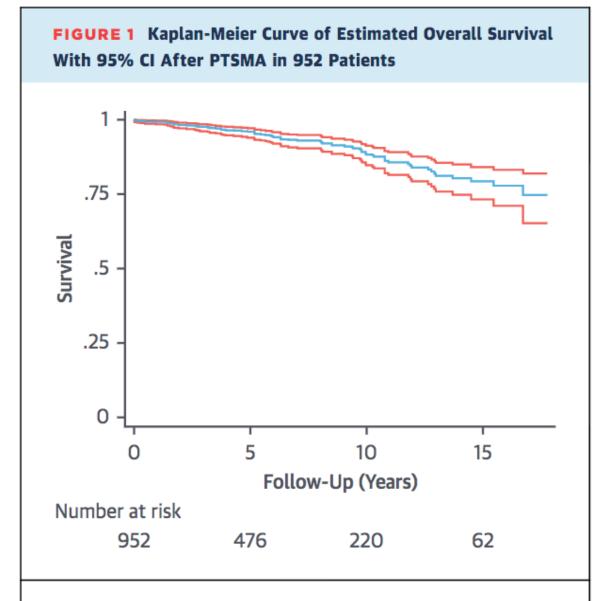
根據過去系統回顧及統合分析研究 (A Systematic Review and Meta-Analysis of Long-Term Outcomes After Septal Reduction Therapy in Patients With Hypertrophic Cardiomyopathy. JACC Heart Fail. 2015 Nov;3(11):896-905.),比較 16 個心室中隔心肌切除術 ( septal myectomy ) 研究族群 (n = 2,791; mean follow-up, 7.4 years),及 11 個酒精中隔消融術 (alcohol septal ablation[ASA]) 研究族群 (n = 2,013; mean follow-up, 6.2 years),長期死亡率 (long-term mortality) 和心臟性猝死率 (sudden cardiac death [SCD]) 同樣很低。與接受心肌切除術的患者相比,接受 ASA 治療的患者植入永久性心臟節律器的風險增加一倍以上,並且需要額外的中隔減容治療 (septal reduction therapy) 的風險增加 5 倍。此篇文章探討了症狀性肥厚型阻塞性心肌病變病患,接受酒精中隔消融術 (ASA) 治療後,更長期的存活追蹤,結果發現其效果良好之外,10 到 15 年的長期預後也相當優異。未來針對此類病患的治療,經皮穿刺腔內間隔心肌消融術,無疑是一個很好的治療選項。

TABLE 1 Baseline Characteristics of 99 During Alcohol Septal Ablation (PTSMA	
Age, yrs	$55.7 \pm 14.9$
Male	564 (59.2)
Height, cm	$170.3 \pm 13.8$
Body weight, kg	$82.8 \pm 17.1$
Dyspnea	
NYHA functional class III/IV	698 (73.3)
Angina pectoris	
CCS class II	354 (34.9)
CCS class III	166 (16.4)
Syncope	
Unexplained	93 (9.6)
Exercise-induced	388 (40.7)
Presyncope	341 (35.8)
Palpitations	293 (30.8)
Medication	
Beta-blocker	662 (69.5)
Verapamil	246 (25.8)
Disopyramide	13 (1.4)
Prior septal reduction	
PTSMA	44 (4.6)
Myectomy	20 (2.1)
Family history	
HCM positive	227 (23.8)
SCD positive	98 (10.3)
Prior pacemaker	52 (5.6)
Prior ICD	90 (9.7)
Cardiovascular diseases	
Hypertension	516 (54.3)
Coronary artery disease	123 (12.9)
Atrial fibrillation	133 (14.0)
Paroxysmal	113 (11.9)
Permanent	20 (2.1)

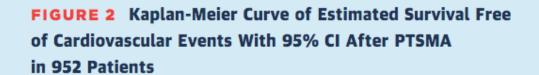
TABLE 2 Hospital Course and Follow-Up Events of 952	Patients With PTSMA
Invasive gradient baseline, mm Hg	
Rest	$51.3 \pm 38.1$
Valsalva	$94.9 \pm 38.6$
Post-extrasystolic beat	134.8 ± 48.8
PTSMA	
Branches tested by contrast echo	$1.2 \pm 0.5$
>1 branch tested	154 (16.2)
Branches treated with alcohol injection	$1.01 \pm 0.12$
>1 branch treated*	11 (1.2)
Alcohol injected, cc	2.1 ± 0.4
Maximal CK rise, U/l	872 ± 489
ECG including Holter	
Sinus rhythm	804 (87.0)
Atrial fibrillation	40 (4.3)
Right bundle branch block	436 (46.1)
Left bundle branch block	137 (14.5)
Nonsustained ventricular tachycardia	77 (8.3)
Paroxysmal supraventricular tachycardia	107 (11.6)
Complications	
Cath lab	
Temporary AV block III	377 (39.6)
Nonsustained ventricular tachycardia	8 (0.9)
Left main dissection	1 (0.1)
Hospital course	
Permanent pacemaker implantation	100 (10.5)
Pericardial effusion	24 (2.5)
Tamponade requiring pericardiocentesis	5 (0.5)
Death	2 (0.2)
Echo Doppler gradients at discharge, mm Hg	
Rest	$33.6\pm29.8\dagger$
Valsalva	56.5 ± 41.0†
Events during follow-up	
Myectomy	18 (1.9)
Re-PTSMA,	164 (18.1)
Permanent pacemaker	25 (2.6)
ICD	49 (5.1)
Permanent atrial fibrillation	50 (5.2)
Stroke	14 (1.5)
Death	70 (7.4)
Causes of death during follow-up	
Cardiovascular	20 (2.1)
Stroke	6 (0.6)
Cardiac	14 (1.5)
Sudden	4 (0.4)
Heart failure	8 (0.9)
Acute myocardial infarction	2 (0.2)
Other	50 (5.3)

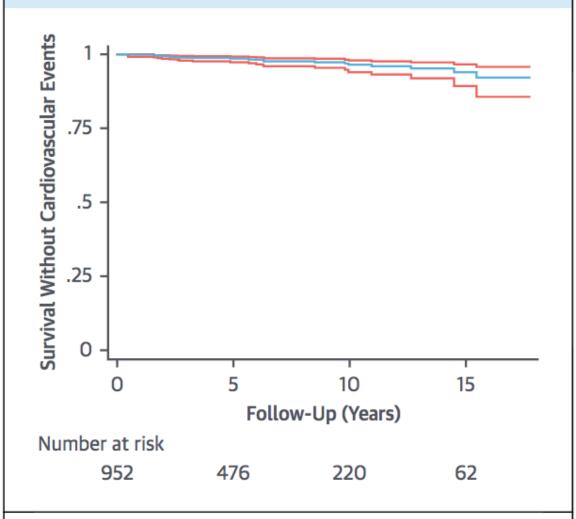
Values are mean  $\pm$  SD or n (%). \*Patients with subaortic and midventricular obstruction.  $tp < 0.0001 \ versus \ baseline \ measurements.$ 

 $<sup>\</sup>label{eq:AV} AV = atrioventricular; \ CK = creatine \ kinase; \ other \ abbreviations \ as \ in \ \textbf{Table 1}.$ 

