

臺灣介入性心臟血管醫學會 (TSCI)

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臺灣介入性心臟血管醫學會會訊 (第六十五期, Oct., 2018)

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各位會員大家好

九月中旬，在超級颱風「山竹」的威脅之下，經過學術、周邊委員會、及秘書處同仁密集的集思廣益協商，大家一致同意基於安全考量和交通運輸在颱風期間勢必不方便，決定取消原訂在高雄舉辦的秋季會活動。但是鑒於轉播及病例的安排，以及外賓邀請已定，學會評估此次颱風對台中的影響應該較小，決定仍依既定計劃辦理 Peripheral Live，並移師中國醫藥大學附設醫院舉行。此次 Live 也安排網路直播，讓無法到場的會員仍能觀賞。



非常感謝陳俊吉主委和徐中和醫師大力協助，在短時間內安排此事，並協助商借場地。秘書處同仁也發揮機動力，在短短兩天內佈置會場、通知會員及 Faculty，並鼓勵中北部會員在天候及交通許可下，踴躍參加。協力廠商們也都卯足全力配合，安排外賓及 Faculty 接送與住宿，讓會議得以順利召開。9 月 15 日當天，非常幸運地，台中風和日麗，大家參會踴躍。由於內容著實精彩，除原本六例複雜周邊介入病例，還加上一例急性下肢近端靜脈栓塞病例的介入處理。另外，還安排了 10 場以上的專題演講，為大家提供最前線的周邊介入資訊，令人獲益匪淺。本次活動顯示國內周邊介入已臻世界水準！無怪乎日、韓、新加坡與會的專家也對徐中和醫師、吳典育醫師，及中國附醫的團隊讚譽有加。事後統計，現場報到人數超過 80 人，網路直播統計顯示兩岸各地有超過 2000 人次上線點閱，結果差強人意。在如此緊迫的準備下有此成績，非常難能可貴！這也充分反映出周邊委員會超級的向心力、執行力，以及秘書處的動員力，非常令人激賞，在下也與有榮焉

九月底，學會和心臟基金會合辦了 2018 Hack x Heart 首屆「生技醫療創新黑客松」活動，這對大家都是一個嶄新嘗試。所謂「黑客松」(Hackathon) 是黑客 + 馬拉松 (Hack + Marathon) 希望結合 IT 或 AI 產業和不同領域的幾個人，聚在一起以馬拉松的方式針對某個特定主題進行一段長時間的 Hack (程式設計) 活動。這類型的活動，實際進行的時間從半天、一天到兩天一夜的長度都有。最終希望能做出有趣的新網站、新 App 等等。本屆活動的主題是希望能解決心臟科醫師臨床上面臨的一大難題：急性冠心症發作後，只要規律用藥，就能減少再發率以及死亡率，但臨床常遇到患者在經過心導管手術治療後「自認為」身體已經恢復正常，便不再按時服藥，甚至自行停藥而發生心肌梗塞復發、中風或猝死的憾事。

本次活動共有 12 個隊伍參賽，介入學會指派給各組一位醫師做醫療專業輔導。經過 28 小時的馬拉松式努力，甚至有領導醫師陪同團隊們一起爆肝燒腦，最後經由六位評審評分後，由「我們走心」團隊作品榮獲冠軍以及新台幣八萬元的獎金。「我們走心」團隊提出的解決方案為軟硬體整合，硬體為感應式藥袋夾，整合 APP 軟體，感應式藥袋夾特殊之處為只要患者剝藥，藥袋夾的感應裝置就會自動啟動，並將數據傳至 APP 上，如果患者忘了服藥或重覆服藥，APP 會主動發訊息至患者及親友手機提醒用藥資訊。這個藥袋夾未來若能落實在臨床上，相信會有助改善服藥依從性，從而降低急性冠心病患者心臟病復發、中風及猝死機率。

此次入選的 12 支隊伍皆深藏不露、臥虎藏龍，來自領域相當多元，其中還有來自日本京都大學、紐約大學以及印度交換學生等，甚至專攻癌症結合人工智慧研究的中研院人才，都組隊角逐本次活動。此外，令我們非常欣慰的是臨床實習的醫師也對黑客松的急性冠心症議題很有興趣，真是「江山代有才人出」，包括台中榮總、臺北榮總、高雄大同等醫院的心臟科實習醫師、復健師等

跨領域組隊。透過醫生們的報名，能夠感受到醫界對急性冠心病治療與預防的重視，未來希望藉由黑客松的活動能產出更多臨床上可行、實用，符合病人所需的衛教軟硬體。

Meeting, meeting, everywhere! 九月的 TCT 和十月的第二屆中國結構週和長城心血管會議無疑是重頭戲。今年 TCT 有許多重量級的研究發表，其中最有臨床衝擊的是 MitraClip 使用於功能性二尖瓣閉鎖不全，但和先前其他研究結果完全相反的 COAPT 研究；一些不同廠牌塗藥支架間的抓對廝殺，如 BIONYX, ReCre8, LEADERS FREE II, SORT OUT IX 和 TALENT；以及臨床技能和介入用藥的研究等等。為了服務會員，我們將在 11 月 10 日及 11 日重返義大皇家酒店，辦理每年叫好又叫座的「Interventional Complication Symposium」，以及搶先整理報告「Express Delivery from TCT 2018」，為大家帶來豐盛的學術饗宴及入冬以前的愉快假期，請各位會員持續關注學會活動公告。

最後，也非常高興向大家報告：醞釀已久的學會新網站，也在近期正式上線，這個學會的門面，在編輯暨登錄主委林宗憲教授的指導，副秘書長陳冠群醫師及秘書處同仁的共同努力之下，終於完成，得以跟大家見面，也算是學會一個重要的里程碑。因為日後許多的活動記錄、會員服務事項、重要公告事項、最新介入新知，都可以跟上腳步及時呈現給會員們。凡事起頭難，相信網站也有不盡如人意之處，請大家不吝指教，讓網站功能更趨完善。更希望大家繼續給予學會回饋，讓我們能做得更好，介入大家庭更加茁壯！

理事長

殷偉賢

2018.10



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		貼相片處 (實貼一張)
英文姓名		身分證 號 碼			
出生日期	年 月 日	出生地	省(市) 縣(市)		
最高學歷	學校				科系(所)
現任醫院			單位/職務	/	
戶籍地址					電 話 (必 填)
通訊地址	☐ 同戶籍地址 ☐ 通訊地址 _____				
E-mail(必填)	_____@_____				
最近一年 介 入 性 工作經歷	(1) 醫院：_____ 期間： _____ 年 _____ 月至 _____ 年 _____ 月 醫師主管姓名：_____ 列印後主管簽名：_____				
	(2) 醫院：_____ 期間： _____ 年 _____ 月至 _____ 年 _____ 月 醫師主管姓名：_____ 列印後主管簽名：_____				
	(3) 醫院：_____ 期間： _____ 年 _____ 月至 _____ 年 _____ 月 醫師主管姓名：_____ 列印後主管簽名：_____				
推薦會員 (1)	姓 名：_____		推薦會員 (2)	姓 名：_____	
	列印後簽名：_____			列印後簽名：_____	

審查結果 (此欄由審 查人員填 寫)	☐ 同意入會 ☐ 不同意入會 審查人員：	會 員 類 別	☐ 普通會員 ☐ 準會員 ☐ 名譽會員 ☐ 贊助會員	會 員 證 號 碼	
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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—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—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满一年，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

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Winter Symposium

2018 Nov. 10-11 高雄皇家義大酒店-皇冠宴會廳
(高雄市大樹區學城路一段153號)

09:00

16:40



TSCI臺灣介入性心臟血管醫學會
Taiwan Society of Cardiovascular Interventions



臺灣介入性心臟血管醫學會
Taiwan Society of Cardiovascular interventions

Winter Symposium

日期：107 年 11 月 10 日(週六) - 11 日(週日)

地點：高雄義大皇家酒店 (高雄市大樹區學城路一段 153 號)

日期/時間	11/10(Sat.)	11/11(Sun.)
09:00 12:15	Interventional Complications	Express Delivery from TCT 2018
12:15 13:25	Lunch Break	
13:25 16:40	Interventional Complications	



臺灣介入性心臟血管醫學會
Taiwan Society of Cardiovascular interventions

CHIP

(Complex and High-Risk Indicated Procedure/Patients)

時間：107 年 12 月 2 日(日) 13:30-17:00

地點：台大醫學院 103 講堂

- Each topic: 15 mins talk+5 mins Q&A

時間	講題	講師	座長
13:30	Opening	殷偉賢 理事長	
13:35	What is CHIP? The rationale for PCI	劉俊廷	盧澤民
13:55	The Value of FFR or iFR in LMCT PCI	王光德	邱俊仁
14:15	Should complete revascularization be achieved for heart failure patients? (with case sharing)	王怡智	顧博明
14:35	How to manage degenerative SVGs disease? (with case sharing)	李文領	張詩聖
14:55	PCI in patients declined by surgeon (with case sharing)	殷偉賢	鄭書孟
15:15	Coffee Break		
15:35	Rotational atherectomy for CHIP (with case sharing)	王志鴻	殷偉賢
15:55	Current left main bifurcation PCI (with case sharing)	曹殿萍	方慶章
16:15	How to select mechanical circulatory support during and after PCI for CHIP?	李國楨	任勗龍
16:35	What is the modern approach for CTO?	吳炯仁	謝宜璋
16:55	Closing	謝宜璋 主委	



臺灣介入性心臟血管醫學會

Taiwan Society of Cardiovascular interventions

CDT & PMT Update

時間：107 年 12 月 8 日(六) 13:30-17:00

地點：台大醫學院 103 講堂

時間	講題	講師
13:30	Opening	盧澤民 秘書長
Moderator：陳俊吉、黃玄禮		
13:35	Peripheral artery disease with thrombolysis treatment (Linkou CGMH IR experience)	許銘益
13:55	Peripheral artery disease PMT (CMUH EKOS experience)	徐中和
14:15	Peripheral artery disease PMT (KMUH Rotarex experience)	許栢超
14:35	Peripheral artery disease PMT (Taichung VGH Angiojet experience)	張偉俊
14:55	Panel Discussion	
15:05	Coffee Break	
Moderator：徐中和、曾維功		
15:25	Acute pulmonary embolism with thrombolysis treatment (Hinchu NTUH experience)	謝慕揚
15:45	Venous thromboembolism PMT(SKMH Angiojet experience)	吳典育
16:05	Venous thromboembolism PMT (CMUH Aspirex experience)	謝禮全
16:25	Venous thromboembolism PMT (Taipei NTUH EKOS experience)	李任光
16:45	Panel Discussion	
16:55	Closing	陳俊吉 主委

TAIWAN TRANSCATHETER THERAPEUTICS

LIVE COURSE



JAN 12-13, 2019 NTUH International Convention Center
Taipei, Taiwan

Course Directors

Wei-Hsian Yin, MD
President, TSCI

Wen-Liang Lee, MD
Chairman, Scientific Committee, TSCI

Tse-Min Lu, MD
Secretary General, TSCI



**臺灣介入性心臟血管醫學會
第七屆第二次醫事人員委員會會議紀錄**

一、時間：107 年 10 月 3 日（星期三）18：30

二、地點：視訊會議

三、出席人員：〈主 委〉李素珠

〈委 員〉林素楓、郭宜蘭、曾欽輝、李庚原、邵雅芬、王鳳花、林見財、
林瓊枝、黃漢龍

四、請假人員：〈委 員〉黃銘玲、朱光華、杜文桂

五、列席人員：〈秘書處〉盧澤民秘書長、黃建龍副秘書長、林佳慧(請假)、彭瑋婷(記錄)、賴瑋儀

六、報告事項：

七、議程：

提案一：「醫事人員繼續教育課程」與「醫事人員 ROTA 課程」，將延至 TTT 2019 舉辦。

說明：因颱風關係秋季會取消大部分課程，請參閱原定節目表及 TTT 2018 「Nurse / Technician Symposium」節目表決定是否有要調整的地方。

決議：1. 原秋季會「醫事人員繼續教育課程」擬於 TTT 2019 舉行。

2. 「醫事人員 ROTA 課程」將延至 2019 秋季會舉辦。

提案二：討論 TTT Learning Center 課程安排。

說明：上次委員會討論到可在 TTT 設 Learning Center 找 2-3 間廠商贊助設備器材給醫事人員實際動手操作，請各委員討論出主題以利節目規劃。

決議：Learning Center 主題將延續醫事人員繼續教育課程內容，請廠商提供 iFR、FFR、OCT 三類設備器材給有興趣之醫事人員實際動手操作，活動時段將限制人數劃分為 2-3 場次，並採會前預約制參加。

提案三：討論明年醫事人員參加國際會議課程安排。

說明：第一次委員會會議殷偉賢理事長提出學會將盡力提供本會醫事會員未來能和其他國外學會或亞洲會議有參加機會，以增加學術交流並汲取國外經驗。

決議：將集中於 TCTAP 及 CCT 兩國際會議，由學會提供名額參加，並於會後舉辦課程由受贊助會員講課或撰寫醫學新知將新資訊即時分享，以增進國內醫療發展。

提案四：討論下次委員會召開日期。

決議：預計於 108 年 5、6 月 (W3) 召開第三次會議。

八、臨時動議

九、散會

未提供

**臺灣介入性心臟血管醫學會
第七屆第二次周邊血管介入委員會會議紀錄**

一、時間：107 年 10 月 19 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〉李任光、吳敘平、黃玄禮、謝慕揚、李政翰、許栢超、曾維功、薛書凱

四、請假人員：〈委 員〉黃柏勳、張偉俊、陳怡芝

五、列席人員：〈秘書處〉秘書長：盧澤民秘書長、林佳慧、彭瑋婷（紀錄）、賴瑋儀

六、報告事項：

七、議程：

提案一：『CDT & PMT Update』節目策劃相關內容。

說明：1. 策劃人：吳敘平委員。

2. 時間：107 年 12 月 8 日（六）。

3. 地點：未訂

4. 節目表（略）

決議：1. 時間：107 年 12 月 8 日（六）13：30 ~ 17：00。

2. 地點：臺大醫學院。

3. 秘書處將依節目表安排進行 Faculty 邀約。

4. 現場錄影以供會後回放。（費用將由節目負責人請廠商增加會議贊助預算）

提案二：討論 TTT 2019 Peripheral 時段節目主題及初步規劃。

說明：1. TTT 2019 時間為 108 年 1 月 12-13 日

2. 如同 TTT 2018，學會於 1/13（日）下午亦規劃兩個小時的時段給 Peripheral 相關議題，再請委員協助討論節目主題及初步安排，以呈理事長、秘書長及學術委員會確認。

