Taiwan Society of Cardiovascular Interventions

臺灣介入性心臟血管醫學會

81期 會訊

2021年06月

110.04.17 AV Access Intervention

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（第八十一期，Jun.，2021）

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目　錄

各位介入學會的會員，大家好：

這兩個月來，因疫情又變得嚴峻的關係，因此一些教育研討會議被迫延後舉行。或是如七月底的秋季會則改為全視訊舉辦。這是學會第一次舉辦全視訊會議，希望在大家的努力之下能順利完成。另外各委員會的會議如編輯暨登錄委員會、學術委員會也依照之前的模式以視訊會議進行，使會務得以繼續推展。值此疫情升溫之際，希望大家在照顧病患之餘，也不要忘了維護好自己的身體健康安全 !!

理事長 謝宜璋

2021.6

臺灣介入性心臟血管醫學會 入會申請表

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）	O:	
			H:	
通訊地址	□ 同戶籍地址 □ 通訊地址 _____		M:1. 2.	
E-mail(必填)	@		Fax:	
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：_____ 列印後簽名：_____	推薦會員（2）	姓 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	

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. 請在入會申請表左上角自行加註「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，指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日起算。
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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臺灣介入性心臟血管醫學會
第八屆第五次學術委員會會議紀錄

一、時　　間：110 年 6 月 30 日（星期三）PM6：30

二、地　　點：視訊 Google Meet

三、出席人員：主　委：曹殿萍
副主委：黃啟宏
委　員：施俊明、李文領、蔡政廷、徐中和、鄭正一、張其任、郭風裕、高憲立

四、請假人員：顧博明、王怡智、羅秉漢

五、列席人員：謝宜璋理事長
秘書處：許榮城秘書長
秘　書：賴瑋儀 (記錄)、陳詠潔、黃玉卉

六、報告事項：(1) 2021 秋季會預定 110 年 7 月 31 日 - 8 月 1 日，線上課程。
(2) TTT 2021 預定 111 年 1 月 8-9 日舉辦，地點：台大醫院國際會議中心 2-4F。

七、議程：

提案一：討論 2021 秋季會相關細節。

說明：(1) 節目規劃 (參閱螢幕)

(2) 討論線上會議進行方式 (演講方式及學分核可標準) (各學會學分核可標準參閱螢幕)

※決議：(1) 秋季會節目表安排沒問題，因 Case Competition-D 類投稿數量未如預期，增收 D 類 Structural 稿件至 7/7。

(2) 為避免即時線上演講中途發生不可控制的連線及設備問題，演講採事先預錄影片方式進行，當日播放影片並請講師同時上線討論。

(3) 各 Session 找一位 Digital Moderator，協助確認並篩選觀看頁面學員的提問，再提至 Zoom 會議室做討論

(4) 秋季會線上課程學分核可標準：

1) 全程參與課程 : 除特定要求簽到次數的學會之外，其他皆為在線時間須達總演講時數 1/3 (210 分鐘)。

2) 依特定學會要求：課後測驗題目共五題，滿分 100 分，通過標準為 60 分

提案二：討論年度國際研討會 TTT 2022 節目及籌備之規劃。

說明：(1) 討論節目內容初步規劃 (參閱附件二，TTT2021 & TTT2020 簡表)

(2) 討論轉播醫院

※ 參考

第八屆 TTT2021 台大醫院、台北國泰、中國附醫

第七屆 TTT2020 台北榮總、國泰醫院

TTT2019 振興醫院、台北榮總、台中榮總

第六屆 TTT2018 台北馬偕、亞東醫院 / TTT2017 台北榮總、高雄榮總

第五屆 TTT2016 台大醫院、新光醫院 / TTT2015 成大醫院、振興醫院

第四屆 TTT2014 台大醫院、新店慈濟 / TTT2013 台大醫院、台北馬偕

第三屆 TTT2012 台中榮總、台大醫院 / TTT2011 台北榮總、台大醫院

第二屆 TTT2010 花蓮 & 新店慈濟醫院、台大醫院

TTT2009 亞東醫院、中國附醫、高雄長庚

TTT2007 台北榮總、中山附醫、高雄榮總

第一屆 TTT2006 台北榮總、振興醫院、三軍總醫院

TTT2005 台大醫院、新光醫院、三軍總醫院

TTT2004 台大醫院、台北榮總、新光醫院

(3) 討論邀請外賓名單 (參閱附件三，2019-2021 年邀請名單)

※決議：(1) 轉播醫院：台中榮總 (W6)、中國附醫 (W6) 、高雄榮總 (W7)