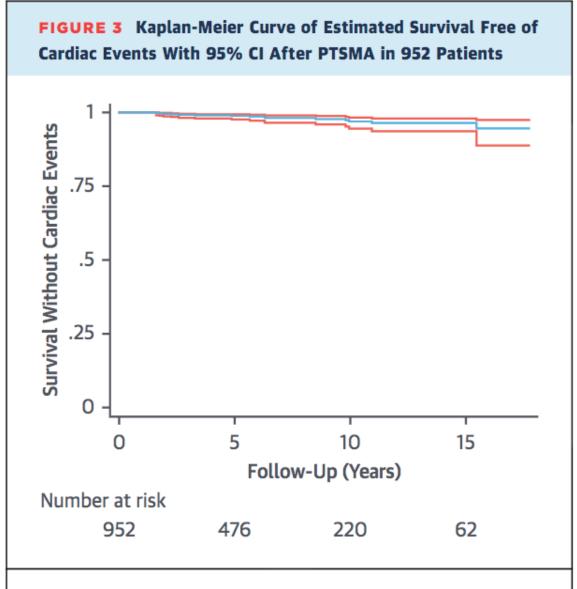


Kaplan-Meier survival analysis after percutaneous transluminal septal myocardial ablation (PTSMA) estimated a 5-year survival of 95.8% (95% confidence interval [CI]: 94.1% to 97.2%), a 10-year survival of 88.3% (95% CI: 84.8% to 91.2%), and a 15-year survival of 79.7% (95% CI: 73.9% to 84.4%). **Orange lines** represent 95% CI.

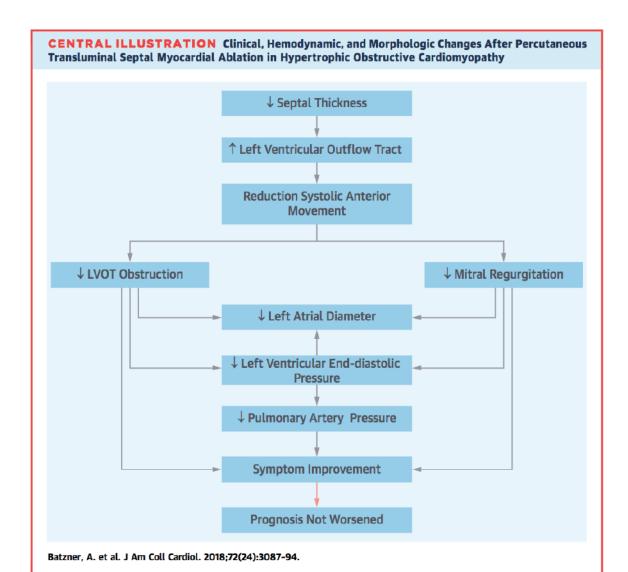




Kaplan-Meier survival analysis after PTSMA in 952 patients resulted in survival free of cardiovascular events after 5 years in 98.6% (95% CI: 97.4% to 99.3%), after 10 years in 96.5% (95% CI: 94.2% to 98.0%), and after 15 years in 92.3% (95% CI: 85.8% to 95.9%). **Orange lines** represent 95% CI. Abbreviations as in **Figure 1**.



Kaplan-Meier survival analysis after PTSMA in 952 patients resulted in survival free of cardiac events after 5 years in 98.9% (95% CI: 97.7% to 99.5%), after 10 years in 97.0% (95% CI: 94.7% to 98.3%), and after 15 years in 96.5% (95% CI: 93.9% to 98.0%). **Orange lines** represent 95% CI. Abbreviations as in **Figure 1**.



Demonstrates clinical, hemodynamic, and morphologic changes (3,7) after successful percutaneous transluminal septal myocardial ablation (PTSMA) in patients with hypertrophic obstructive cardiomyopathy. The **downward arrows** indicate reduction and the **upward arrows** 

indicate widening. LVOT = left ventricular outflow tract.

# 5-Year Outcomes According to FFR of Left Circumflex Coronary Artery After Left Main Crossover Stenting

Lee CH, et al. JACC Cardiovasc Interv. 2019 May 13;12(9):847-855.

#### **OBJECTIVES**

The aim of the current study was to evaluate the long-term clinical impact of fractional flow reserve (FFR) in jailed left circumflex coronary artery (LCx) after left main coronary artery (LM) simple crossover stenting.

#### **BACKGROUND**

Although the provisional side-branch intervention with FFR guidance has been validated for non-LM bifurcation lesions, the outcome of such a strategy in LM bifurcation disease is not well-known.

#### METHODS AND RESULTS

Patients who underwent LM-to-left anterior descending coronary artery simple crossover stenting and who had FFR measurements in the LCx thereafter were enrolled. A low FFR was defined as  $\leq 0.80$ . The clinical outcomes were assessed by the 5-year rate of target lesion failure (TLF) (a composite of cardiac death, target-vessel myocardial infarction, or target lesion revascularization).

#### **RESULTS**

In 83 patients, the mean FFR of the LCx after LM stenting was  $0.87 \pm 0.08$ , and 14 patients (16.9%) had a low FFR. There was no correlation between the FFR and angiographic % diameter stenosis in jailed LCx ( $R^2 = 0.039$ ; p = 0.071) and there was no difference in the angiographic % diameter stenosis in the high and low FFR groups. At 5 years, the low FFR group had a significantly higher rate of TLF than the high FFR group (33.4% vs. 10.7%; hazard ratio: 4.09, 95% confidence interval: 1.15 to 14.52; p = 0.029). However, there was no difference in the clinical outcomes according to the angiographic % diameter stenosis. In a multivariate analysis, a low FFR was an independent predictor of the risk for a 5-year TLF (hazard ratio: 6.49; 95% confidence interval: 1.37 to 30.73; p = 0.018).

#### CONCLUSIONS

The patients with a high FFR in jailed LCx had better 5-year outcomes than those with a low FFR. The FFR measurement in jailed LCx can be helpful in selecting an adequate treatment strategy and may reduce unnecessary complex procedures.

# 左主冠狀動脈支架置放後之左迴旋冠狀動脈血流儲備分數數值 - 五年追蹤結果分析

編譯:國軍新竹地區醫院 心臟內科 曾國翔醫師

#### 目標

此篇研究主要目的是在評估於左主冠狀動脈(LM)放置單一支架後(simple crossover stenting), 左迴旋冠狀動脈(LCx)的血流儲備分數(FFR)數值對於病患臨床預後之長期影響。

#### 背景

藉由血流儲備分數導引的臨時性分叉病變介入治療(provisional side-branch intervention)雖然已被證實對於非左主冠狀動脈(non-LM)分叉病變的處置有所助益,然而如此介入治療方式對於左主冠狀動脈(LM)分叉病變的臨床治療效果,卻不為眾人所熟知。

#### 方法

本研究收納病患的準則為接受 LM 到左前降冠狀動脈(LAD)置放單一支架後,並隨後於 LCx 進行了血流儲備分數測量。低血流儲備分數(low FFR)定義為 $\leq 0.80$ 。接下來再分析比較 5 年內的標的病灶失敗率(target lesion failure,TLF)(含括心因性死亡、標的病灶造成的心肌梗塞或血管再重建)。

#### 結果

本篇文章共納入83位病患進行分析(表一),於LM放置支架後,所有病患LCx的FFR平均測量數值為 $0.87\pm0.08$ ,其中有 14位病人(16.9%) FFR  $\leq 0.80$ 。FFR 的數值和LCx 在血管攝影的狹窄程度百分比(angiographic % diameter stenosis)並沒有相關聯( $R^2=0.039$ ; p=0.071)(圖一),且不管在 FFR 數值高(FFR > 0.80)或 FFR 數值低(FFR  $\leq 0.80$ )的群組中,兩組病患的 LCx 血管攝影狹窄程度百分比亦沒有明顯差異(表二)。