決議：1. 擬安排提案三之秋季會 2018 因故取消之『An Era for Atherectomy and Drug Coating Device』課程。

2. TTT 2019 周邊外賓：Osamu Iida、Yoshimitsu Soga、Jae-Hwan Lee。

提案三：討論『An Era for Atherectomy and Drug Coating Device』活動日期。

說明：因颱風關係秋季會取消大部分課程，請參閱原定節目表決定是否有要調整的地方。

1. 策劃人：徐中和委員。

2. 時間：未訂

3. 地點：未訂

4. 節目表（略）

決議：1. 時間：TTT 2019，108 年 1 月 13 日（日）14：00 ~ 16：00。

2. 地點：台大國際會議中心 R301。

3. 共 9 個 Topic，Each topic: 10 mins talk+ 2 mins Q&A。

提案四：2018 秋季會暨周邊介入手術示範課程 - Peripheral Live 活動反饋。

說明：參考各委員意見，以供下次活動改善。

決議：1. 明年 Peripheral Live 預計也將與秋季會合辦。

2. 建議統一由一間公司負責轉播及設備。

提案五：討論下次召開會議日期。

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：暫訂 108 年 1 月第五週召開第三次會議。

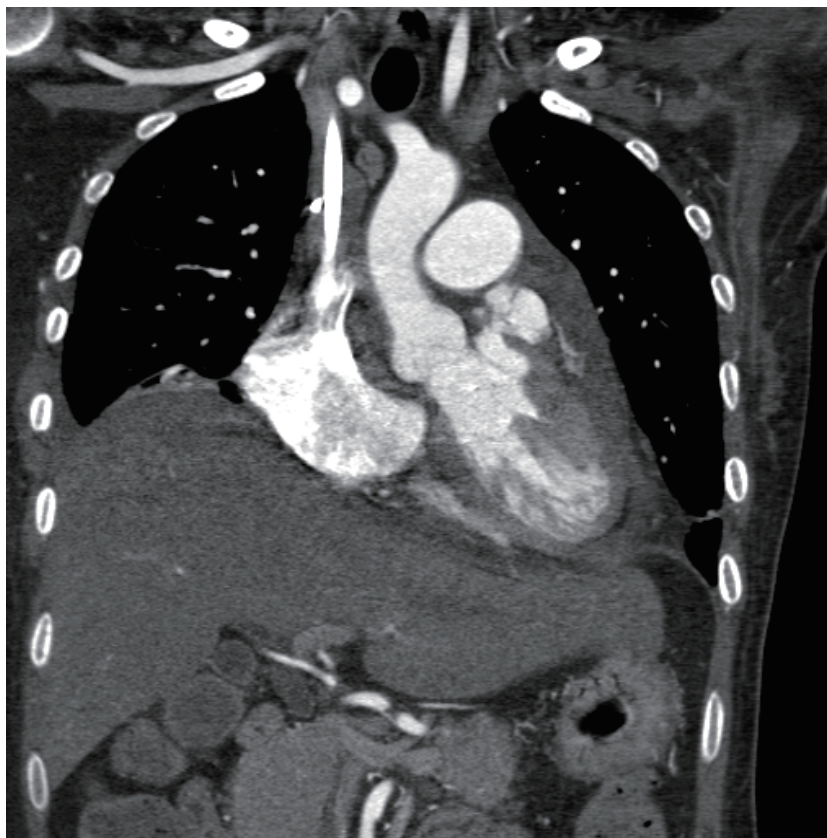
八、臨時動議

九、散會

本期案例

【案例1】

46 歲女性，患有風濕性心臟病合併二尖瓣狹窄，今年五月於外院接受二尖瓣置換手術。術後無特別症狀，追蹤電腦斷層檢查結果如下



【試問】

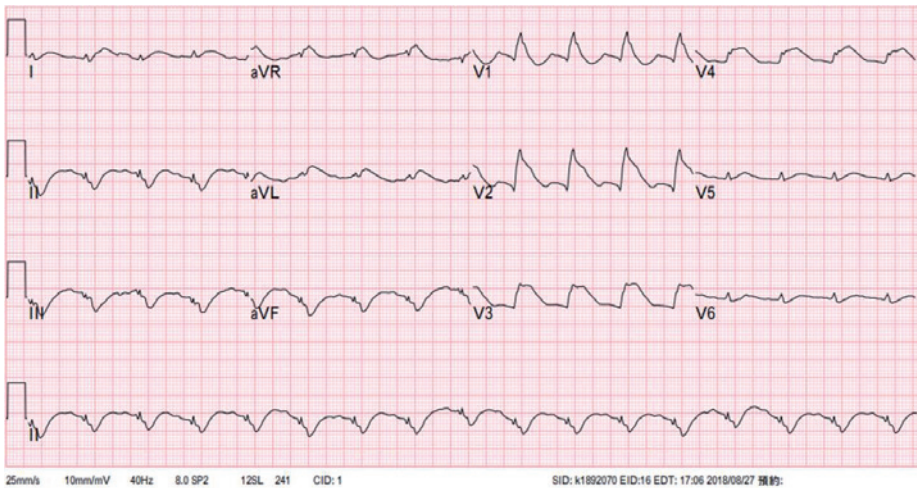
請問有何異常？

中國醫藥大學兒童醫院 兒童心臟科 徐宗正 / 傅雲慶

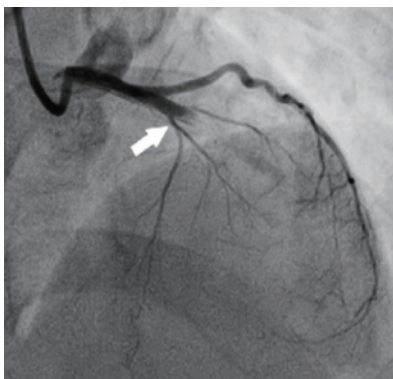
本期案例

【案例 2】

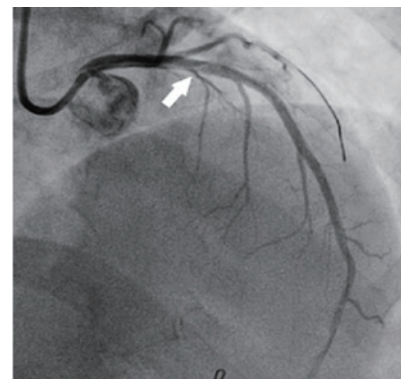
34 歲女性，吸菸，無其他內科病史，亦無家族心血管疾病史，在健身房運動時突然倒下，OHCA 由 EMT 送入急診，ROSC 後啟動緊急心導管，心電圖及血管攝影如下圖



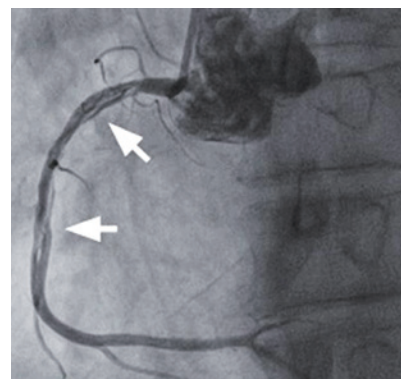
ECG



Wires to distal LAD and
diagonal branch with
STRAW technique



LCA



RCA

【試問】

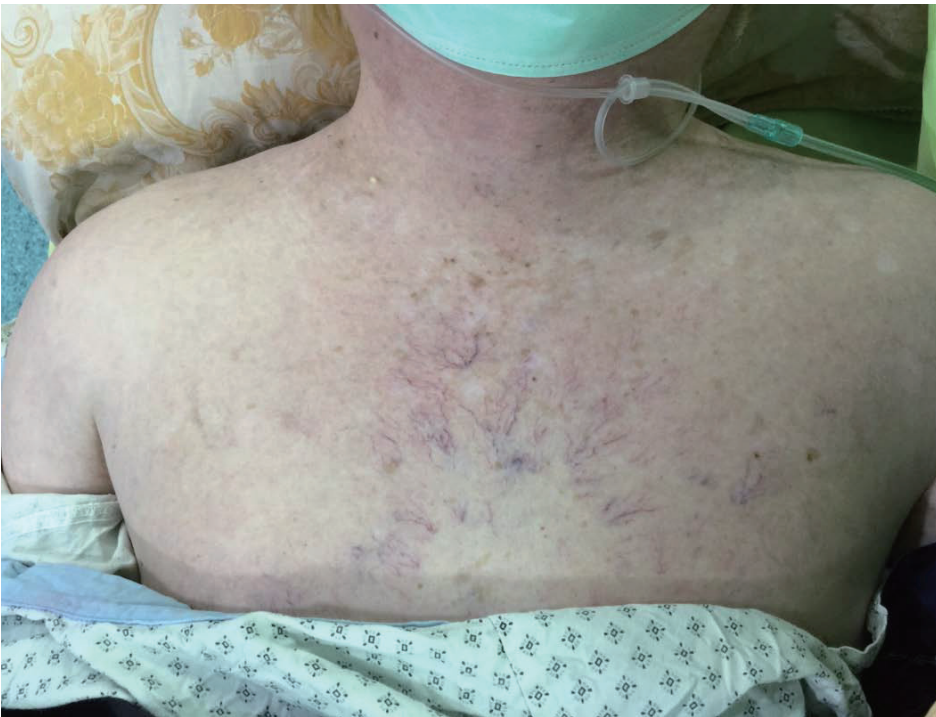
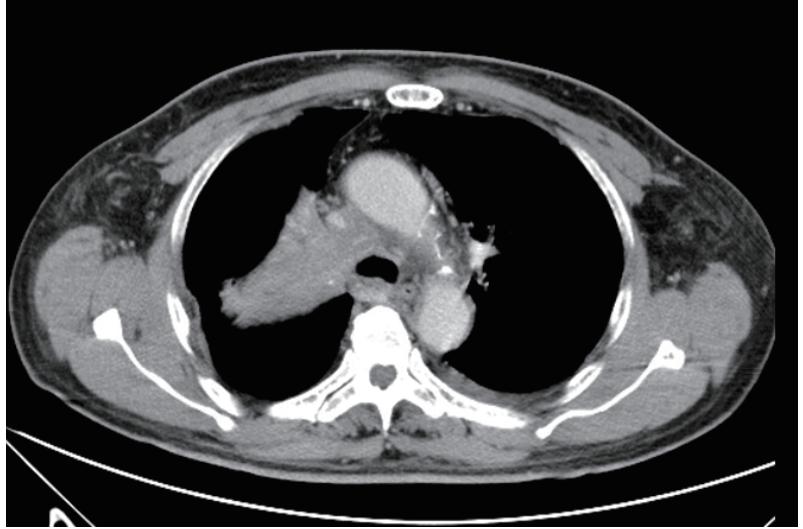
依此病人之冠狀動脈血管攝影，此狀況可能為何？

1. Catheter related coronary artery dissection
2. Diffuse long thrombus formation in coronary artery
3. Iatrogenic along with spontaneous coronary artery dissection
4. Multi-vessel spontaneous coronary artery dissection