(2) 因會議時間關係，外賓名單將於會後提供給各委員，提於下次會議討論。

提案三：討論召開 TTT2022 第一次籌備會議日期及出席名單。

說明：(1) 確認日期

(2) 確認列席人員名單

※決議：(1) 預計 8 月第一週以視訊方式召開，請秘書處再調查。

(2) 列席人員：兩院負責醫師、導管室人員、主委及秘書長。

提案四：討論下次召開委員會會議日期。

※決議：預計於 9 月底召開，請秘書處再調查。

八、臨時動議

九、散會

本期案例

【案例】

This 52-year-old male had past history of hypertension and dyslipidemia. He suffered from worsen chest tightness and shortness of breath upon exertion for 1 year. Previous Treadmill test revealed significant ST-T depression. Physical examination showed harsh ejection systolic murmur over left lower sternal border, and grade 3 pansystolic murmur over apex. Echocardiogram (Figure 1) and coronary angiogram (Figure 2) were showed as below. The discomfort improved after a catheter-based intervention treatment. (Figure 3 and 4)

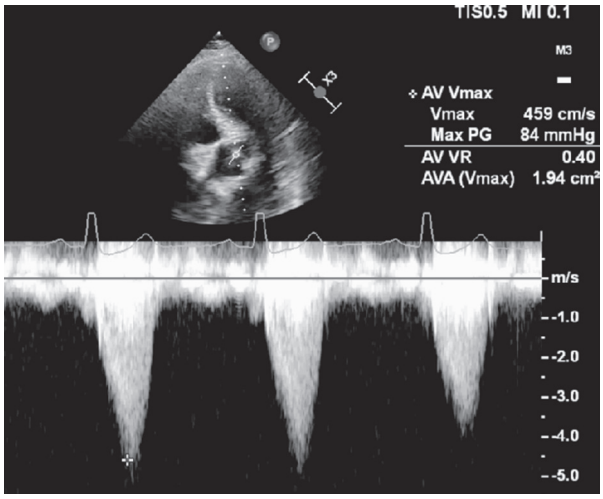

Figure 1

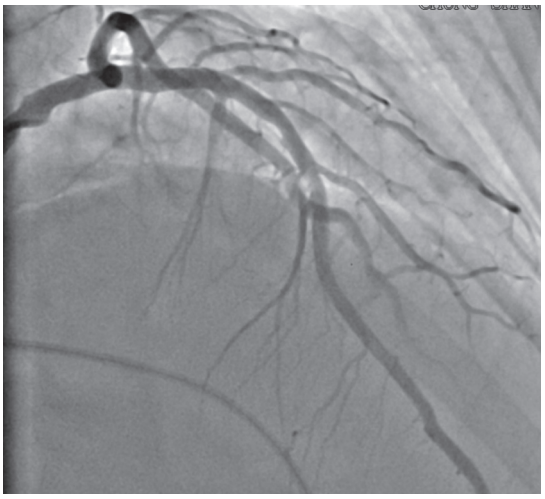

Figure 2

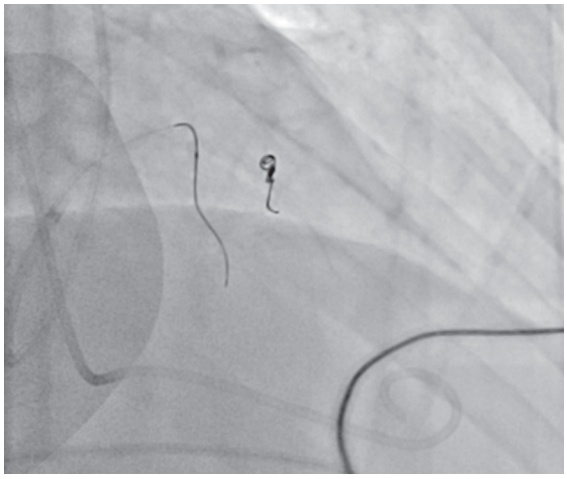

Figure 3

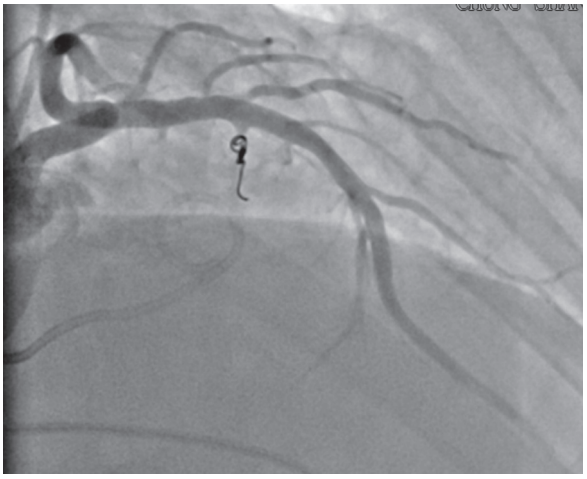

Figure 4

[Question]

What is the intervention procedure of this case?