經過五年的追蹤,FFR 數值低的群組 TLF 比率顯著高於 FFR 數值高的群組(33.4% 及 10.7%;風險比率:4.09,95% 信賴區間:1.15~14.52;p=0.029)(表三)(圖二)。此外,根據 LCx 的血管攝影狹窄程度來進行分析,其對於病患臨床預後的影響並沒有明顯差異。然而在多變量分析(multivariate analysis)中發現,FFR 數值低 (FFR  $\leq 0.80$ )為五年內發生 TLF的獨立預測危險因子(風險比率:6.49;95% 信賴區間:1.37~30.73;p=0.018)(表四)(圖三)。

# 36 醫學新知 (III)

### 實驗限制

這個研究的限制有以下幾點:

- 1. 病患收集數量太少。
- 2. Selection bias,納入研究病患的 LCx 並無嚴重的血管阻塞(non-true LM bifurcation disease)。
- 3. 無其他額外血管內影像學檢查(IVUS 或 OCT),以提供 jailed LCx 血管內斑塊的改變。

### 結論

本篇研究指出,對於病患接受LM到LAD置放單一支架後,倘若LCx的FFR測量數值高(FFR > 0.80),相較於FFR測量數值低的病人,會有更好的長期臨床效果。因此,在治療左主冠狀動脈分叉病變時,藉由測量 jailed LCx的 FFR數值,有助於術者擬定適當的治療方針,及減少不必要的複雜處置(圖四、五)。

TABLE 1 Baseline Charact	eristics of Patients	5		
	All Patients (N $=$ 83)	High FFR (n = 69)		p Value
Age, yrs	63.8 (59.0-70.0)	63.8 (58.0-71.0)	64.1 (61.8-68.5)	0.93
Men	68 (81.9)	59 (85.5)	9 (64.3)	0.13
Hypertension	49 (59.0)	37 (53.6)	12 (85.7)	0.054
Diabetes mellitus	33 (39.8)	27 (39.1)	6 (42.9)	0.99
Hyperlipidemia	38 (45.8)	30 (43.5)	8 (57.1)	0.52
Current smoker	25 (30.1)	21 (30.4)	4 (28.6)	0.99
Previous MI	3 (3.6)	3 (4.3)	0 (0.0)	0.99
Previous PCI	13 (15.7)	9 (13.0)	4 (28.6)	0.29
Ejection fraction, %	62.0 (59.0-67.0)	61.2 (57.0-67.0)	66.3 (60.5-69.5)	0.19
Clinical presentation Stable angina Acute coronary syndrome	46 (55.4) 37 (34.5)	38 (55.1) 31 (34.9)	8 (57.1) 6 (42.9)	0.57
Multivessel disease	45 (54.2)	35 (50.7)	10 (71.4)	0.26

Values are mean (interquartile range) or n (%).

 $\mathsf{FFR} = \mathsf{fractional} \; \mathsf{flow} \; \mathsf{reserve}; \\ \mathsf{MI} = \mathsf{myocardial} \; \mathsf{infarction}; \\ \mathsf{PCI} = \mathsf{percutaneous} \; \mathsf{coronary} \; \mathsf{intervention}.$ 

	All Patients (N = 83)	High FFR (n = 69)	Low FFR $(n = 14)$	p Value
Baseline				
LM-LAD				
Reference vessel diameter, proximal, mm	3.9 (3.5-4.3)	3.9 (3.5-4.4)	3.7 (3.3-4.1)	0.34
Reference vessel diameter, distal, mm	3.1 (2.8-3.4)	3.1 (2.8-3.4)	3.0 (2.5-3.4)	0.41
Minimal lumen diameter, mm	1.0 (0.8-1.3)	1.0 (0.8-1.2)	1.1 (0.9-1.4)	0.34
Diameter stenosis, %	70.1 (64.0-78.0)	71.0 (64.0-78.5)	66.0 (57.8-71.8)	0.039
LCx				
Reference vessel diameter, distal, mm	2.9 (2.7-3.1)	3.0 (2.7-3.3)	2.7 (2.5-2.9)	0.012
Minimal lumen diameter, mm	2.3 (1.9-2.6)	2.4 (2.1-2.7)	1.9 (1.6-2.1)	< 0.001
Diameter stenosis, %	29.7 (22.0-38.0)	28.8 (20.5-36.5)	34.1 (28.0-43.0)	0.014
LM-LAD stent				
Stent length, mm	27.9 (18.0-30.0)	27.5 (18.0-29.0)	30.2 (21.8-30.8)	0.66
Stent diameter, mm	3.5 (3.5-4.0)	3.6 (3.5-4.0)	3.3 (3.0-3.5)	0.00
After LM-LAD stenting				
LM-LAD				
Minimal lumen diameter, mm	3.0 (2.7-3.3)	3.0 (2.8-3.3)	2.9 (2.7-3.2)	0.40
Diameter stenosis, %	17.7 (12.0-23.0)	17.7 (11.0-22.5)	17.9 (12.8-25.3)	0.93
Ostial LCx				
Minimal lumen diameter, mm	1.9 (1.6-2.2)	2.0 (1.6-2.3)	1.5 (1.2-1.9)	0.025
Diameter stenosis, %	40.6 (34.0-50.0)	40.1 (33.5-50.5)	43.4 (38.5-51.5)	0.66
FFR	0.87 (0.83-0.94)	0.90 (0.86-0.95)	0.74 (0.73-0.79)	< 0.00

Values are mean (interquartile range). QCA measurements were all calculated as per lesion.

FFR = fractional flow reserve; LAD = left anterior descending artery; LCx = left circumflex coronary artery; LM = left main coronary artery; QCA = quantitative coronary analysis.

	High FFR (n = 69)	Low FFR (n = 14)	p Value	Hazard Ratio (95% CI)	p Value
Target lesion failure*	6 (10.7)	4 (33.4)	0.018	4.09 (1.15-14.52)	0.029
Target vessel failure	8 (13.7)	4 (33.4)	0.067	2.92 (0.88-9.72)	0.080
Death from any cause Cardiac death Noncardiac death	2 (3.8) 0 (0.0) 2 (3.8)	1 (10.0) 1 (10.0) 0 (0.0)	0.34 0.016 0.57	3.02 (0.27-33.31) - -	0.37 _ _
Myocardial infarction Target vessel	4 (7.0) 3 (5.5)	1 (7.7) 1 (7.7)	0.77 0.59	1.38 (0.15-12.38) 1.84 (0.19-17.67)	0.77 0.60
Repeat revascularization Target vessel Target lesion	10 (17.5) 8 (13.9) 6 (11.3)	4 (34.7) 3 (23.8) 3 (23.8)	0.12 0.22 0.098	2.45 (0.77-7.83) 2.23 (0.59-8.45) 3.05 (0.76-12.26)	0.13 0.24 0.12
MACE	11 (19.1)	5 (42.9)	0.045	2.82 (0.98-8.15)	0.055
Definite or probable stent thrombosis	1 (2.0)	0 (0.0)	0.67	-	-

Values are n (%) unless otherwise indicated. Event rates are based on the Kaplan-Meier estimates. \*Target lesion failure was defined as a composite of death of cardiac causes, target vessel myocardial infarction, or target lesion revascularization.