上期解答

【案例】

81 歲男性抱怨咳嗽以及呼吸困難，下肢水腫，接受 CXR 以及 CT 檢查如附圖



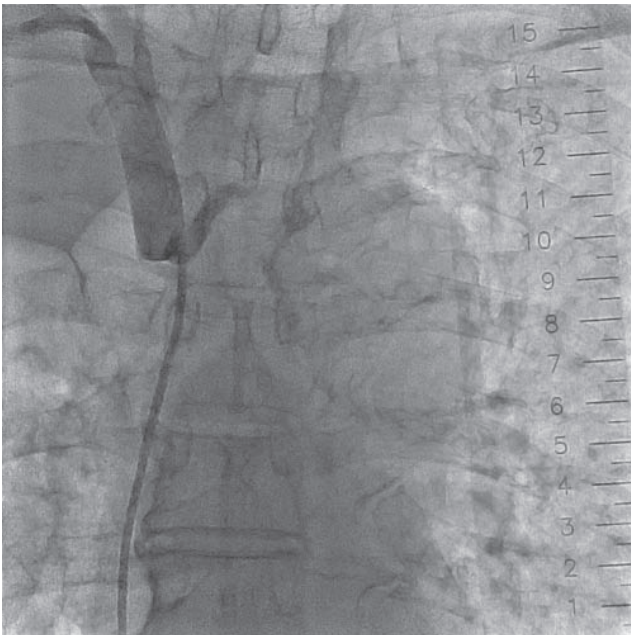
【試問】

請問診斷為何？介入治療能否改善？

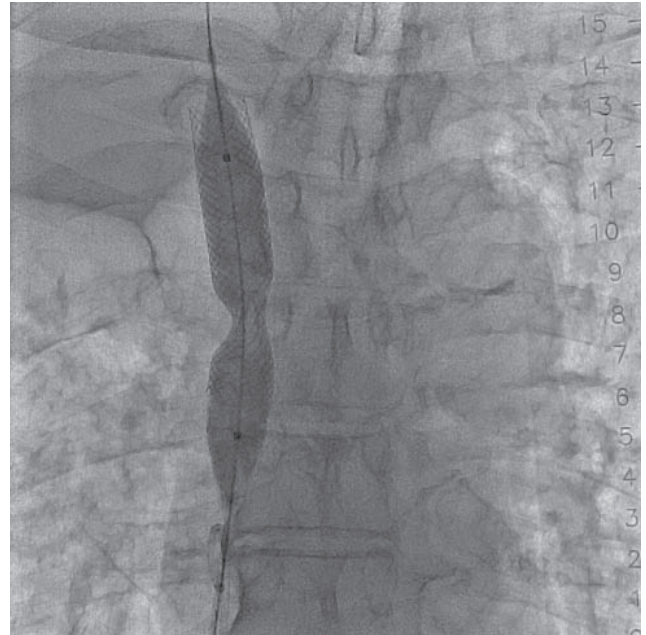
高醫附醫 朱俊源醫師 / 林治瑩放射師

【答案】

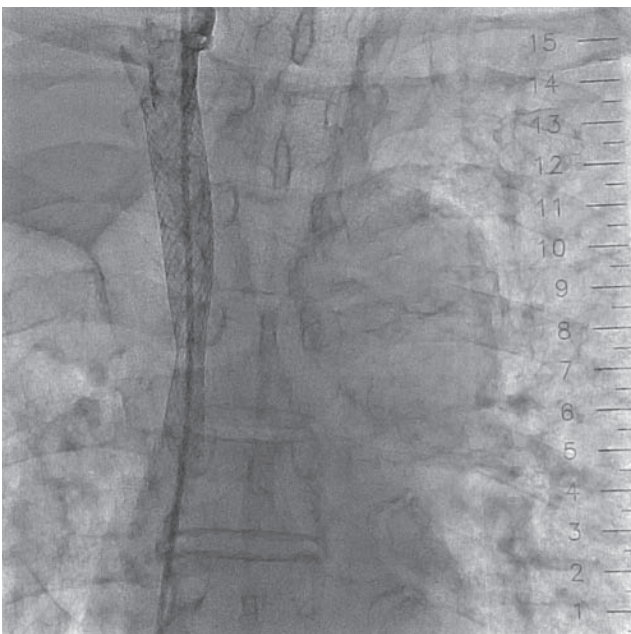
1. 病人外觀呈現臉、頸、上胸部水腫和胸部淺層靜脈擴張，CXR 呈現右上部 Wedge infiltration，Chest CT 呈現 Bronchogenic tumor and obstructive pneumonia in the right upper lobe of the lung with tumor extending to the adjacent mediastinum with encasement of the adjacent the superior vena cava，診斷確認是 SVC syndrome secondary to external compression of bronchogenic tumor。
2. 從 Right femoral vein approach，JR4 診斷導管攝影顯示 SVC external compression，經過順利置放 wall stent 14 x 60 mm 後，選擇 14mm balloon 進行 postdilatation，頭頸部靜脈得以順利回流，術後追蹤，病人頭頸部水腫以及下肢水腫獲得顯著改善。



經過右股靜脈血管攝影顯示
SCV external compression



置放 Wall stent, 14 x 60 mm 並進行後擴張



經過置放支架後，頸部靜脈血能順利回流



頭頸部以及下肢水腫皆獲得顯著改善

Transcatheter Mitral-Valve Repair in Patients with Heart Failure

G.W. Stone, et al, for the COAPT Investigators. September 23, 2018 at NEJM

BACKGROUND

Among patients with heart failure who have mitral regurgitation due to left ventricular dysfunction, the prognosis is poor. Transcatheter mitral-valve repair may improve their clinical outcomes.

METHODS

At 78 sites in the United States and Canada, we enrolled patients with heart failure and moderate-to-severe or severe secondary mitral regurgitation who remained symptomatic despite the use of maximal doses of guideline-directed medical therapy. Patients were randomly assigned to transcatheter mitral-valve repair plus medical therapy (device group) or medical therapy alone (control group). The primary effectiveness end point was all hospitalizations for heart failure within 24 months of follow-up. The primary safety end point was freedom from device-related complications at 12 months; the rate for this end point was compared with a prespecified objective performance goal of 88.0%.

RESULTS

Of the 614 patients who were enrolled in the trial, 302 were assigned to the device group and 312 to the control group. The annualized rate of all hospitalizations for heart failure within 24 months was 35.8% per patient-year in the device group as compared with 67.9% per patient-year in the control group (hazard ratio, 0.53; 95% confidence interval [CI], 0.40 to 0.70; $P<0.001$). The rate of freedom from device-related complications at 12 months was 96.6% (lower 95% confidence limit, 94.8%; $P<0.001$ for comparison with the performance goal). Death from any cause within 24 months occurred in 29.1% of the patients in the device group as compared with 46.1% in the control group (hazard ratio, 0.62; 95% CI, 0.46 to 0.82; $P<0.001$).

CONCLUSIONS

Among patients with heart failure and moderate-to-severe or severe secondary mitral regurgitation who remained symptomatic despite the use of maximal doses of guideline-directed medical therapy, transcatheter mitral-valve repair resulted in a lower rate of hospitalization for heart failure and lower all-cause mortality within 24 months of follow-up than medical therapy alone. The rate of freedom from device-related complications exceeded a prespecified safety threshold.

經導管二尖瓣修復在心衰竭患者 (COAPT trial)

編譯：中國醫藥大學附設醫院 內科部心臟血管系 陳業鵬醫師

在左心室功能不良而具有二尖瓣逆流的心衰竭患者中，預後較差。經導管二尖瓣修復可改善其臨床結果。

方法

在美國和加拿大的 78 個中心，我們納入了心衰竭合併中度至重度或嚴重繼發性二尖瓣逆流，儘管使用了最大劑量的 guideline-directed medical therapy，但仍有症狀的患者。患者被隨機分配到經導管二尖瓣修復加藥物治療 (device group) 或單獨藥物治療 (control group)。主要的有效 end point 為追蹤 24 個月內因心衰竭而住院。主要安全 end point 是在 12 個月內不發生 device 相關的併發症 (Table 2); 並將該 end point 的比率與預先設定的 88.0% 的客觀績效目標進行比較。

結果

在參加試驗的 614 名患者中，302 名被分配到 device group，312 名被分配到 control group。Device group 中 24 個月內發生心衰竭住院率的年化率為每患者年 35.8%，而 control group 為每患者年 67.9% (HR, 0.53; 95%CI, 0.40-0.70; P <0.001) (Figure A)。12 個月時 device 相關併發症的 freedom rate 為 96.6% (lower 95% confidence limit, 94.8%; P<0.001 for comparison with the performance goal)(Figure B)。Device group 中患者在 24 個月內因任何原因死亡為 29.1%，而對照組為 46.1% (HR, 0.62; 95% CI, 0.46-0.82; P <0.001) (Figure C)。

討論

COAPT 試驗評估了經導管二尖瓣修復在心衰竭合併中度至重度或嚴重繼發性二尖瓣閉鎖不全患者的安全性和有效性，儘管使用了最大劑量的指引針對性藥物治療，但仍有症狀的患者。在該試驗中，使用 device 治療發生心衰竭再住院率顯著降低，死亡率降低，且追蹤 24 個月內的生活品質和功能均高於單獨的藥物治療。此外，經導管二尖瓣修復術中與 device 相關併發症的 freedom rate 超出了預先設定的客觀性能目標。許多次分析結果的益處亦是一致的，包括患有缺血性和非缺血性心肌病變的患者以及那些手術相關併發症或死亡風險高的患者，並且益處與起始的二尖瓣逆流等級和左心室容量及功能無關。

該試驗中使用的 MitraClip 是於 2013 年獲得美國食品和藥物管理局批准，用於治療高手術相關併發症或死亡風險的原發性二尖瓣閉鎖不全的患者。在美國，MitraClip 主要用於此適應症。但是，在美國以外，MitraClip 更常用於治療繼發性二尖瓣逆流的心衰竭患者。心衰竭和繼發性二尖瓣閉鎖不全患者的預後很差；在這項試驗中，儘管使用了指引針對性的藥物治療，仍有大約三分之二的此類患者在 2 年內因心衰竭死亡或住院治療。MitraClip 治療之後可降低繼發性二尖瓣閉鎖不全的嚴重度；這可能是患者預後，生活品質和功能能力改善的機制。值得注意的是，MitraClip 治療後 30 天內發生心衰竭的住院率較低；較低的死亡率主要出現在治療 1 年後，一年後左心室容量超負荷持續降低的長期益處一致且延續。

在該試驗中，Clip 植入率為 98%，95% 的患者立即達到 2+ 或更低的二尖瓣逆流等級，遠遠優於 EVEREST II 於低風險患者的結果。此結果可能反映了操作者植入經驗增加和改善心臟超音波的指引。使用 MitraClip，二尖瓣逆流嚴重程度的降低也隨著時間持續可見。在 device group 中存活的患者中，2 年的二尖瓣閉鎖不全等級為 3+ 或更高，僅為 0.9%，2+ 或更高僅為 22.8%。相較之下，之前的一項隨機試驗評估縮小瓣環成形術環 (downsized annuloplasty ring) 在繼發性缺血性二尖瓣逆流患者中的有效

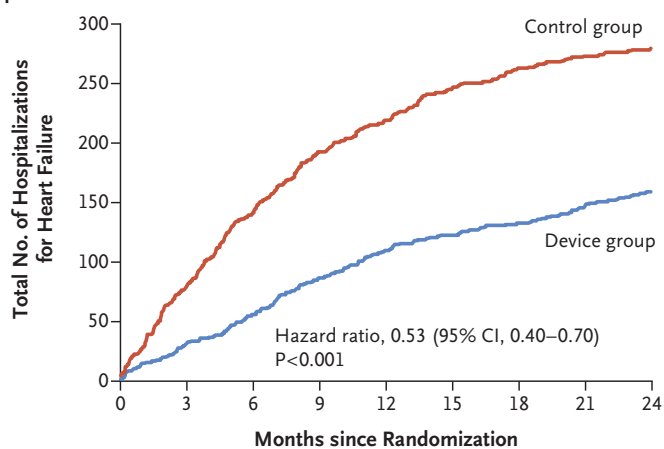
性，該患者的嚴重程度與本試驗中所見相似；在使用縮小的瓣環成形術環治療的存活患者中，2 年時二尖瓣關閉不全等級為 3+ 或更高的為 14.0%，58.8% 為 2+ 或更高。

COAPT trial 亦有一些研究侷限。首先，因為 MitraClip 在影像研究中是可見的，所以研究人員知道試驗組的分配。所以致力減輕偏差的方法包括嚴格的規定心臟超音波檢查程序，以及標準化指引性治療和使用獨立事件委員會及心臟超音波核心實驗室。雖然 device group 因心衰竭住院率較低，死亡率較低，且二尖瓣病變嚴重程度持續下降，生活品質和功能能力的提高和改進，該組都支持主要研究結果的有效性，儘管如此，仍不能完全排除潛在的偏見。第二，device group 追蹤時間的中位數長於對照組，部分原因是 device group 的死亡率較低。然而，對照組中退出試驗更為頻繁。在此對於缺失數據進行估算後，與主要結果是一致的。第三，renin-angiotension axis 的藥劑影響在 device group 的 baseline 使用頻率較高。在調整這些差異後，與主要研究結果仍是一致的。第四，為了充分表徵 MitraClip 的安全性和有效性，必須進行長達 5 年的長期追蹤。目前該分析的結果適用於 COAPT trial 中以 MitraClip 治療繼發性二尖瓣閉鎖不全；但是其他經導管手術方法或外科手術方法是否會有類似結果尚不確定。最後，所有納入的患者常伴有共存的情況包括儘管使用了最大劑量的指引性藥物治療（超過三分之一的患者接受了心臟再同步治療）仍然有症狀（NYHA II 級，III 級或 IVa [ambulatory]）並且具有中度至嚴重或嚴重的二尖瓣閉鎖不全以及 LVEF 為 20% 至 50%。但是，MitraClip 對於臨床病情較輕或再更加嚴重的患者，或二尖瓣逆流不太嚴重的患者是否具有相似的益處尚不得而知。

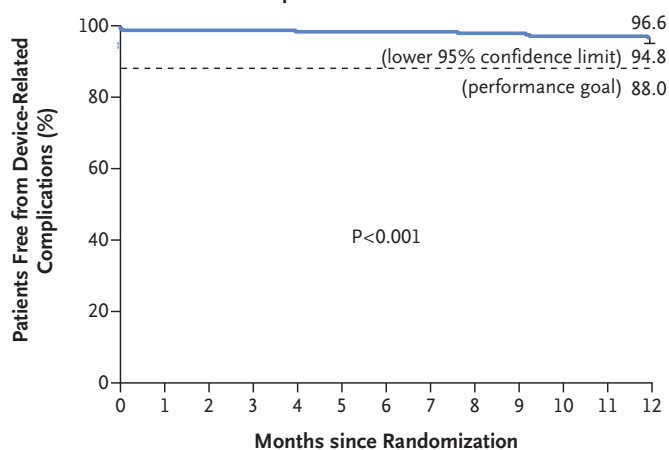
結論

在心衰竭合併中重度或嚴重繼發性二尖瓣逆流，儘管使用最大劑量的指引針對性藥物治療仍有症狀的患者中，經導管二尖瓣修復後發生心衰竭住院率較低，且追蹤 24 個月內的全因死亡率也低於單獨的藥物治療。與 device 相關併發症的 freedom rate 也超過了預定的安全閾值。