中山醫學大學附設醫院 心臟內科 蘇峻弘醫師

上期解答

【案例】

A 65-year-old woman presented to our emergency room with dyspnea, palpitation and dizziness. Transthoracic echocardiogram revealed a right atrial mass (Figure 1, black arrow). The mass prolapsed to the right ventricle during diastolic phase. Transesophageal echocardiogram also identified a right atrial mass with the stump attached to the RA free wall and is adjacent to the IVC. (Figure 2, black arrow). The patient was hospitalized for surgery. Before operation, Coronary angiography revealed there is no significant coronary artery disease. When contrast filling the RCA, there are collateral vessels suppling to the mass (Figure 3, black arrow).

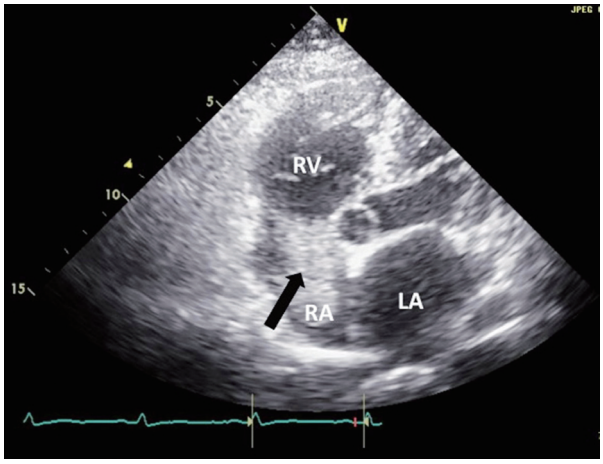

Figure 1

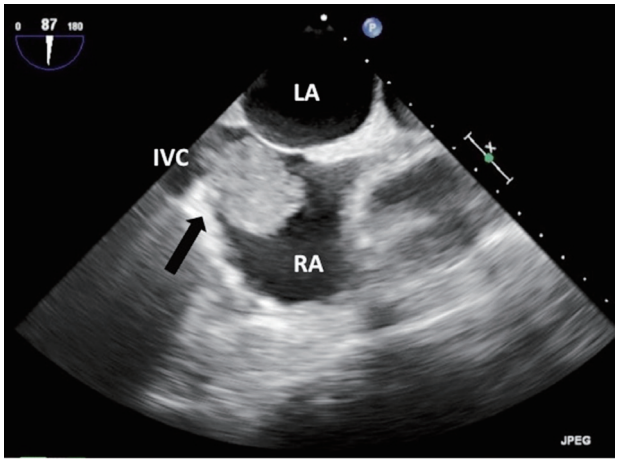

Figure 2

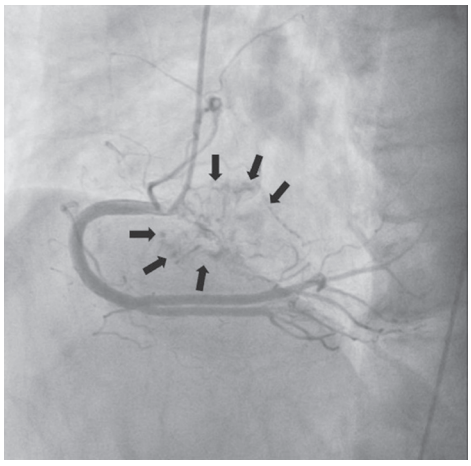

Figure 3

[Question]

What is the diagnosis?

What is treatment plan?

馬偕紀念醫院 心臟內科 林書毅醫師

【Answer】

Transesophageal echocardiogram revealed a right atrial mass with a stump attached to the RA free wall. This is typical description of myxoma; however, the local is atypical (around 18% of cases). On coronary angiography, rich blood supply and vascular blush during contrast injection is also a common presentation of myxoma.

Surgical excision is suggested strategy without delays to prevent thromboembolic events and obstruction of blood flow. During operation in this case, a fragile, soft tumor with size of 3.0x5cm was excised from the right atrium. Pathologic study confirmed the myxoma. After operation, the woman has no recurrent dizziness or palpitation.