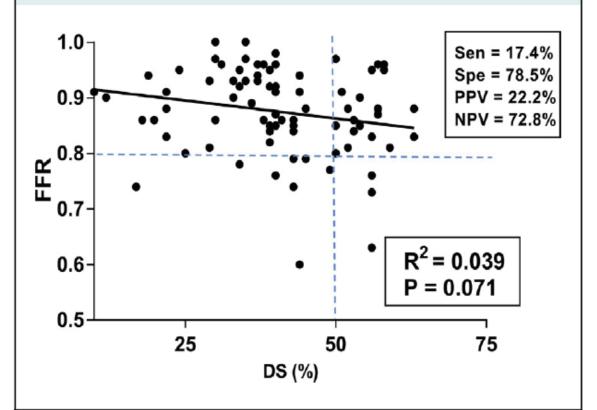
 ${\sf CI}={\sf confidence}$  interval; MACE = major adverse cardiac event; other abbreviations as in Table 2.

	Univariate	•	Multivariate			
	HR (95% CI)	p Value HR (95% CI)		p Value		
Multivessel disease	9.18 (1.16-72.55)	0.036	*	*		
PS LCx FFR ≤0.80	4.09 (1.15-14.52)	0.029	6.49 (1.37-30.73)	0.018		
Male	3.74 (1.05-13.27)	0.041				
LM-LAD lesion length, per mm	0.90 (0.03-1.22)	0.077	*	•		
PS LM-LAD MLD, per mm	0.19 (0.03-1.22)	0.081	0.01 (0.01-0.39)	0.013		
Stent generation, 2nd generation	0.16 (0.05-0.55)	0.004	0.12 (0.02-0.80)	0.025		
Mean stent diameter, per mm	0.08 (0.01-0.57)	0.012	0.04 (0.01-0.77)	0.035		

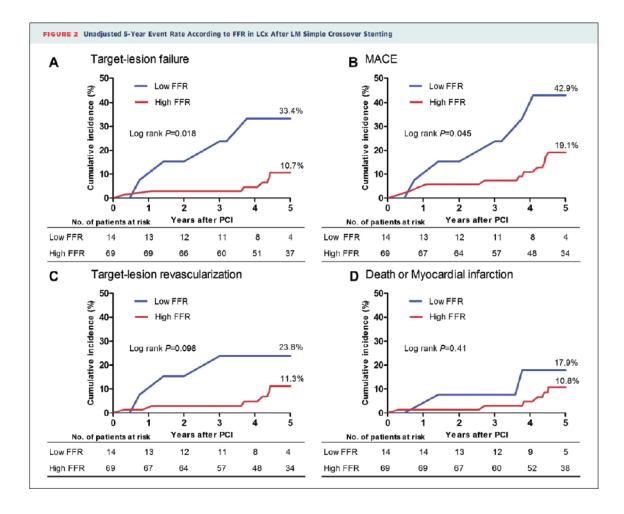
\*Not retained as independent predictor in multivariate analysis.

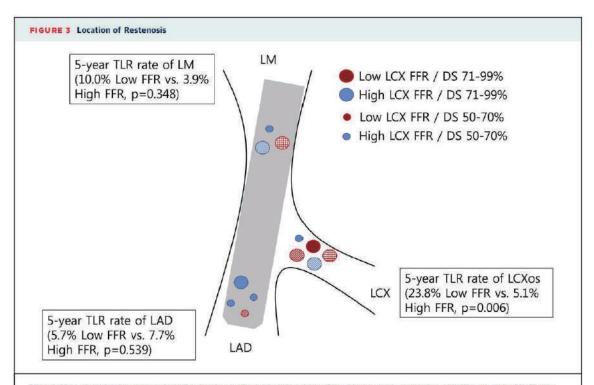
 $HR = hazard\ ratio;\ MLD = minimal\ lumen\ diameter;\ PS = post-stent;\ TLF = target\ lesion\ failure;\ other\ abbreviations\ are\ as\ in\ Tables\ 2\ and\ 3.$ 

FIGURE 1 Correlation Between FFR and % DS of Jailed LCx After LM Simple Crossover Stenting

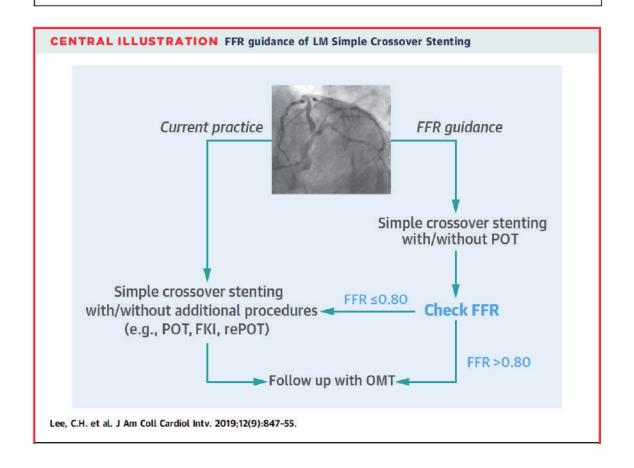


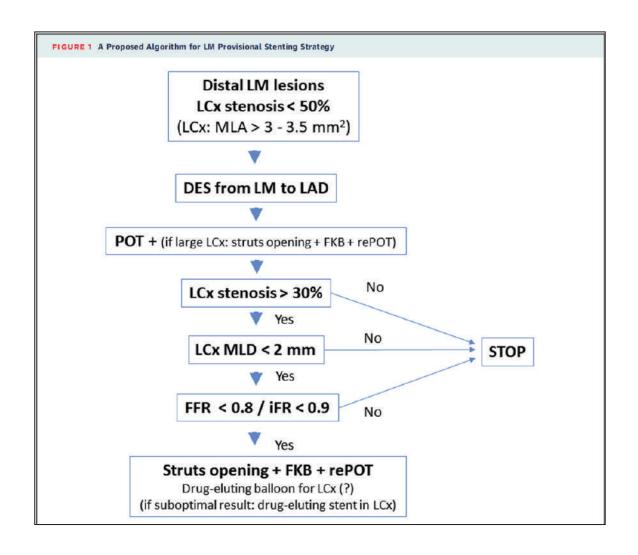
FFR = fractional flow reserve; DS = diameter stenosis; LCx = left circumflex coronary artery; LM = left main coronary artery; NPV = negative predictive value; PPV = positive predictive value; Sen = sensitivity; Spe = specificity.





Over 5 years, target lesion revascularization (TLR) events occurred in a total of 9 patients. Three patients had 2 sites of restenosis (same pattern in dots) and a total of 12 restenosis sites were observed. The Kaplan-Meier method was used to calculate the 5-year TLR rate at each location. LAD = left anterior descending coronary artery; LCxos = left circumflex coronary artery ostium; other abbreviations as in Figures 1 and 2.





# **Drug-coated Balloon for Treatment of De-novo Coronary Artery Lesions in Patients With High Bleeding Risk** (DEBUT): a Single-blind, Randomised, Non-inferiority Trial

Tuomas T Rissanen, et al. Lancet 2019, published online ahead of print

### **BACKGROUND**

The optimal technique of percutaneous coronary intervention in patients at high bleeding risk is not known. The hypothesis of the DEBUT trial was that percutaneous coronary intervention with drug-coated balloons is non-inferior to percutaneous coronary intervention with bare-metal stents for this population.