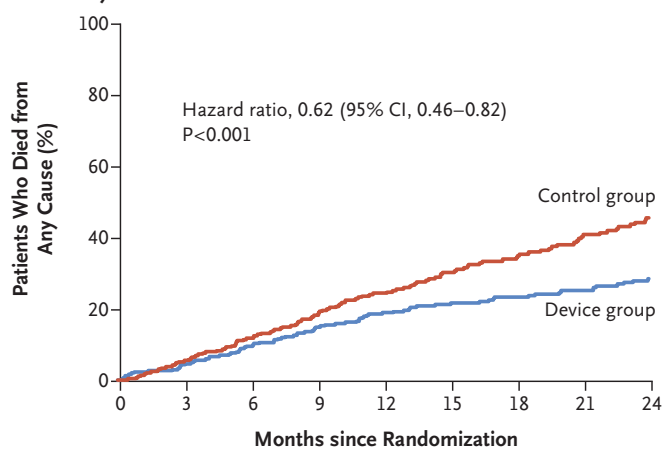
Table 2. Primary and Secondary End Points.*				
End Point	Device Group (N = 302)	Control Group (N = 312)	Hazard Ratio (95% CI)	P Value†
Primary				
Effectiveness: all hospitalizations for heart failure within 24 mo — no. of events/total no. of patient-yr (annualized rate)	160/446.5 (35.8)	283/416.8 (67.9)	0.53 (0.40 to 0.70)‡	<0.001§
Safety: freedom from device-related complications at 12 mo — Kaplan–Meier estimate of event-free rate (lower 95% confidence limit)	96.6 (94.8)	—	—	<0.001 for comparison with goal of 88.0%¶
Secondary, listed in hierarchical order				
Mitral regurgitation grade of 2+ or lower at 12 mo — no./total no. (%)	199/210 (94.8)	82/175 (46.9)	—	<0.001**
Death from any cause at 12 mo — no. of events (Kaplan–Meier estimate of event rate)	57 (19.1)	70 (23.2)	0.81 (0.57 to 1.15)††	<0.001 for noninferiority‡‡
Death or hospitalization for heart failure within 24 mo	—	—	—	<0.001§§
Change in KCCQ score from baseline to 12 mo — points¶¶	12.5±1.8	-3.6±1.9	16.1 (11.0 to 21.2)	<0.001***
Change in distance on 6-min walk test from baseline to 12 mo — m†††	-2.2±9.1	-60.2±9.0	57.9 (32.7 to 83.1)	<0.001***
All hospitalizations for any cause within 24 mo — no. of events/total no. of patient-yr (annualized rate)	474/446.5 (106.2)	610/416.8 (146.4)	0.76 (0.60 to 0.96)	0.02§
NYHA functional class of I or II at 12 mo — no./total no. (%)	171/237 (72.2)	115/232 (49.6)	—	<0.001**
Change in left ventricular end-diastolic volume from baseline to 12 mo — ml	-3.7±5.1	17.1±5.1	-20.8 (-34.9 to -6.6)	0.004***
Death from any cause within 24 mo — no. of events (Kaplan–Meier estimate of event rate)	80 (29.1)	121 (46.1)	0.62 (0.46 to 0.82)	<0.001‡‡‡
Freedom from death from any cause, stroke, myocardial infarction, and nonelective cardiovascular surgery for a device-related complication at 30 days — % (lower 95% confidence limit)	96.9 (94.7)	—	—	<0.001 for comparison with goal of 80.0%**

A Hospitalization for Heart Failure**No. at Risk**

Control group	312	294	271	245	219	176	145	121	88
Device group	302	286	269	253	236	191	178	161	124

B Freedom from Device-Related Complications**No. at Risk**

Device group	293	283	282	277	272	269	261	258	251	245	241	236	221
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C Death from Any Cause**No. at Risk**

Control group	312	294	271	245	219	176	145	121	88
Device group	302	286	269	253	236	191	178	161	124

Table 3. Adverse Events within 24 Months in the Intention-to-Treat Population.*

Event	Device Group (N = 302)	Control Group (N = 312)	Hazard Ratio (95% CI)	P Value
<i>no. of patients with event (Kaplan–Meier estimate of event rate)</i>				
Death from any cause	80 (29.1)	121 (46.1)	0.62 (0.46–0.82)	<0.001
Cardiovascular cause	61 (23.5)	97 (38.2)	0.59 (0.43–0.81)	0.001
Related to heart failure	28 (12.0)	61 (25.9)	0.43 (0.27–0.67)	<0.001
Not related to heart failure	33 (13.1)	36 (16.6)	0.86 (0.54–1.38)	0.53
Noncardiovascular cause	19 (7.3)	24 (12.7)	0.73 (0.40–1.34)	0.31
Hospitalization for any cause	194 (69.6)	228 (81.8)	0.77 (0.64–0.93)	0.01
Cardiovascular cause	138 (51.9)	180 (66.5)	0.68 (0.54–0.85)	<0.001
Related to heart failure	92 (35.7)	151 (56.7)	0.52 (0.40–0.67)	<0.001
Not related to heart failure	72 (29.4)	72 (31.0)	0.98 (0.71–1.36)	0.92
Noncardiovascular cause	124 (48.2)	128 (52.9)	0.91 (0.71–1.17)	0.47
Death or hospitalization for heart failure	129 (45.7)	191 (67.9)	0.57 (0.45–0.71)	<0.001
Death from cardiovascular cause or hospitalization for heart failure	117 (42.7)	177 (63.6)	0.56 (0.44–0.70)	<0.001
Unplanned mitral-valve intervention	10 (4.0)	15 (9.0)	0.61 (0.27–1.36)	0.23
MitraClip implantation	9 (3.7)	8 (6.6)	0.99 (0.38–2.58)	0.99
Mitral-valve surgery	1 (0.4)	7 (2.5)	0.14 (0.02–1.17)	0.07
PCI or CABG	7 (2.8)	13 (4.3)	0.62 (0.24–1.60)	0.32
PCI	7 (2.8)	11 (3.6)	0.75 (0.28–2.02)	0.57
CABG	0	2 (0.7)	—	—
Stroke	11 (4.4)	11 (5.1)	0.96 (0.42–2.22)	0.93
Myocardial infarction	12 (4.7)	14 (6.5)	0.82 (0.38–1.78)	0.62
New cardiac resynchronization therapy	7 (2.9)	8 (3.3)	0.85 (0.31–2.34)	0.75
LVAD implantation or heart transplantation	9 (4.4)	22 (9.5)	0.37 (0.17–0.81)	0.01
LVAD implantation	6 (3.0)	16 (7.1)	0.34 (0.13–0.87)	0.02
Heart transplantation	3 (1.4)	8 (3.6)	0.35 (0.09–1.32)	0.12

Intravascular Ultrasound-Guided Versus Angiography-Guided Implantation of Drug-Eluting Stent in All-Comers: The ULTIMATE trial.

Zhang J et al., J Am Coll Cardiol. 2018 Sep 17. pii: S0735-1097(18)38433-X. doi: 10.1016/j.jacc.2018.09.013.

Background

Intravascular ultrasound (IVUS)-guided drug-eluting stent (DES) implantation is associated with less major adverse cardiovascular events (MACE) compared with angiography guidance for patients with individual lesion subset. However, the beneficiary effect on MACE outcome of IVUS guidance over angiography guidance in all-comers who undergo DES implantation still remains understudied.

Objectives

This study aimed to determine the benefits of IVUS guidance over angiography guidance during DES implantation in all-comer patients.

Methods

A total of 1448 all-comer patients who required DES implantation were randomly assigned (1:1 ratio) to either IVUS guidance or Angiography guidance group. Primary endpoint was target vessel failure (TVF) at 12 months, including cardiac death, target vessel myocardial infarction (TV-MI), and clinically-driven target vessel revascularization (TVR). Procedure was defined as success if IVUS-defined all optimal criteria were met.

Results

At 12 months follow-up, 60 (4.2%) TVFs occurred, with 21 (2.9%) in the IVUS group and 39 (5.4%) in the Angiography group (hazard ratio [HR] 0.530, 95% confidence interval [CI] 0.312-0.901; $p=0.019$). In the IVUS group, TVF was recorded in 1.6% of patients with successful procedures, compared to 4.4% in patients who failed to achieve all optimal criteria (HR: 0.349; 95%CI: 0.135-0.898; $p=0.029$). The significant reduction of clinically-driven target lesion revascularization (TLR) or definite stent thrombosis (HR: 0.407; 95% CI: 0.188-0.880; $p=0.018$) based-on lesion level analysis by IVUS guidance was not achieved when patient-level analysis was performed.

Conclusions

The present study demonstrated that IVUS-guided DES implantation significantly improved clinical outcome in all-comers, particularly for patients who had an IVUS-defined optimal procedure, compared to angiography guidance.

IVUS-guided PCI 對於”All-comers”，包括非複雜性冠狀動脈疾病的藥物支架介入是否有助益？ - the ULTIMATE trial

編譯：中國醫藥大學附設醫院 內科部心臟血管系 陳科維醫師

血管內影像包括 IVUS、OCT 的發展對於心血管介入治療的進步至關重要，IVUS 能夠提供過去單純血管造影上所無法了解的重要資訊，包括病灶近遠端參考管徑、實際血管大小、斑塊分佈及性質、支架植入後的效果及是否有併發症等。過去的許多研究已經證實了 IVUS-guided PCI 在處理複雜冠狀動脈病變，包括 CTO、長病灶或左主幹，以及高危的急性冠心症（如不穩定性心絞痛合併複雜分叉病變）時，能夠改善藥物支架植入的預後。然則對於我們每天處理的大多數患者，包括 type A-B1 的非複雜性冠狀動脈病變，IVUS-guided PCI 是否有帶來幫助則未有共識。今年的 TCT 2018 會議上公布的 ULTIMATE trial 為我們提供了答案：在隨機分配至 angiography-guided 和 IVUS-guided 兩組的 “All-comers”，臨床情況包含 silent ischemia、穩定性心絞痛到心肌梗塞患者，病灶涵蓋 type A, B1/2 到 C，結果顯示 IVUS-guided PCI 仍能提供明顯助益，改善臨床預後。以下簡述此臨床試驗的設計及重要結果。

方法

這個前瞻性的 RCT 研究主要由 8 個醫學中心參與，納入 1448 位接受冠狀動脈介入治療的 “all-comers”，涵蓋了 silent ischemia, stable or unstable angina 和 myocardial infarction（包括 ST-elevation MI 和 non-ST elevation MI; onset > 24hours before admission）。排除發生 24 小時之內 MI、未開通的 CTO 病變、需進行旋磨的重度鈣化及其他如預期壽命小於一年、無法耐受雙重血小板治療等。參與試驗的手術醫師均須有年 200 例以上的冠狀動脈介入經驗。主要試驗終點 (primary endpoint) 為 index procedure 後 12 個月的 target vessel failure (TVF) 比例，包括 cardiac death（排除有明確非心臟死因）、target vessel myocardial infarction 和 clinical driven target vessel revascularization (TLR)。

試驗中也對 Angiography-guided 和 IVUS-guided 兩組是否達到各自影像上的理想標準進行評估，分別定義如下：

Angiography：stent/vessel ratio 1.1:1.0, non-compliance balloon/stent 1:1 達到大於 18atm，由手術者肉眼評估 TIMI-3 flow，residual stenosis<20%，沒有 type B 以上 dissection。

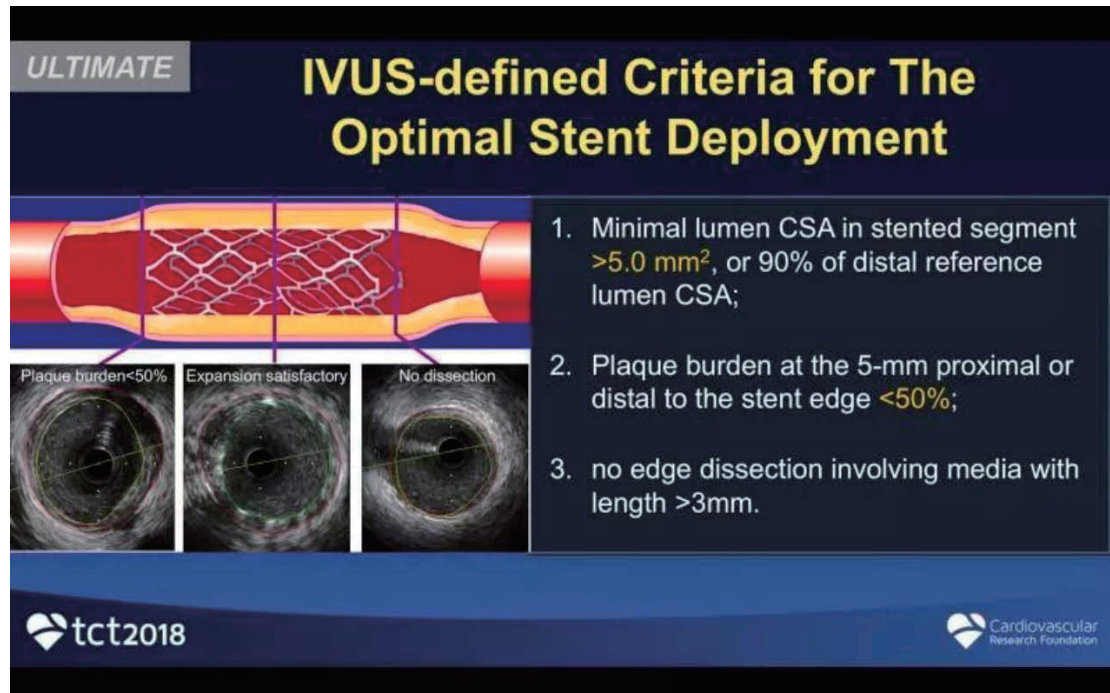
IVUS：

Reference site plaque burden < 40%，stent size = distal reference lumen diameter*1.0 或 media diameter*0.8，landing zone plaque burden <50%，non-compliance balloon/stent 1:1 達到大於 18atm。

IVUS 評估 optimal stent deployment 的定義為：

1. 術後支架段 MLA (minimal lumen area) > 5mm², 或達到遠端 reference vessel 截面積的 90%。
2. 支架前後緣 (stent edge) 5mm 內 plaque burden <50%。
3. 沒有深度到中膜 (media)，長度超過 3mm 的 edge dissection。

以上三項均需滿足才為達標。



結果及討論

Angiography-guided 和 IVUS-guided 兩組各為 724 位患者接受 DES (Everolimus, Zotarolimus, Sirolimus-eluting stent) 植入，全部 1448 位患者中有 78.5% 為急性冠心症（多為 unstable angina, 佔六到七成），54% 為 multi-vessel disease，AHA/ACC type B2/C 病灶為 66.4%。與 angiography-guided 組相較，IVUS 組的患者會植入更大的支架 ($3.15 \pm 0.42 \text{ mm}$ vs. $2.99 \pm 0.38 \text{ mm}$, $p < 0.001$)，以較大的後擴張球囊 ($3.84 \pm 0.52 \text{ mm}$ vs. $3.62 \pm 0.51 \text{ mm}$, $p < 0.001$) 打到更高的壓力 ($19.8 \pm 3.7 \text{ atm}$ vs. $19.2 \pm 3.6 \text{ atm}$, $p = 0.003$)。IVUS 組也相關於較長的手術時間和較多的顯影劑使用量，但並未造成更多的 contrast-induced nephropathy (CIN)。

兩組的 statin 使用率均達 95% 以上，LDL 相近。DAPT 使用到 12 個月的比例也都達到 96-97%。（但並未比較使用 Plavix、Ticagrelor 的比例）