MacKay Memorial Hospital
Dr. Shu-I Lin, M.D.

Management of Antithrombotic Therapy after Acute Coronary Syndromes

Fatima Rodriguez, M.D., M.P.H., and Robert A. Harrington, M.D.

N Engl J Med 2021;384:452-60.

ABSTRACT

Because of rapidly changing guidelines in response to multiple clinical trials of new therapies, the management of antithrombotic agents for patients after an acute coronary syndrome is becoming increasingly complex. Patients and clinicians must make treatment decisions by weighing the antithrombotic benefits of antiplatelet agents and the anti-ischemic benefits of anticoagulant agents against the risk of bleeding, including severe, life-threatening bleeding. Treatment decisions should be individualized by incorporating additional variables in this risk–benefit assessment, including but not limited to demographic characteristics of the patient, examination findings, laboratory testing, and imaging, as well as the patient's values and preferences.

The pathobiology of acute coronary syndromes is characterized by disruption of coronary atherosclerotic plaque through fissure, erosion, or rupture, resulting in activation of platelets and the coagulation system; the clinical result is myocardial ischemia or infarction, depending on the extent of coronary-artery occlusion. Acute coronary syndromes are initially categorized on the basis of the 12-lead electrocardiogram (ECG), with patients separated into two treatment pathways: one for patients with ST-segment elevation (STE) and one for patients without persistent STE. This initial ECG-guided risk stratification drives most treatment decisions during hospitalization and is also important for prognosis and treatment recommendations after discharge.

Every year, an estimated 720,000 people in the United States are hospitalized with an acute coronary syndrome or have a fatal coronary heart disease event. Advanced age and coexisting conditions are characteristic of patients presenting with an acute coronary syndrome; more than 60% of hospital admissions for acute coronary syndromes involve patients over the age of 65 years. Large clinical trials that are the basis for clinical practice guidelines might not enroll patients who are as diverse as those seen in clinical practice. In particular, older adults, women, and racial or ethnic minority groups continue to be underrepresented in contemporary clinical trials of treatment approaches for patients with acute coronary syndromes. Registry and other observational data may serve as valuable tools for studying the effects of guideline-recommended therapies in a diverse patient population.

The recommended initial care of all patients with acute coronary syndromes consists of rapid diagnosis, risk assessment and stratification, treatment of ischemic symptoms, initiation of

antithrombotic therapies with antiplatelet and anticoagulant agents, and risk-based triaging for the timing of invasive strategies. On the basis of extensive clinical trial data, the scales are tipped toward an intensive approach to reducing thrombotic complications with aggressive use of antiplatelet and anticoagulant agents during this initial phase of an acute coronary syndrome.

For most high-risk patients presenting with acute coronary syndromes, current U.S. and European guidelines favor an early invasive approach. Subsequent management requires individualized approaches to antithrombotic treatments, with the benefits weighed against the risk of bleeding (Fig. 1).

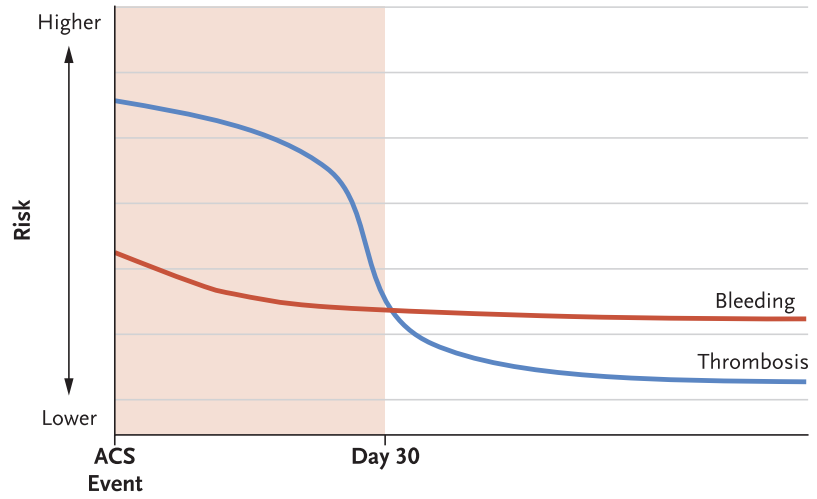

Figure 1. Risks of Thrombosis and Bleeding after an Acute Coronary Syndrome (ACS).

In the first 30 days after an ACS event, the benefits of intensive antithrombotic therapy generally outweigh the increased risk of bleeding. However, this benefit dissipates with additional time after the ACS event, favoring a therapeutic approach that considers the risks of both bleeding and thrombosis.