### **METHODS**

The DEBUT trial is a randomised, single-blind non-inferiority trial done at five sites in Finland. Patients were eligible if they had an ischaemic de-novo lesion in a coronary artery or bypass graft that could be treated with drug-coated balloons, at least one risk factor for bleeding, and a reference vessel diameter of 2.5-4.0 mm. Those with myocardial infarction with ST-elevation, bifurcation lesions needing a two-stent technique, in-stent restenosis, and flow-limiting dissection or substantial recoil (>30%) of the target lesion after predilation were excluded. After successful predilation of the target lesion, patients were randomly assigned (1:1), by use of a computer-generated random sequence, to percutaneous coronary intervention with a balloon coated with paclitaxel and iopromide or a bare-metal stent. The primary outcome was major adverse cardiac events at 9 months. Non-inferiority was shown if the absolute risk difference was no more than 3%. All prespecified analyses were done in the intention-to-treat population. This trial is registered with ClinicalTrials.gov, number NCT01781546.

### **FINDINGS**

Between May 22, 2013, and Jan 16, 2017, 220 patients were recruited for the study and 208 patients were assigned to percutaneous coronary intervention with drug-coated balloon (n=102) or bare metal stent (n=106). At 9 months, major adverse cardiac events had occurred in one patient (1%) in the drugcoated balloon group and in 15 patients (14%) in the bare-metal stent group (absolute risk difference -13. 2 percentage points [95% CI -6·2 to -21·1], risk ratio 0·07 [95% CI 0·01 to 0·52]; p<0·00001 for noninferiority and p=0.00034 for superiority). Two definitive stent thrombosis events occurred in the bare metal stent group but no acute vessel closures in the drug-coated balloon group.

### INTERPRETATIONS

Percutaneous coronary intervention with drug-coated balloon was superior to bare-metal stents in patients at bleeding risk. The drug-coated balloon-only coronary intervention is a novel strategy to treat this difficult patient population. Comparison of this approach to the new generation drug-eluting stents is warranted in the future.

### 44 醫學新知 (IV)

# 在高出血風險的病人,藥物塗層氣球是否可以用於治療新發生的冠狀動脈病灶?單盲、隨機分配及非劣性試驗

編譯:三軍總醫院 心臟內科 周琰璉醫師

### 背景

目前尚不清楚,在高出血風險病人族群,經皮冠狀動脈介入治療的最佳方法。DEBUT 試驗的假設 是對於這一類族群病人在經皮冠狀動脈介入治療中,藥物塗層氣球的療效不亞於裸金屬支架。

### 方法

DEBUT 試驗是在芬蘭五個不同的醫院進行的單盲、隨機分配及非劣性試驗。病人如果在冠狀動脈或繞道血管中有新發生的缺血性損傷,又合併有至少有一個出血的危險因素(服用口服抗凝血劑,80歲以上的老人,在進行介入治療之前6個月內檢查出有貧血(男性小於13.4g/dL;女性小於11.7g/dL)或血小板低下(小於100x10³/ul),活動性的惡性腫瘤,先前有缺血性中風或是腦內出血,嚴重腎功能不全(eGFR<30ml/kg/min),肝衰竭(膽紅素大於兩倍的正常上限值或是ALT大於三倍的正常上限值),計劃在接受經皮冠狀動脈介入治療的12個月內進行選擇性非心臟類手術,身體嚴重虛弱(BMI<20kg/m²),先前藥物順從性很差,或是先前有臨床有重大出血需要專業醫護人員照護)及血管參考直徑為2.5-4.0毫米為有資格進行藥物塗層氣球的治療。此試驗排除ST段心肌梗塞,分叉病灶需要雙支架技術,支架內在狹窄病灶,及在病灶經氣球預先擴張後產生流速限制性血管剝離和病灶實際回彈大於30%以上。在病灶經氣球預先擴張成功後,病人經由電腦隨機分配為1:1的經皮冠狀動脈介入治療兩組,一組接受藥物塗層氣球(紫杉醇和碘普羅胺-paclitaxel and iopromide)治療,另一組接受裸金屬支架置放。主要結果為9個月之後發生的主要心臟不良事件(心血管疾病死亡率,非致命性心肌梗塞,先前治療病灶再次缺血需要血管重建)。非劣性試驗定義為絕對風險差不超過3%。所有預先指定的分析都是在意向治療中進行的族群。

### 結果

此研究從 2013 年 5 月 22 日到 2017 年 1 月 16 日總共招募 220 位病人,當中 208 位病人被分配進入經皮冠狀動脈介入治療,其中 102 位病人被分配到藥物塗層氣球治療,另外 106 位被分配到裸金屬支架置放(如圖一)。兩組病人的基本資料及血管病灶分析如表一及表二,病人平均年紀為 77 歲,60% 為男性,46% 為急性冠心症,另外大部分糖尿病病人被分配到裸金屬支架組;病灶血管直徑大於 3mm 以上在藥物塗層氣球佔了 64%,而在裸金屬支架組占了 73%。嚴重心臟不良事件經過 9 個月追蹤之後在藥物塗層氣球組有 1 例 (1%)而在裸金屬支架組有 15 例 (14%)(絕對風險差為 -13.2%;風險比為 0.07; p 值 <0.00001 在非劣性組, p 值 =0.00034 在績優組)(如表三)。兩件明確的支架內血栓事件發生在裸金屬支架組但是沒有急性血管阻塞發生在藥物塗層氣球組。主要療效指標及次要療效指標的存活曲線分析如圖二,在 36 個月的追蹤之後,重大心臟不良事件比例在藥物塗層氣球組低於裸金屬支架組 (p 值 =0.013),另外先前治療病灶再次缺血需要血管重建的比例在兩組比較上並沒有特別差異 (p 值 =0.33)。藥物塗層氣球治療在追蹤 9 個月之後的重大心臟不良事件上優於裸金屬支架治療,不管在哪一類族群病人(穩定冠狀動脈疾病,急性冠心症,糖尿病,大小血管病灶或是分叉病灶)如圖四。在此試驗中更多的糖尿病病人被分配到裸金屬支架組,因此在糖尿病病人中使用藥物塗層氣球的重大心臟不良事件比例發生率比使用裸金屬支架低,另外在非糖尿病的病人也觀察到類似的現象。在校正糖尿病的風險之後的重大心臟不良事件比例發生率後,藥物塗層氣球治療在追蹤 9 個月之後的重大心臟不良事件上仍然明顯低於裸金屬支架治療(如圖四)。

### 討論

DEBUT 試驗告訴臨床醫師: (1) 在追蹤高出血風險病人進行經皮冠狀動脈介入治療後的9個月重大心臟不良事件上,藥物塗層氣球治療策略應優先考慮裸金屬支架治療策略,而這種差異會一直持續到治療的36個月之後。(2) 不管在先前治療病灶再次缺血需要血管重建或是急性血管阻塞的事件中,藥物塗層氣球還是優先於裸金屬支架。(3)DEBUT 試驗納入了臨床上比較複雜的病人,例如貧血或是使用口服抗凝血劑治療的病人。(4) 在此試驗中接受藥物塗層氣球治療的病人,64% 的病灶的直徑至少都大於3mm以上。(5) 在使用藥物塗層氣球之前,預先擴張氣球的最大直徑應該和標靶病灶的血管大小直徑一致。如果血管有鈣化的話,動脈粥狀硬化旋轉切除術也可以考慮在使用藥物塗層氣球前來除去鈣化斑塊。(6) 藥物塗層氣球的直徑應該為標靶血管直徑的0.8 到1.0 倍。另外,如果血管的限制流量小於TIMI3或是血管回彈超過30%以上時,應考慮緊急支架的置放(在上述狀況下,裸金屬支架應該盡量被避免因為會增加重大心臟不良事件發生率)。