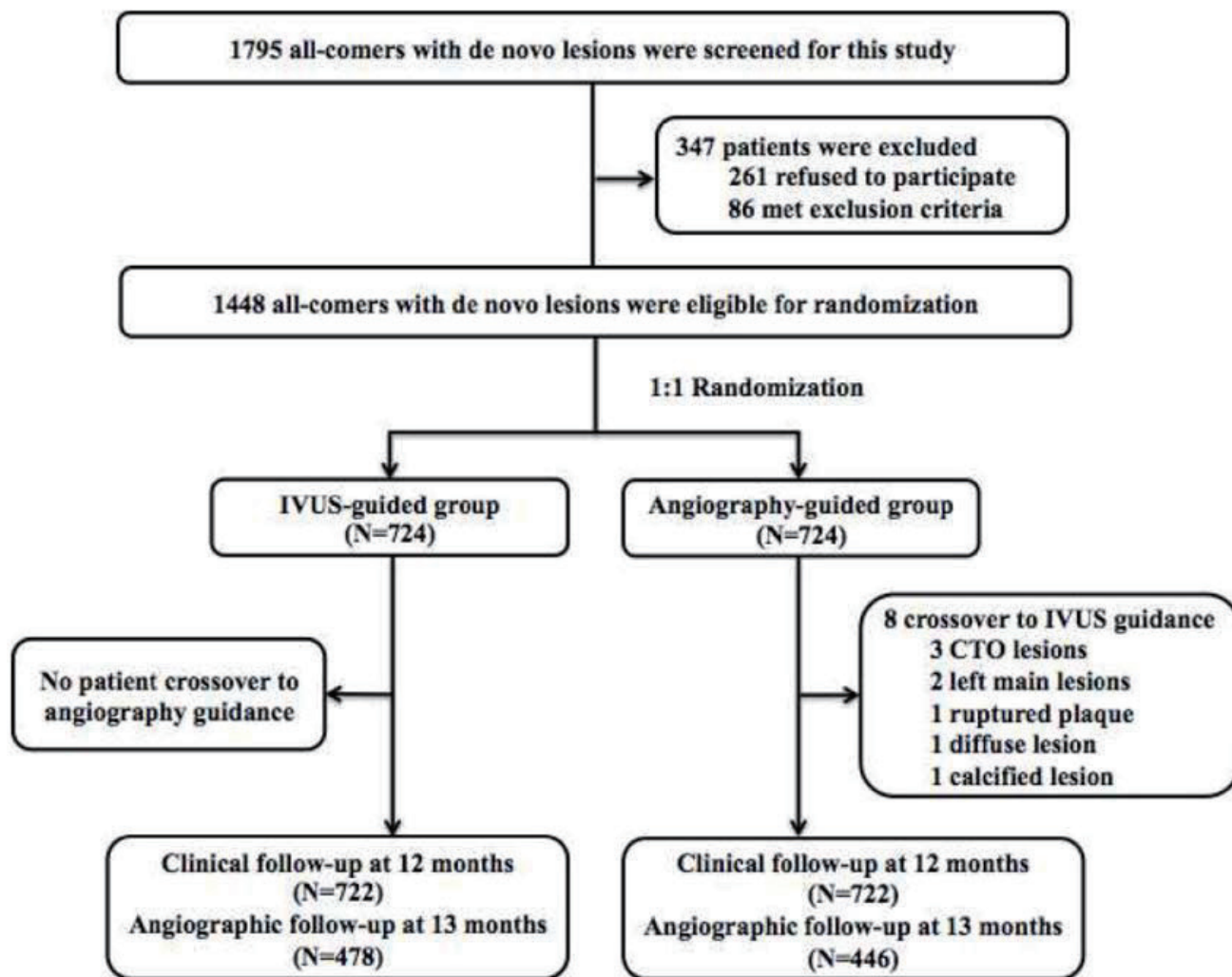
圖二中顯示兩組 primary endpoint 的比較：術後 12 個月的 TVF 比例，IVUS 組為 2.9%，明顯低於 angiography 組 (5.4%；HR: 0.530；95% CI: 0.312-0.901； $p = 0.019$)。其餘心因性死亡、target vessel MI、clinical-driven TVR or definite ST 則未達到統計學上差異，但仍有 IVUS 組較低的趨勢。

圖三 C，base on 病灶的分析來看，IVUS guidance PCI 能明顯減少 clinical-driven TLR 或 definite stent thrombosis。

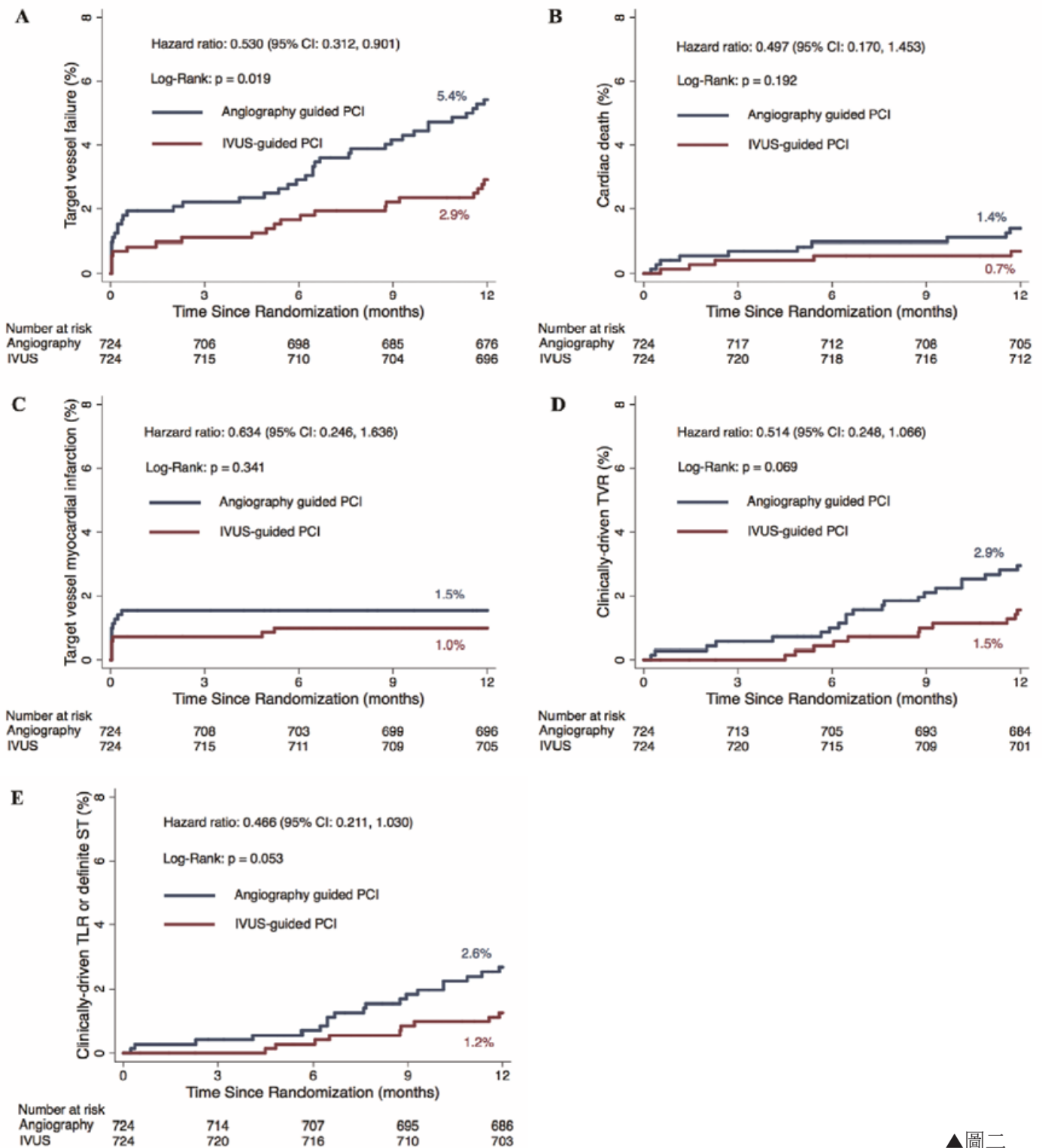
值得注意的是，若將 IVUS 組再細分，在 IVUS 達標的患者中術後 12 個月的 TVF 比例為 1.6%，更低於未達標組的 4.4% (HR 0.349；95% CI 0.135-0.898； $p = 0.029$)。

結語

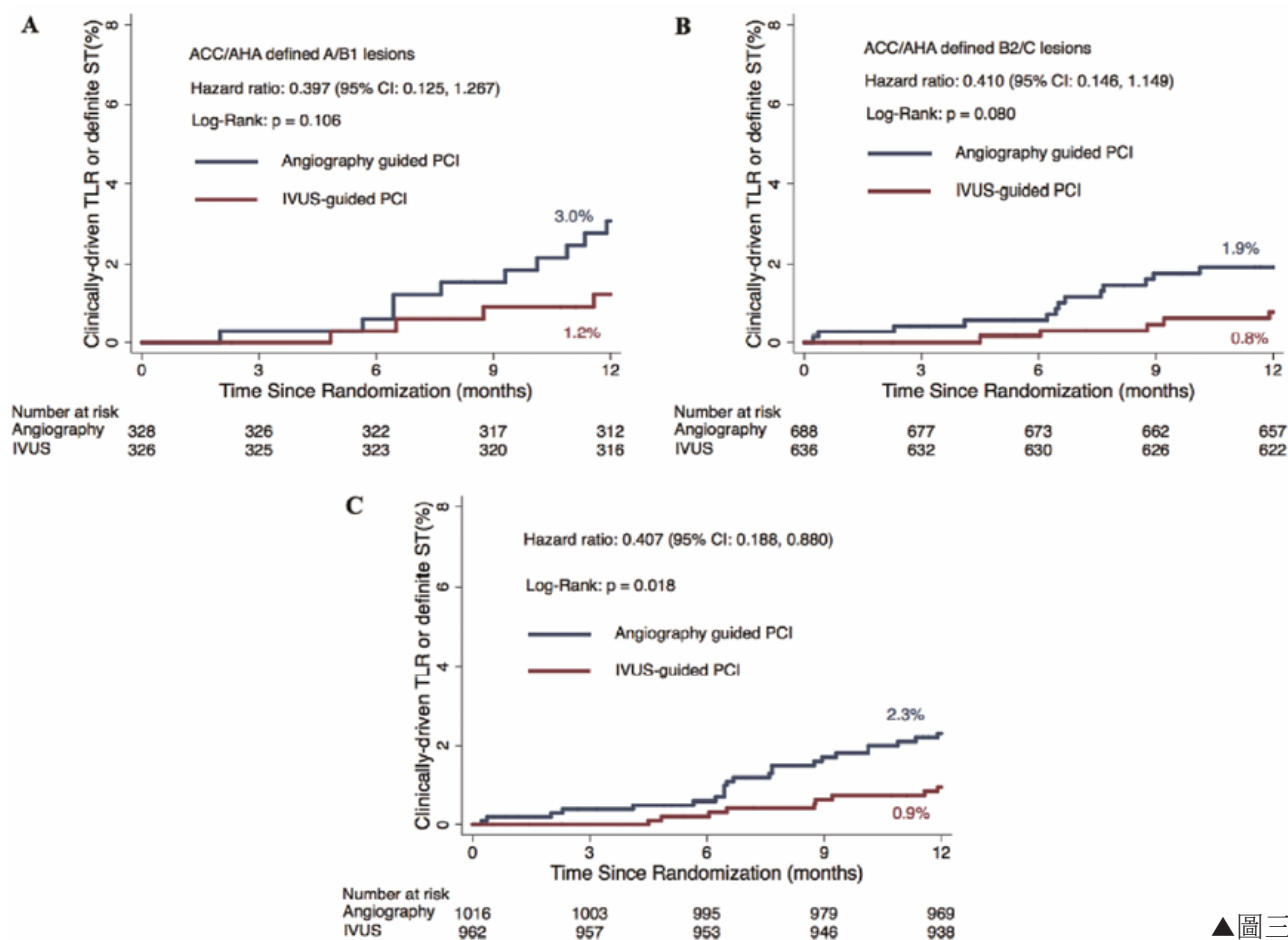
ULTIMATE trial 傳遞出了很重要的訊息：IVUS-guide DES implantation 對 all-comers 能藉由明顯降低 target vessel failure 比例來改善臨床預後。如能依據前文所述 IVUS 的 criteria 達成 optimal stent deployment，則更能大幅降低不良預後。隨著各種血管內影像工具解析度的進步，使用便利性的提升，以血管內影像的導引來優化支架的植入將是目前介入治療的趨勢。



▲圖一



▲圖二



▲圖三

An Open-Label Randomized Trial Comparing Oral Anticoagulation with and without Single Antiplatelet Therapy in Patients with Atrial Fibrillation and Stable Coronary Artery Disease Beyond One Year after Coronary Stent Implantation: The OAC-ALONE Study

Yukiko Matsumura-Nakano et al., published 24 Sep 2018 Circulation

Background

Despite recommendations in the guidelines and consensus documents, there has been no randomized controlled trial evaluating oral anticoagulation (OAC) alone without antiplatelet therapy (APT) in patients with atrial fibrillation (AF) and stable coronary artery disease (CAD) beyond 1 year after coronary stenting.

Methods

This study was a prospective, multicenter, open-label, non-inferiority trial, comparing OAC alone to combined OAC and single APT among AF patients beyond 1 year after stenting in a 1:1 randomization fashion. The primary endpoint was a composite of all-cause death, myocardial infarction (MI), stroke, or systemic embolism. The major secondary endpoint was a composite of primary endpoint or major bleeding according to the International Society on Thrombosis and Haemostasis (ISTH) classification. Although the trial was designed to enroll 2,000 patients during 12 months, enrollment was prematurely terminated after enrolling 696 patients in 38 months.