在 ESC 準則中,藥物塗層氣球使用在支架內再狹窄不管是在裸金屬支架或是藥物塗層支架是 class IA 的適應症。但是因為現今塗藥支架的的進步,支架內發生再狹窄的比率少於 5%。在過去的幾年中,有很多的大型研究證實藥物塗層氣球治療對於新發生的病灶有很大的療效,且先前治療病灶再次缺血需要血管重建在 12 個月之內的發生率低於 3%。另外藥物塗層氣球在先前許多的研究中都被使用在小血管中。然而在 DEBUT 試驗中,使用碘普羅胺作為輔料的紫杉醇藥物塗層氣球對於新發生的病灶具有良好的療效且具有良好的安全性,其結果顯示在 9 個月之後的重大心臟不良事件發生數目較低且沒有發生先前治療病灶再次缺血需要血管重建的事件。

可能會發生多達 10% 的正性血管重塑在經過藥物塗層氣球治療之後,這是因為沒有任何金屬物質留在血管內來防止以後的擴張。另外,經皮冠狀動脈介入使用藥物塗層氣球後的兩個抗血小板藥物治療的推薦時間較短(穩定冠狀動脈疾病只要 1 個月)。更重要的是,對於接受經皮冠狀動脈介入使用藥物塗層氣球的病人發生嚴重出血後,可以立即停止兩個抗血小板藥物的治療,但是在 4 週之內停止兩個抗血小板藥物治療在使用藥物塗層支架的病人上是不被建議的。另外對於 85 歲以上的老人或是使用口服抗凝血劑的病人在接受經皮冠狀動脈介入使用藥物塗層氣球後,抗血小板藥物的使用目前並沒有一定的準則,這方面未來應該再被深入的探討和研究。

DEBUT 試驗依然有一些限制存在,例如收案速度太慢而提早結束,藥物塗層氣球在當時並不是治療的主流等等。

### 結論

在高出血風險的病人接受經皮冠狀動脈介入治療時,使用藥物塗層氣球治療是優於裸金屬支架治療。使 用藥物塗層氣球冠狀動脈治療對於這一類困難病人是一種新的治療策略。未來將此種方法和新型藥物塗層支架 進行比較是必要的。

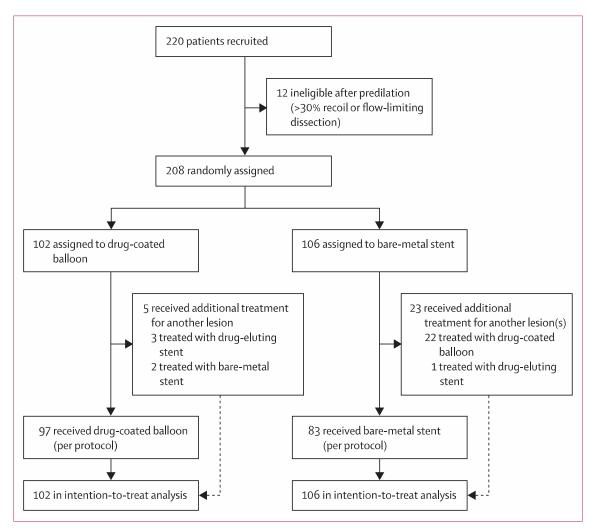


Figure 1: Trial profile

	Drug-coated balloon (n=102)	Bare-mental stent (n=106)
Patient characteristics		
Age, years	77-6 (8-4)	76-2 (8-5)
Sex		
Male	63 (62%)	68 (64%)
Female	39 (38%)	38 (36%)
Smoking	34 (34%)	36 (33%)
Current smoker	4 (4%)	7 (7%)
Ex-smoker	30 (29%)	29 (27%)
Hypertension	89 (87%)	96 (91%)
Hypercholesterolaemia	80 (78%)	89 (84%)
Diabetes	27 (26%)	52 (49%)
Non-insulin dependent	16 (16%)	31 (29%)
Insulin dependent	9 (9%)	18 (17%)
New onset*	2 (2%)	3 (3%)
Previous myocardial infarction	23 (23%)	20 (19%)
Acute coronary syndrome	47 (46%)	49 (46%)
Severity of symptoms†		
0	4 (4%)	3 (3%)
1	5 (5%)	1 (1%)
2	25 (25%)	26 (25%)
3	33 (32%)	38 (36%)
4	35 (34)	38 (36%)
Haemoglobin, g/L	135 (17)	132 (16)
Creatinine, µmol/L	91 (29)	103 (79)
Inclusion criteria‡		
Age ≥80 years	54 (53%)	53 (50%)
Anaemia or thrombocytopenia	30 (29%)	36 (34%)
Previous intracerebral haemorrhage or stroke	11 (11%)	12 (11%)
Planned elective surgery	7 (7%)	1 (1%)
Severe renal dysfunction	3 (3%)	8 (8%)
Non-compliant for 12 months of dual antiplatelet therapy	3 (3%)	4 (4%)
Active malignant disease	2 (2%)	1 (1%)
Previous bleeding	1 (1%)	3 (3%)
Frailty or cachexia	1 (1%)	1 (1%)
Severe liver dysfunction	0	0
Use of anticoagulation	58 (57%)	66 (62%)
Warfarin	54 (53%)	64 (60%)
Novel oral anticoagulant	4 (4%)	2 (2%)
Indication for anticoagulation		
Atrial fibrillation	42 (41%)	53 (50%)
Prosthetic valve	4 (4%)	5 (5%)
Thromboembolism	7 (7%)	5 (5%)
Other or not known	5 (5%)	3 (3%)

Data are n (%) or mean (SD). \*Diagnosed at the time of index procedure. †Measured with the Canadian Cardiovascular Society grading scale. ‡Patients with at least one criterion were included in the study.

Table 1: Baseline patient characteristics and study inclusion criteria (bleeding risk factors)

	Drug-coated ba <b>ll</b> oon (n=125)	Bare-metal stent (n=118)	p value
Target vessel			0.94
Left anterior descending artery	50 (40%)	45 (38%)	
Diagonal branch	6 (5%)	9 (8%)	
Left circumflex artery	22 (18%)	20 (17%)	
Marginal branch	10 (8%)	9 (8%)	
Right coronary artery	31 (25%)	28 (24%)	
Right posterior descending	1 (1%)	0	
Right posterior lateral	1 (1%)	3 (3%)	
Vein graft	4 (3%)	4 (3%)	
Bifurcated lesion	21 (17%)	15 (13%)	0.47
Calcified lesion	13 (10%)	13 (11%)	1.0
Cutting ba <b>ll</b> oon	11 (9%)	8 (7%)	0.64
Rotational atherectomy	6 (5%)	4 (3%)	0.75
Mean device diameter, mm	3.0 (0.4)	3.1 (0.4)	0.35
Device diameter, mm*			0.47
2.5	30 (23%)	22 (18%)	
2.75	16 (12%)	12 (10%)	
3.0	48 (37%)	57 (46%)	
3.5	25 (19%)	23 (18%)	
4.0	10 (8%)	11 (9%)	
Maximum dilation pressure, atm	9 (2)	16 (4)	<0.0001
Dilatation time, s	35.8 (10.4)		
Mean length of device, mm	19.6 (4.8)	16-2 (5-2)	<0.0001
Devices used per lesion			1.0
1	117 (94%)	110 (93%)	
2	8 (6%)	7 (6%)	
3	0	1 (1%)	
Oata are n (%) or mean (SD). *Info			ces.