Results

Mean age was 75.0 ± 7.6 years, and 85.2% of patients were men. OAC was warfarin in 75.2% and direct oral anticoagulants in 24.8% of patients. The mean CHADS2 score was 2.5 ± 1.2 . During a median follow-up interval of 2.5 years, the primary endpoint occurred in 54 patients (15.7%) in the OAC alone group and in 47 patients (13.6%) in the combined OAC and APT group (HR, 1.16; 95% confidence interval [CI], 0.79-1.72; $P=0.20$ for non-inferiority; $P=0.45$ for superiority). The major secondary endpoint occurred in 67 patients (19.5%) in the OAC alone group and in 67 patients (19.4%) in the combined OAC and APT group (HR, 0.99; 95% CI, 0.71-1.39; $P=0.016$ for non-inferiority; $P=0.96$ for superiority). MI occurred in 8 (2.3%) and 4 (1.2%) patients, while stroke or systemic embolism occurred in 13 (3.8%) and 19 (5.5%) patients, respectively. Major bleeding occurred in 27 (7.8%) and 36 (10.4%) patients, respectively.

Conclusions

This randomized trial did not establish non-inferiority of OAC alone to combined OAC and APT in patients with AF and stable CAD beyond 1 year after stenting. Because patient enrollment was prematurely terminated, the study was underpowered and inconclusive. Future larger studies are required to establish the optimal antithrombotic regimen in this population.

An Open-Label Randomized Trial 比較單獨使用口服抗凝血藥與口服抗凝血藥合併抗血小板藥物治療於穩定冠狀動脈疾病在冠狀動脈支架置入一年後之心房顫動患者：The OAC-ALONE Study

編譯：中國醫藥大學附設醫院 內科部心臟血管系 呂尚謁醫師

背景：

針對心房顫動 (AF) 合併心臟冠狀動脈支架置放術後 (CAD with stenting) 的病人，口服抗凝血劑的指引建議置放支架一年後可單用抗凝血劑 (OAC)，不需要抗血小板治療 (APT)。但是目前並沒有大型隨機臨床試驗支持這樣的建議。

方法：

此項研究是一項前瞻性，多中心，開放標籤，非劣效性試驗，AF 患者進行支架術後 1 年，比較單獨 OAC 治療與合併 OAC 和一種 APT 治療之間的差異，以 1：1 的隨機化方式分配病人。主要終點是全因死亡，心肌梗塞 (MI)，中風或全身性栓塞的綜合。根據國際血栓形成和止血學會 (ISTH) 分類，主要次要終點是主要終點或大出血的複合。儘管該試驗的目的是在 12 個月內招募 2,000 名患者，但在 38 個月內招募了 696 名患者後，患者招募提前終止。

結果：

平均年齡為 75.0 ± 7.6 歲，85.2% 的患者為男性。OAC 為 75.2% 的 warfarin，24.8% 患者為直接口服抗凝劑。平均 CHADS2 評分為 2.5 ± 1.2 。在中位隨訪時間間隔為 2.5 年時，主要終點發生在 OAC 單獨組中的 54 名患者 (15.7%) 和組合 OAC 和 APT 組中的 47 名患者 (13.6%) (HR, 1.16; 95% 信賴區間 0.79-1.72; 非劣效性 $P = 0.20$; 優勢 $P = 0.45$)。主要次要終點發生在 OAC 單獨組的 67 名患者 (19.5%) 和組合 OAC 和 APT 組中的 67 名患者 (19.4%) 中 (HR, 0.99; 95% 信賴區間 0.71-1.39; 非劣效性 $P = 0.016$; 優勢 $P = 0.96$)。心肌梗塞發生於 8 例 (2.3%) 和 4 例 (1.2%) 的患者中，而腦中風或全身性栓塞分別發生在 13 例 (3.8%) 和 19 例 (5.5%) 患者中。大出血分別發生在 27 例 (7.8%) 和 36 例 (10.4%) 患者中。

結論：

對於 AF 患者合併冠狀動脈支架置放一年後，這項隨機試驗未確定 OAC 單獨使用和合併 OAC 和 APT 治療一樣好。由於患者入組過早終止，該研究的強度不足且尚無定論。未來需要進行更大規模的研究才能確定該人群的最佳抗血栓策略。

Table 1. Baseline Characteristics

Characteristics	OAC alone		Combined OAC and APT	
	(N=344)		(N=346)	
Age, y	74.9±0.4		75.2±0.4	
Age ≥75 y	190	(55.2)	185	(53.5)
Male sex	294	(85.5)	294	(85.0)
Body mass index	24.3±3.4		24.4±3.4	
Hypertension	292	(84.9)	301	(87.0)
Diabetes mellitus	152	(44.2)	138	(39.9)
On insulin therapy	30	(8.7)	26	(7.5)
Dyslipidemia	294	(85.5)	298	(86.1)
Current smoker	27	(7.9)	23	(6.7)
Heart failure	140	(40.7)	151	(43.6)
Ejection fraction ≤40 %	49	(15.2)	60	(18.6)
Prior myocardial infarction	129	(37.5)	137	(39.6)
Prior stroke	55	(16.0)	49	(14.2)
Aortic/Peripheral vascular disease	40	(11.6)	42	(12.1)
eGFR <30 ml/min/1.73m ² , not on hemodialysis	34	(10.0)	17	(4.9)
Hemodialysis	2	(0.6)	2	(0.6)
Anemia (Hemoglobin <11 g/dl)	44	(12.9)	34	(9.9)
Thrombocytopenia (Platelet <10×10 ⁴ /μl)	12	(3.5)	18	(5.2)
Chronic obstructive pulmonary disease	12	(3.5)	14	(4.1)
Chronic liver disease	10	(2.9)	6	(1.7)
Malignancy	53	(15.4)	52	(15.0)
CHADS ₂ score	2.6±1.2		2.5±1.2	
0	11	(3.2)	9	(2.6)
1	49	(14.2)	59	(17.1)
2	112	(32.6)	118	(34.1)
≥3	172	(50.0)	160	(46.2)
CHA ₂ DS ₂ -VASc score	4.6±1.4		4.6±1.4	
0	0	(0.0)	0	(0.0)
1	1	(0.3)	3	(0.9)
2	20	(5.8)	15	(4.3)
≥3	323	(93.9)	328	(94.8)
HAS-BLED score				
0	0	(0.0)	0	(0.0)
1	18	(5.2)	12	(3.5)
2	176	(51.2)	179	(51.7)
≥3	150	(43.6)	155	(44.8)
Type of atrial fibrillation				
Paroxysmal	158	(45.9)	143	(41.3)
Persistent	27	(7.9)	23	(6.7)
Permanent	159	(46.2)	180	(52.0)

Procedural characteristics				
Number of PCI procedures	1 (1-3)		1 (1-2)	
Number of stents	2 (1-3)		2 (1-3)	
Type of stent				
Drug-eluting	246	(71.7)	240	(70.6)
1st generation	80	(23.4)	74	(22.0)
2nd generation	165	(48.3)	163	(48.4)
Bare metal	97	(28.3)	100	(29.4)
Left main coronary stenting	23	(6.7)	22	(6.4)
Multivessel stenting	119	(34.6)	119	(35.0)
Years from the last PCI	4.4 (1.8-7.7)		4.6 (2.4-7.4)	
Medications				
Aspirin	294	(85.5)	299	(86.4)
Clopidogrel	52	(15.1)	48	(13.9)
Warfarin	255	(74.1)	264	(76.3)
INR at enrollment	2.05 (1.81-2.35)		2.02 (1.80-2.27)	
DOACs	89	(25.9)	82	(23.7)
Approved dose	72	(80.9)	68	(82.9)
Standard dose	35	(39.3)	40	(48.8)
Reduced dose	37	(41.6)	28	(34.1)
Non-approved dose	17	(19.1)	14	(17.1)
Over-dose	4	(4.5)	0	(0)
Under-dose	13	(14.6)	14	(17.1)
Dabigatran	21	(23.6)	20	(24.4)
Rivaroxaban	24	(27.0)	17	(20.7)
Apixaban	32	(36.0)	37	(45.1)
Edoxaban	12	(13.5)	8	(9.8)
Statins	268	(77.9)	277	(80.1)
Beta-blockers	219	(63.7)	234	(67.6)
ACE-I/ARB	227	(66.0)	235	(67.9)
NSAIDs	15	(4.4)	16	(4.6)
Proton pump inhibitors	183	(53.2)	216	(62.4)

Categorical variables were presented as number (percentage), and continuous variables were presented mean $\pm$ standard deviation or median with interquartile range. Values were missing for body mass index in 14 patients, ejection fraction in 44 patients, eGFR in 5 patients, anemia in 3 patients, thrombocytopenia in 3 patients, number of PCI procedures in 3 patients, number of stents in 3 patients, type of stent in 1 patient, and type of drug-eluting stent in 5 patients. ACE-I=angiotensin-converting enzyme inhibitor; APT=antiplatelet therapy; ARB=angiotensin receptor blocker; DOACs=direct oral anticoagulants; eGFR=estimated glomerular filtration rate; INR=international normalized ratio; NSAIDs=non-steroidal anti-inflammatory drugs; OAC=oral anticoagulation; PCI=percutaneous coronary intervention.

Table 2. Clinical Outcomes

Endpoints	OAC alone		Combined OAC and APT		Hazard Ratio (95% CI)	P value for non-inferiority	P value
	(N=344)		(N=346)				
	N of patients with event (Crude incidence rate /Annualized event rate, %)						
Primary endpoint:							
A composite of all-cause death, myocardial infarction, stroke, or systemic embolism	54	(15.7/6.4)	47	(13.6/5.5)	1.16 (0.79-1.72)	0.20	0.45
Major secondary endpoint:							
A composite of all-cause death, myocardial infarction, stroke, systemic embolism, or ISTH major bleeding	67	(19.5/8.1)	67	(19.4/8.2)	0.99 (0.71-1.39)	0.016	0.96
Other secondary endpoints:							
All-cause death	40	(11.6/4.6)	31	(9.0/3.5)	1.30 (0.82-2.10)		0.27
Cardiovascular death	20	(5.8/2.3)	17	(4.9/1.9)	1.18 (0.62-2.28)		0.62
Myocardial infarction	8	(2.3/0.93)	4	(1.2/0.46)	2.03 (0.64-7.59)		0.23
Stent thrombosis	2	(0.58/0.23)	0	(0.0/0.0)	NA*		0.15†
Stroke or systemic embolism	13	(3.8/1.5)	19	(5.5/2.2)	0.69 (0.33-1.38)		0.29
Stroke‡	13	(3.8/1.5)	18	(5.2/2.1)	0.73 (0.35-1.47)		0.38
Ischemic stroke	12	(3.5/1.4)	12	(3.5/1.4)	1.01 (0.45-2.27)		0.99
Hemorrhagic stroke	4	(1.2/0.46)	6	(1.7/0.69)	0.66 (0.17-2.32)		0.52
Systemic embolism	1	(0.29/0.11)	2	(0.58/0.23)	0.94 (0.81-1.09)		0.42
ISTH major bleeding	27	(7.8/3.2)	36	(10.4/4.3)	0.73 (0.44-1.20)		0.22
Fatal bleeding	7	(2.0/0.80)	4	(1.2/0.45)	1.77 (0.54-6.77)		0.35
Intracranial bleeding	9	(2.6/1.0)	14	(4.0/1.6)	0.63 (0.26-1.43)		0.27
TIMI major bleeding	17	(4.9/1.9)	29	(8.4/3.4)	0.57 (0.31-1.03)		0.07
minor bleeding	5	(1.5/0.58)	6	(1.7/0.69)	0.84 (0.24-2.78)		0.77
Hospitalization for heart failure	39	(11.3/4.7)	41	(11.8/4.9)	0.96 (0.62-1.49)		0.85
Post hoc endpoints:							
Ischemic endpoint							
A composite of cardiovascular death, myocardial infarction, ischemic stroke, or systemic embolism	36	(10.5/4.2)	31	(9.0/3.6)	1.17 (0.73-1.91)	0.32	0.51
Ischemic or bleeding endpoint							
A composite of cardiovascular death, myocardial infarction, ischemic stroke, systemic embolism, or ISTH major bleeding	55	(16.0/6.7)	59	(17.1/7.2)	0.92 (0.64-1.33)	0.009	0.66

Data were presented as number of patients with event, crude and annualized incidence rates, and hazard ratios with 95% CIs of OAC alone relative to combined OAC and APT for each endpoint by the Cox proportional hazard model. The annualized event rate represented the average number of events per patient during a 1-year period.

* Not available because of no event in the combined OAC and APT group.

† Assessed by the log-rank test. All other P values were assessed by the Cox proportional hazard models.

‡ The sum of the numbers of ischemic and hemorrhagic stroke events was not necessarily equal to the number of overall stroke events because of 3 patients with both ischemic and hemorrhagic stroke in the OAC alone group.

APT=antiplatelet therapy; CI=confidence interval; ISTH=International Society on Thrombosis and Haemostasis; NA=not available; OAC=oral anticoagulation; TIMI=Thrombolysis in Myocardial Infarction.

Table 3. Details of Patients with Myocardial Infarction

Patient	Age	Gender	Assigned	Years from	At enrollment			Days from	ARC	STEMI	Stent	Fatal	At the time of event		
Number			therapy	the last PCI	OAC	APT	INR	enrollment	Classification		thrombosis		OAC	APT	INR
2	78	Female	OAC alone	13.9	Warfarin		2.40	833	Spontaneous	No	No	No	Warfarin		2.41
50	80	Female	OAC alone	5.9	Warfarin		2.44	35	Spontaneous	NA	No	Yes	Warfarin		3.22
83	74	Male	OAC alone	4.8	Warfarin		1.76	447	Spontaneous	Yes	Yes	No	Warfarin		1.66
163	81	Male	OAC plus APT	6.2	Warfarin	Aspirin	2.17	288	Spontaneous	No	No	No	Warfarin	Aspirin	NA
175	73	Male	OAC plus APT	1.5	Warfarin	Aspirin	2.26	131	Spontaneous	Yes	No	No	Warfarin	Aspirin	1.58
286	77	Male	OAC plus APT	4.5	Warfarin	Aspirin	1.62	403	Spontaneous	No	No	No	Warfarin	Aspirin	2.15
289	85	Male	OAC plus APT	2.9	Warfarin	Aspirin	2.76	389	Spontaneous	No	No	No	Warfarin	Aspirin	2.01
329	80	Male	OAC alone	7.0	Warfarin		1.70	537	Spontaneous	No	No	No	Warfarin		2.87
337	82	Male	OAC alone	2.7	Warfarin		1.67	42	Spontaneous	No	No	No	Warfarin		1.31
349	77	Male	OAC alone	4.5	Warfarin		3.18	372	Spontaneous	No	No	No	Warfarin		2.07
416	81	Male	OAC alone	3.3	Warfarin		1.83	252	Spontaneous	Yes	Yes	No	Warfarin		1.62
547	74	Male	OAC alone	2.3	Warfarin		2.26	679	Spontaneous	No	No	No	Warfarin		2.03

APT=antiplatelet therapy; ARC=Academic Research Consortium; INR=international normalized ratio; NA=not available; OAC=oral anticoagulation; PCI=percutaneous coronary intervention; STEMI=ST-segment elevation myocardial infarction.

Stent thrombosis in the patient No. 83 occurred 6.0 years after implantation of a sirolimus-eluting stent, and stent thrombosis in the patient No. 416 occurred 12.7 years after implantation of a bare-metal stent.

Figure 1. Study Flow Chart. Follow-up interval was presented as median with interquartile range. * Final follow-up data were collected between October 1, 2017 and May 18, 2018.

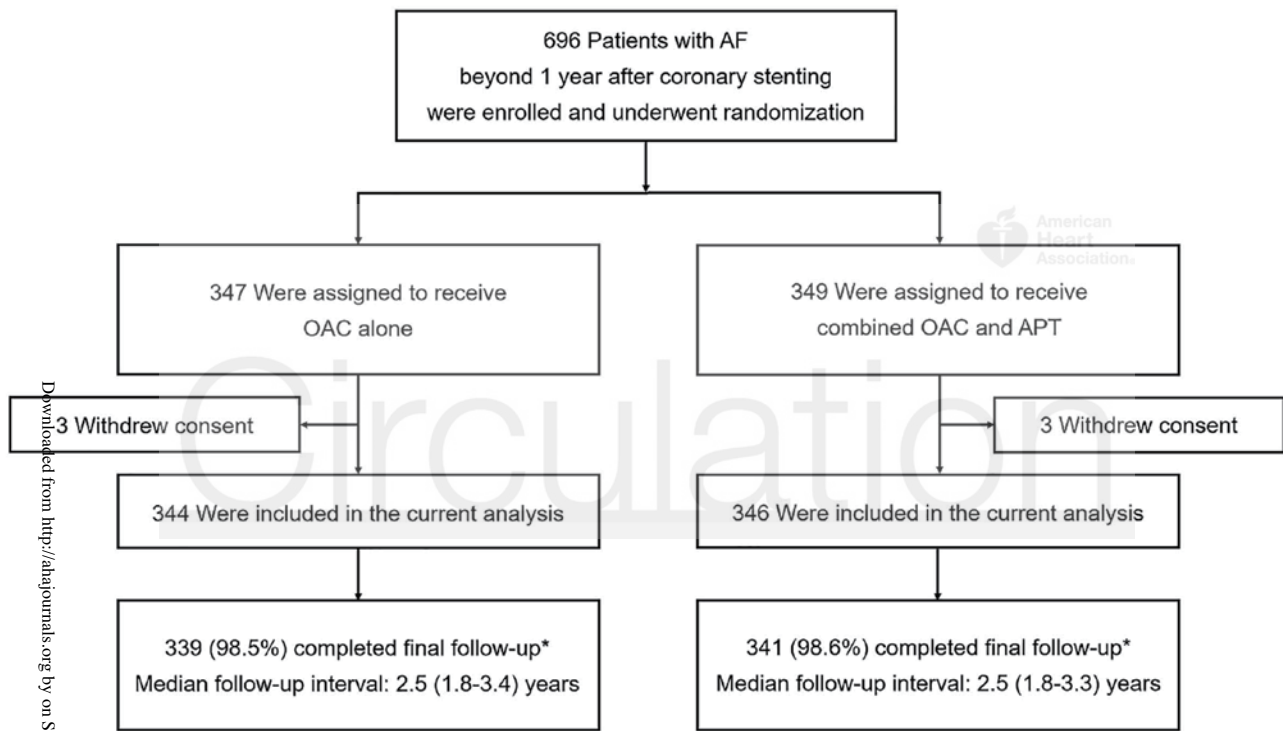
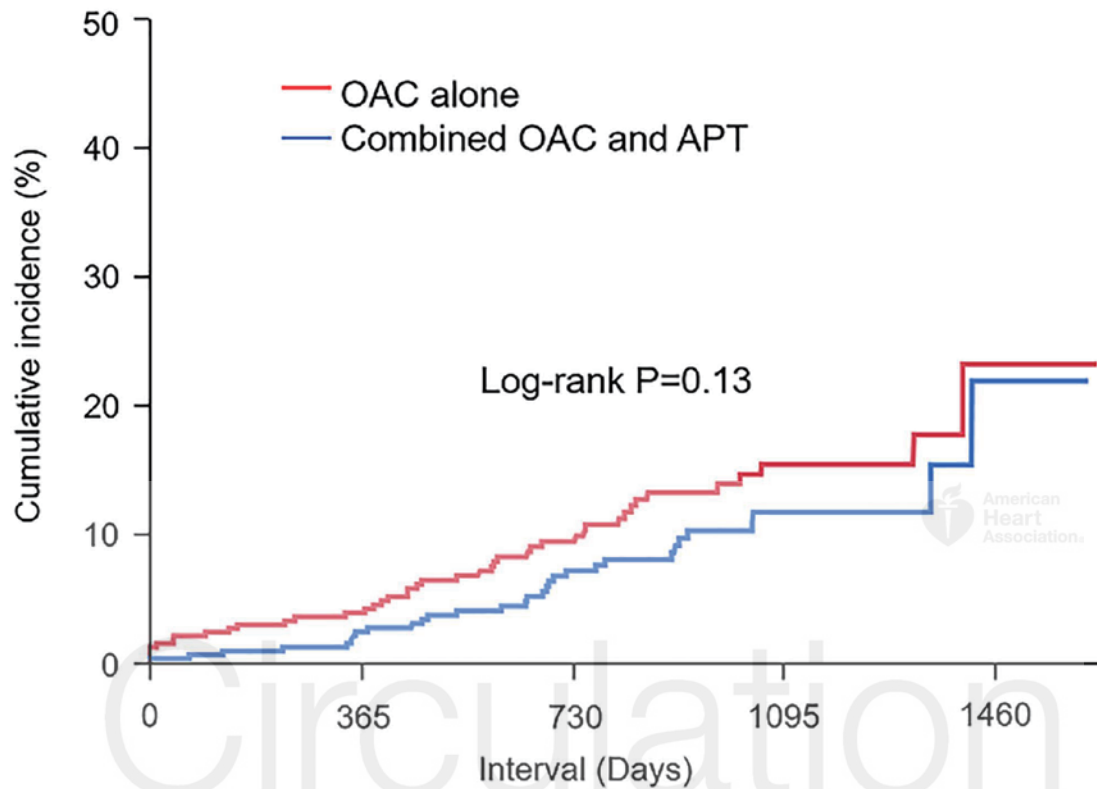


Figure 2. Cumulative Incidence of Crossover from the Original Regimen.

Crossover indicated changes in antithrombotic regimen from OAC alone to OAC plus APT



Interval (Days)	0	365	730	1095	1460
OAC alone					
N of patients at risk	344	311	214	105	10
N of patients with crossover		13	29	40	42
Cumulative Incidence		3.8%	9.4%	15.4%	23.1%
Combined OAC and APT					
N of patients at risk	346	323	227	109	10
N of patients with crossover		8	21	29	31
Cumulative Incidence		2.4%	7.1%	11.6%	21.8%

Figure 3. Time in Therapeutic Range in Patients Receiving Warfarin.

(A) Time spent below, within, and above the predefined therapeutic INR range based on the Japanese guidelines, (B) Time spent below, within, and above the post hoc therapeutic INR range of 2.0-3.0, and (C) Time spent in the INR ranges of <1.6, 1.6-2.0, 2.0-2.6, 2.6-3.0, and >3.0.

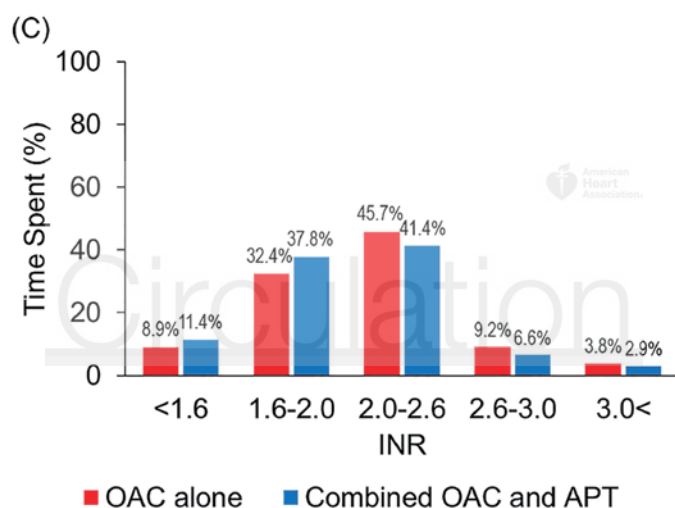
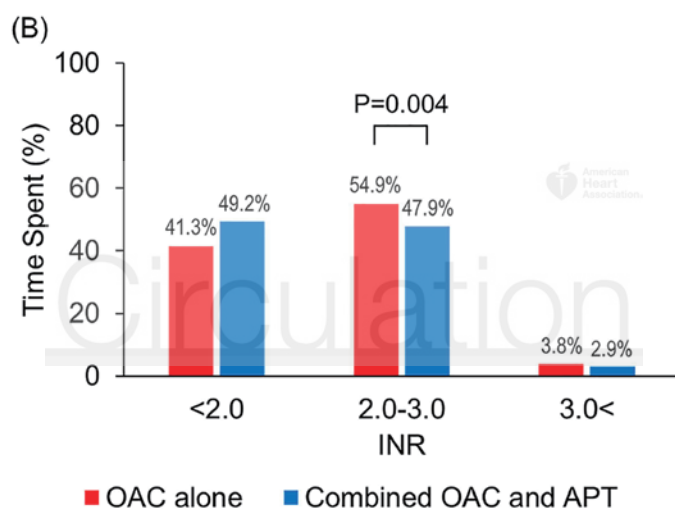
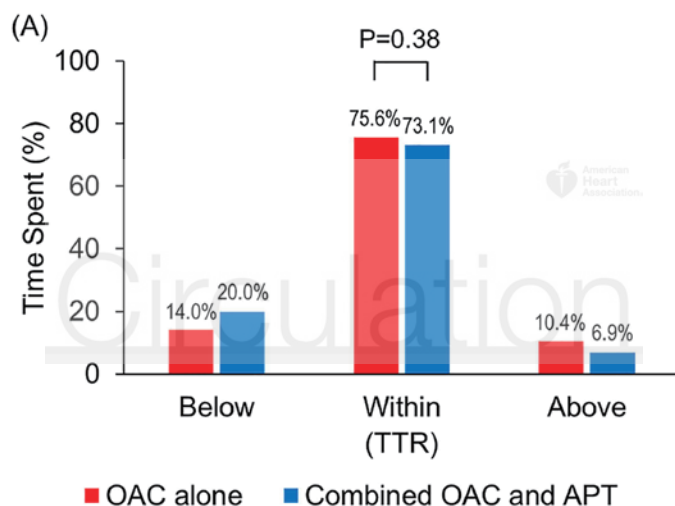


Figure 4. Cumulative Incidence of the Primary and Major Secondary Endpoints. KaplanMeier curves showing the cumulative incidence of the (A) Primary endpoint (a composite of allcause death, myocardial infarction, stroke, or systemic embolism), and (B) Major secondary endpoint (a composite of primary endpoint or major bleeding).