	Drug-coated balloon (n=102)	Bare-metal stent (n=106)	Risk ratio (95% CI)	p value (non-inferiority)	p value (superiority)
Major adverse cardiac event (primary outcome)	1 (1%)	15 (14%)	0.07 (0.01-0.52)	<0.0001	0.00034
Target-lesion revascularisation	0	6 (6%)	0.08 (0.01–1.40)	<0.0001	0.015
Cardiovascular death	1 (1%)	6 (6%)	0.17 (0.02-1.41)	0.00085	0.061
Non-fatal myocardial infarction	0	6 (6%)	0.08 (0.01-1.40)	<0.0001	0.015

Data are n (%) unless stated otherwise. In addition to cardiovascular deaths, one patient in the bare metal stent group died by suicide 216 days after randomisation, and one patient in the drug-coated balloon group died of cancer 223 days after randomisation.

Table 3: Prespecified outcomes and study endpoints at 9 months (intention-to-treat analysis)

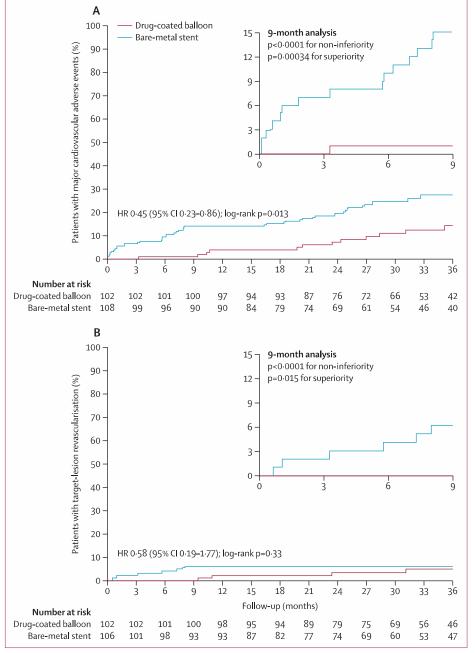


Figure 2: Kaplan-Meier curves of the cumulative proportion of patients with major cardiovascular adverse events (A) and target-lesion revascularisation (B)

# 醫學新知 (IV) 49

	Major adverse cardiac events at 9 months					Major adverse cardiac events during fo <b>ll</b> ow-up	
	Drug-coated balloon	Bare-metal stent	p value for difference	OR (95% CI)	p value for OR	HR (95% CI)	p value for HR
Clinical presentation				0.06 (0.01-0.46)	0.0067	0.45 (0.24-0.85)	0.015
Stable coronary artery disease	0/55	6/57 (11%)	0.027	NC		0.35 (0.11 <b>-</b> 1.09)	0.069
Acute coronary syndrome	1/47 (2%)	9/49 (18%)	0.016	0.10 (0.01-0.80)	0.030	0.52 (0.24-1.14)	0.10
Diabetes				0.07 (0.01 <b>-</b> 0.55)	0.011	0.46 (0.24-0.89)	0.021
Yes	0/27	10/52 (19%)	0.013	NC		0.20 (0.05-0.87)	0.032
No	1/75 (1%)	5/54 (9%)	0.035	0.13 (0.02-1.17)	0.069	0.68 (0.31-1.52)	0.68
Target vessel diameter*				0.12 (0.03-0.55)	0.0060	0.50 (0.27-0.92)	0.025
<3 mm	0/44	3/33 (9%)	0.041	NC		0.57 (0.17-1.86)	0.35
≥3 mm	2/81 (2%)	11/82 (13%)	0.010	0.16 (0.04-0.76)	0.021	0.48 (0.24-0.97)	0.040
Bifurcated lesion				0.12 (0.03-0.52)	0.0051	0.48 (0.26-0.86)	0.018
Yes	0/21	3/15 (20%)	0.032	NC		0.35 (0.10-1.27)	0.11
No	2/105 (2%)	11/102 (11%)	0.085	0.16 (0.04-0.74)	0.019	0.53 (0.27-1.05)	0.070
All patients	1/102 (1%)	15/106 (14%)	0.00037	0.06 (0.01-0.46)	0.0070	0.45 (0.23-0.86)	0.016

Data are n/N (%) unless stated otherwise. Data were adjusted for clinical presentation, diabetes, target vessel diameter, and bifurcated lesions. OR=odds ratio. HR=hazard ratio. NC=non-calculable because there were no events in at least one of the groups. \*Information missing for three (one in the drug-coated balloon group and two in the bare metal stent group) of 243 vessels.

Table 4: Prespecified subgroup analyses of the proportion of patients with, and the risk of, major adverse cardiac events at 9 months and during follow-up

### 108.08.03 Structural Heart Intervention-Complication and Update







































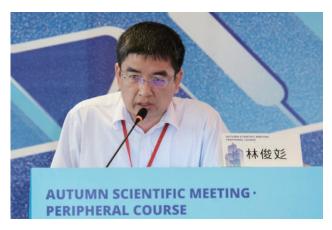


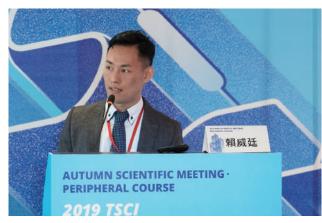








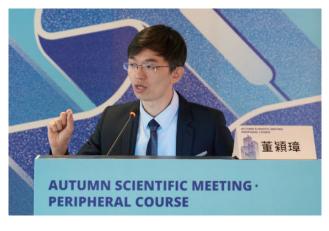


























































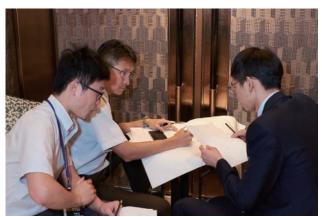
















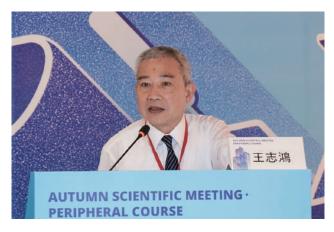




































































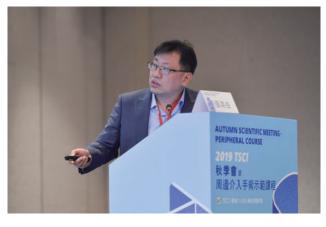




















































































































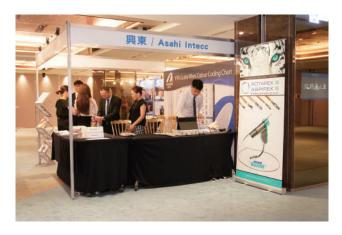






















### INFORMATION FOR AUTHORS

### Scope

*Journal of Taiwan Society of Cardiovascular Interventions* (J Taiwan Soc Cardiovasc Intervent) is an official Journal of Taiwan Society of Cardiovascular Interventions. It is a peer reviewed journal and aims to publish highest quality material, both clinical and scientific, on all aspects of Cardiovascular Interventions. It is published on a basis of 6 months.