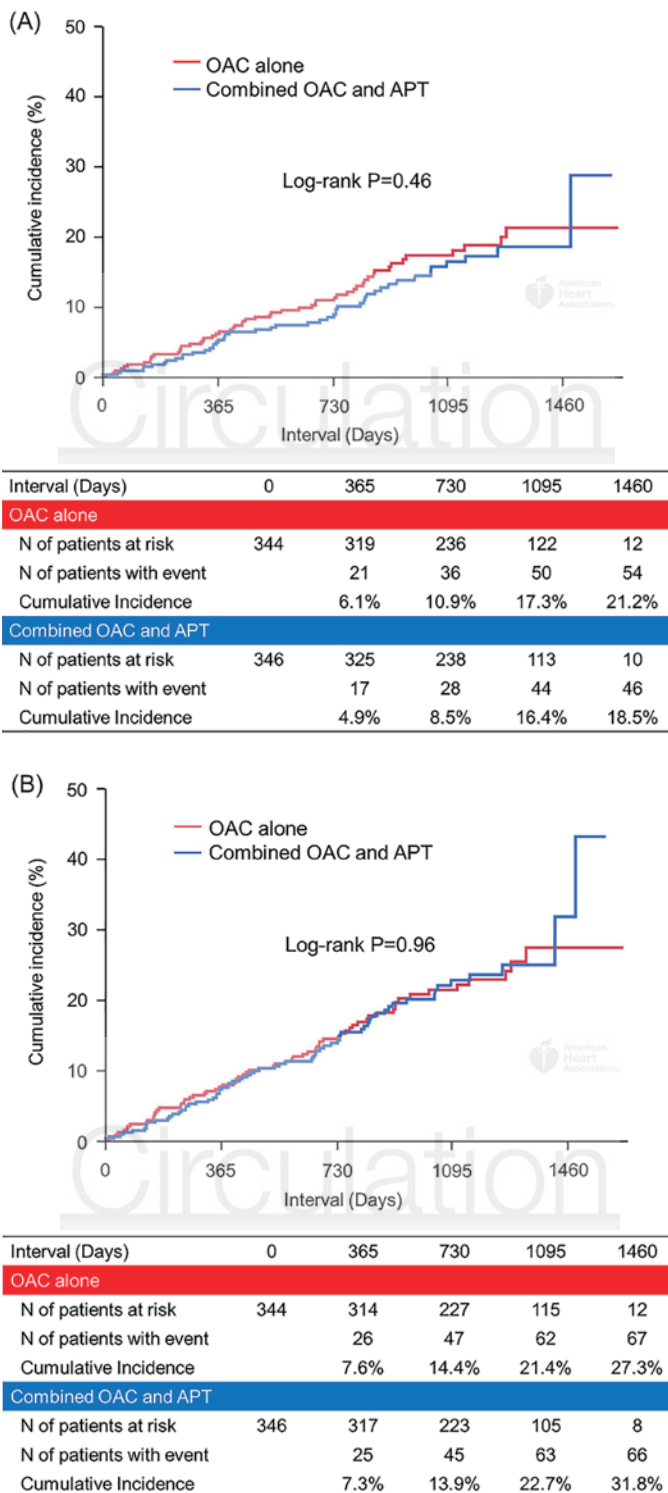
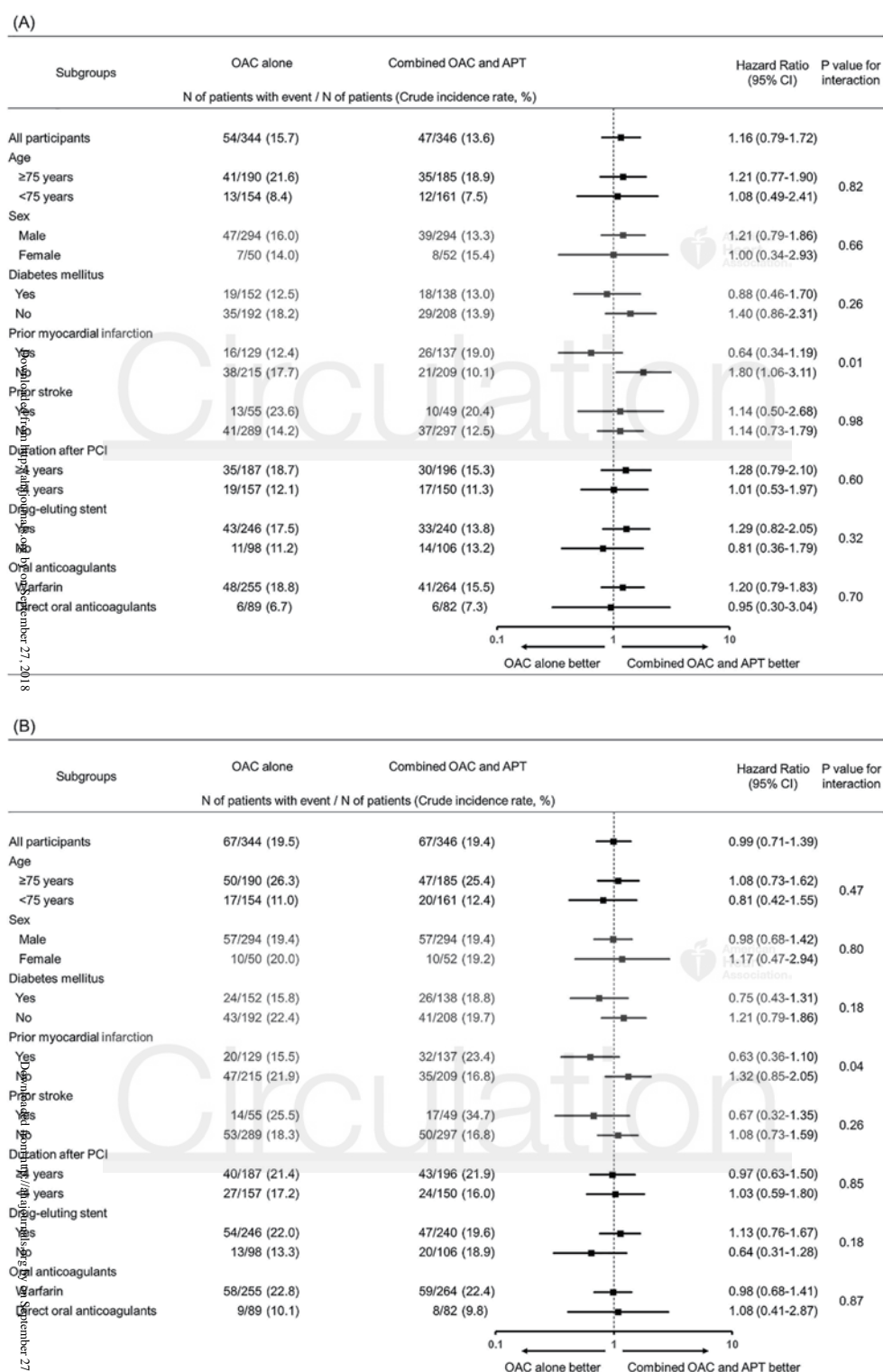


Figure 5. Pre-Specified Subgroup Analyses for the Primary and Major Secondary Endpoints. (A) Primary endpoint (a composite of all-cause death, myocardial infarction, stroke, or systemic embolism), and (B) Major secondary endpoint (a composite of primary endpoint or major bleeding). Data were presented as number of patients with event, crude incidence rates, and hazard ratios with 95% CIs of OAC alone relative to combined OAC and APT for the primary and major secondary endpoints.







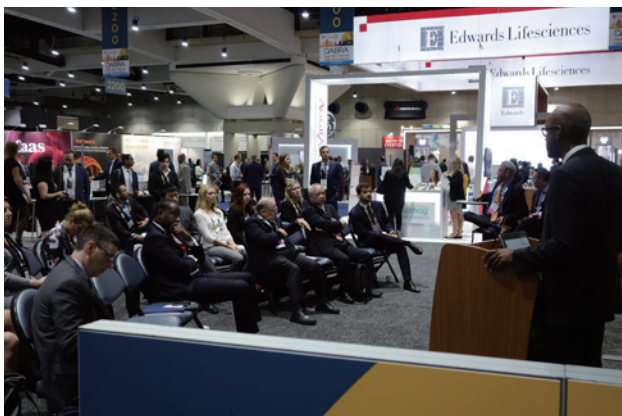
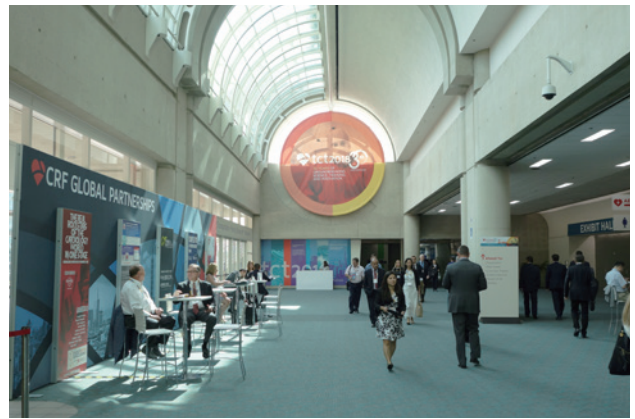
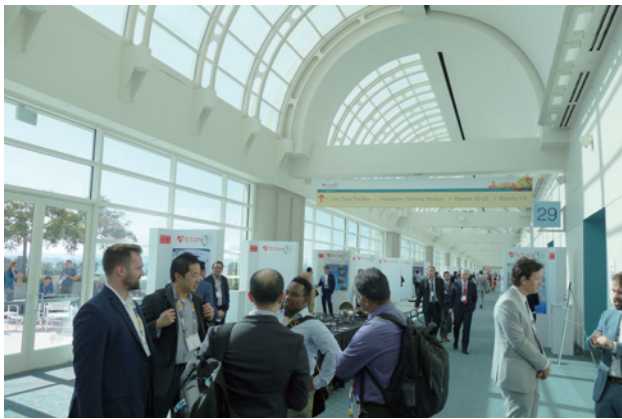


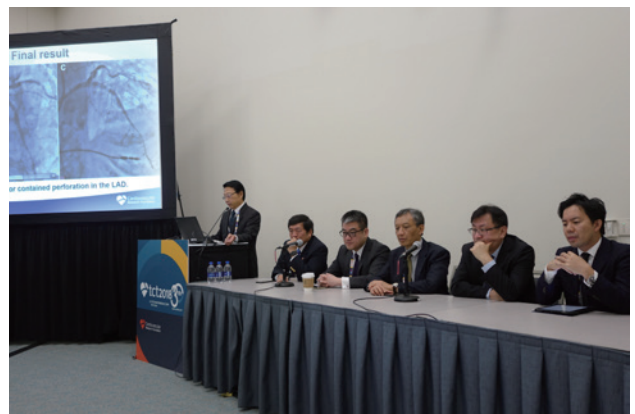


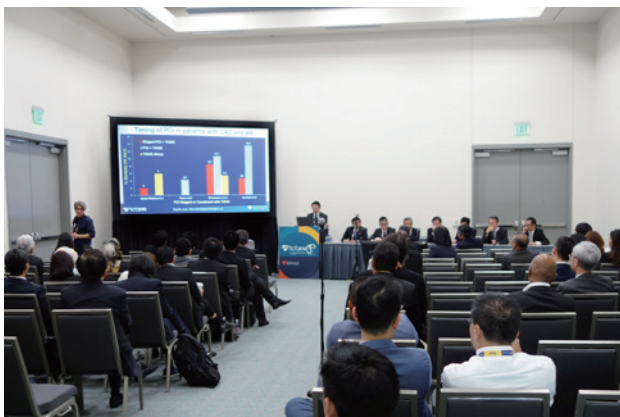


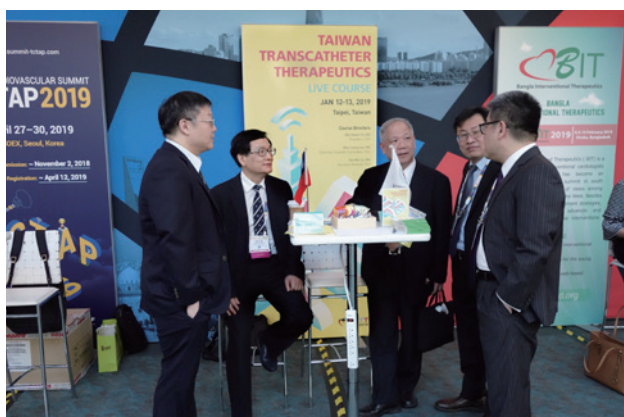
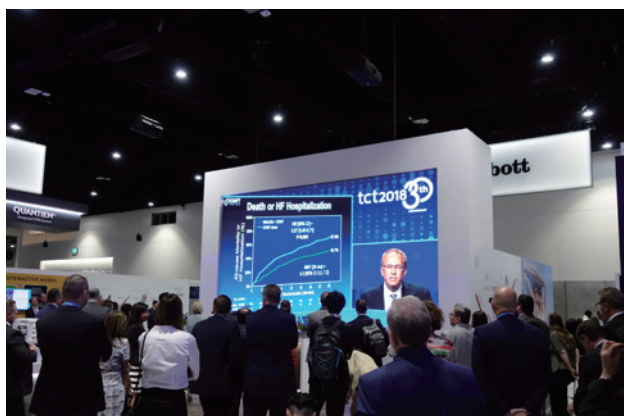














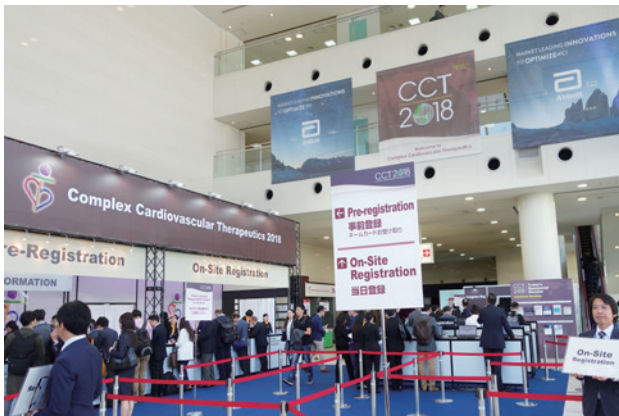


Lesion Characteristics & Procedure
108 patients and 116 lesions

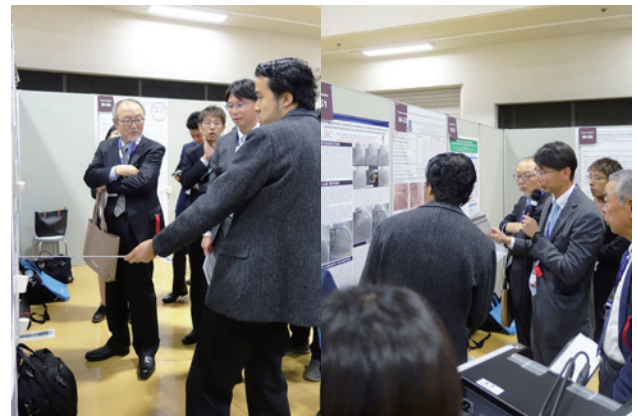
Variable	108 pts 116 lesions
LAD LCx RCA	60% 11% 29%
Calcification: mild moderate severe	8% 2% 4%
Tortuosity: moderate severe	9% 2%
SB $\geq$ 2 mm (visual estimation)	29%
Lesion class: A B1 B2 C	7% 32% 56% 5%
Baseline TIMI 3 flow	97%
Lesions per patient	1.07 $\pm$ 0.35
Nominal scaffold diameter: 2.75 3.0 3.5 mm	11% 51% 38%
Nominal scaffold length: 19 24 mm	65% 35%
High pressure postdilatation	100%
Device Procedure success	100% 99%*

*One patient received a metal DES to cover a residual dissection during post dilatation.









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- Case: Heavily Calcified LM Bifurcation and Near Ostial Occlusion of a Highly Angulated Dominant LCX

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- Conquer ALI - Exhaust All the Weapons in Taiwan

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- Left anterior descending artery stumpless chronic total occlusion

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- Bare wire rotablation for LAD CTO and heavy calcification lesion

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- UM case presentation

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- CTO PCI at ostial LAD instent and LIMA to LAD anastomosis

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- The nightmare of stent underexpansion

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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.

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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"×7" 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 Editor-in-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.

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