#### **Article Categories**

Reviews, Original Articles, Brief articles including images, Case Reports, Letters to the Editor, Editorial Comments. Please look into each category for specific requirements and manuscript preparation.

#### **Manuscript Preparation: General Guidelines**

Taiwan Society of Cardiovascular Interventions reserves copyright and renewal on all material published. Permission is required from the copyright holder if an author chooses to include in their submission to *Journal of Taiwan Society of Cardiovascular* Interventions any tables, illustrations or other images that have been previously published elsewhere. Copy of the letter of permission should be included with the manuscript at the time of submission.

Manuscripts should conform to the Uniform Requirements for Manuscripts Submitted to Biomedical Journals (*N Engl J Med* 1997;336:309-15). Text should be double-spaced throughout. The Title page, Abstract, Body Text, Acknowledgments, References, Legends, Tables and Figures should appear in that order on separate sheets of paper. Define all abbreviations at first appearance, and avoid their use in the title and abstract. Use generic names of drugs.

### **Covering Letter**

The main author should write a covering letter requesting the publication of the manuscript and assuring that the other authors have read the manuscript and agree to its submission. The editorial board reserves the right to confirm this in case it needs to.

### **Title Page**

The title page should include a Title, full names and affiliations of all authors, and an address, telephone number, facsimile number and E-mail address for correspondence. Acknowledgment of grant support should be cited. A short Running Title (40 characters or less) should be provided.

#### **Abstract**

A concise description (not more than 250 words) of the Purpose, Methods, Results, and Conclusions is required. Give 3-6 key words for indexing.

#### **Body Text**

The text of Original Articles should be divided into Introduction, Materials and Methods, Results and Discussion sections. Other article types may use other formats as described in specefic guidelines against each category of manuscript below. Acknowledgments are typed at the end of the text before references.

### References

References are cited numerically in the text and in superscript. They should be numbered consecutively in the order in which they appear. References should quote the last name followed by the initials of the author(s). For less than four authors provide all names; for more than four, list the first three authors' names followed by "et al.". List specific page numbers for all book references. Refer to Index Medicus for journal titles and abbreviations. Examples are provided below. Authors are responsible for the accuracy of the citation information that they submit.

### **Journals**

- 1. Xu J, Cui G, Esmailian F, et al. Atrial extracellular matrix remodeling and the maintenance of atrial fibrillation. *Circulation* 2004;109:363-8.
- 2. Boos CJ, Lip GY. Targeting the renin-angiotensin-aldosterone system in atrial fibrillation: from pathophysiology to clinical trials. *J Hum Hypertens* 2005;19:855-9.

#### **Books**

- 1. Gotto AJ, Farmer JA. Risk factors for coronary artery disease. In: Braunwald E, Ed. *Heart Disease: A Textbook of Cardiovascular Medicine*. 3rd ed. Philadelphia: Saunders, 1988:1153-90.
- 2. Levinsky NG. Fluid and electrolytes. In: Thorn GW, Adams RD, Braunwald E, et al, Eds. *Harrison's Principles of Internal Medicine*. 8th ed. New York: McGraw-Hill, 1977:364-75.

### 雜誌投稿須知

#### **Tables**

All tables should be cited, by number, in the text. It should be typed double spaced, give a title to each table and describe all abreviations or any added relevant information as a footnote. Type each table on a separate page.

#### **Figures & Illustrations**

Number figures in the order in which they appear in the text. Figure legends should correspond to figure/illustration numbers and appear on a separate sheet of paper. Prepare your figures according to your mode of submission:

*e-mail Submission:* Figures should be submitted in high-resolution TIF format, or alternatively in GIF, JPEG/JPG, or EPS format. The figures should be placed in separate files, named only with the figure numbers (e.g. "Figure1.tif".)

Regular Mail: Photographs and drawings should be unmounted, glossy prints,  $5"\times7"$  in size. Three sets of each illustration must be submitted in a separate envelope. Label the back of each figure with the title of the article and an arrow indicating the top of the figure.

### **Manuscript Preparation: Specific Guidelines**

**Review Articles.** These are scholarly, comprehensive reviews whose aims are to summarize and critically evaluate research in the field and to identify future implications. Unsolicited reviews may be submitted to the editor-in-chief and will be subject to approval by the editorial board. Instructions for Title page, Abstract, References, Tables and Illustrations/figures remains the same. The text can follow independent pattern as per the authors desire, subject to approval of the editorial board.

**Original Articles.** Clinical human studies and experimental studies will appear in this category. It should not exceed 6,000 words including references and figure legends. It should conform the general pattern of submission i.e., Title page, Abstract, Body Text, References, Tables and Illustrations/figures.

**Brief Articles including images.** These will present brief clinical, technical, or preliminary experimental results or cardiovascular intervention related images and should not exceed 3,000 words. It should conform the general pattern of submission i.e., Title page, Abstract (< 200 words), Body Text, References, Tables and Illustrations/figures.

Case Reports. Case reports should not exceed 2,000 words in total with not more than 6 authors. Abstract should be less than 150 words. In the body text, the Materials and Methods and Results sections should be replaced with a Case Report(s) section which should describe the patient's history, diagnosis, treatment, outcome, and any other pertinent information. All other sections should follow the general format. Only two figures/illustrations are permitted. The number of references should not exceed 15.

Letters to the Editor. The editors welcome all opinions and suggestions regarding the journal or articles appearing in the journals. A title for the letter should be provided at the top of the page. The writer's full name should be provided. The Letter should be no more than 250 words long and may include one table or figure and up to four references. The editorial board reserves the right to edit any letter received. Author should provide a covering letter, on his/her own letterhead, to the Editorin-Chief stating why the Letter should be published. If it is concerning a particular article in *Journal of Taiwan Society of Cardiovascular Intervention* it should be within 6 months of that article's publication.

**Editorial Comments.** These will include invited articles or brief editorial comments representing opinions of local and foreign experts in cardiovascular medicine and research. They should be 1000-1500 words in length and not more than 20 references should be cited.

#### Submission of Manuscripts: e-mail submission is preferable

e-mail submission to tsci.med@msa.hinet.net

Please prepare text file or Microsoft Word file for your manuscript. Figures should be submitted in high-resolution TIF format, or alternatively in GIF, JPEG/JPG, or EPS format. The figures should be placed in separate files, named only with the figure numbers (e.g. "Figure1.tif".)

Regular Mail: Three copies any kind of Manuscripts including figures/illustrations should be submitted to:

Editorial Office, Taiwan Society of Cardiovascular Interventions,

16F-18, No.50, Sec. 1, Zhongxiao W. Rd., Taipei 10041, Taiwan, R.O.C.

### Time Line

The first decision will be made within 6 weeks from receipt of the manuscript. Once a manuscript, if sent by regular mail has been accepted, it should be submitted on a compact disc as a text file or Microsoft Word file.

### **Author Reprints and Costs**

Fifty reprints of each article will be furnished to authors free of charge. Additional reprints will be charged at a rate of US\$20 per 50 copies. No charges will be instituted for articles less than seven printed pages. The cost of color reproductions will be borne by the author.