圖一、急性冠心症後的血栓及出血風險。

在急性冠心症後 30 天內，血栓風險高於出血風險，因此較強效的抗血栓治療策略所得到的好處大於出血風險。而 30 天後血栓風險降低，此時就需考慮到治療所帶來的出血風險。

急性冠心症後的抗血栓治療

編譯：中山醫學大學附設醫院 心臟內科 張凱為醫師

前言

針對急性冠心症 (Acute Coronary Syndrome, ACS) 的治療，醫師和患者必需權衡抗血小板藥物及抗凝血藥物的效果及出血風險。治療需個人化，根據每位患者的身體狀況、偏好、及價值觀，來評估治療的風險及效益。

ACS 的病理機轉為冠狀動脈的粥樣硬化斑塊破裂，導致血小板活化及凝血系統的活化，因而造成心肌缺氧或梗塞。

臨床治療指引主要都是依據大型臨床研究而來，但研究中收錄的患者的病情相對單純，不如臨床實務上，有各式各樣的狀況。此時登錄型及觀察型的研究就有其價值。

對於大部分 ACS 的患者，美國及歐洲的指引均建議早期的侵入性治療方式 (Early Invasive Approach)，接著，需權衡血栓及出血的風險，來選擇治療藥物 (圖一)。

抗血小板製劑 Antiplatelet Agents

雙重抗血小板治療 (Dual Antiplatelet Therapy, DAPT) - 典型的用法為 Aspirin 加上一個 ADP Inhibitor - 是 ACS 治療的基礎。然而，血栓風險的降低卻伴隨著出血風險的上升。

CURE Trial[1] 確立了在 ACS 患者，Clopidogrel 合併 Aspirin 使用的好處。雖然 Clopidogrel 目前在美國仍是最常使用的 P2Y12 Inhibitor，但美國及歐洲的指引建議優先選擇較強效的、新世代的 P2Y12 Inhibitors (Ticagrelor 及 Prasugrel)。此二藥作用較快、抗血小板效果更強且藥效更可預測。

2014 年美國心臟病學學院 (American College of Cardiology, ACC) 及美國心臟協會 (American Heart Association, AHA) 建議在 Non-STE ACS 使用 Clopidogrel or Ticagrelor，不論是否將接受心導管治療 (Ticagrelor 的建議是根據 PLATO Trial[2])。Prasugrel 建議使用在預計接受心導管治療 (Percutaneous Coronary Intervention, PCI) 的患者 (TRITON-TIMI 38 Trial[3])。2020 年歐洲心臟學會 (European Society of Cardiology, ESC) 指引也建議在 Non-STE ACS 使用 Ticagrelor or Prasugrel 治療。

雙重抗血小板製劑的療程 Duration of DAPT

一般來說，ACS 後給予 DAPT 治療至少一年，除非患者需要緊急手術、同時需使用抗凝血劑治療、或出血風險過高。ESC 指引建議 Aspirin 每日劑量 75~100 mg，而 ACC/AHA 指引建議每日 81~325 mg。ADAPTABLE Trial 探討冠心病患者長期 Aspirin 治療的最適劑量，預

計今年 (2021) 會發表結果。另外，ACS 患者接受心臟繞道手術後，也應使用 DAPT 至少 12 個月。

延長 DAPT 使用時間至 12 個月以上，可減少缺血性事件的發生，但也增加了出血的風險。DAPT Study 研究在支架置入術後，DAPT 使用 30 個月和 12 個月的比較，結果顯示 30 個月的 DAPT 比起 12 個月，可減少較多的主要心臟腦血管事件 (Major Adverse Cardiac and Cerebrovascular Events, MACCE)，但增加了出血風險[4]。同樣的，PEGASUS-TIMI 54 Trial 顯示在 AMI 後，持續使用 Ticagrelor 大於 12 個月，可減少 MACCE，但增加出血風險[5]。

另一個想法是停止 Aspirin，單用 P2Y12 Inhibitor 治療。TWILIGHT Trial 在高風險患者 (一半以上是 ACS) 接受冠狀動脈介入治療並使用 3 個月 DAPT (Aspirin + Ticagrelor) 後，一組持續 DAPT 治療而另一組單用 Ticagrelor，一年後在 Ticagrelor Monotherapy 組有較低的顯著出血比率，且並未增加缺血事件[6]。其他如 TICO Trial[7] 及一個 Meta-analysis[8] 也顯示相同的結果。目前可得的資料支持在早期的 DAPT 後，可降階成單用 P2Y12 Inhibitor (停止 Aspirin)，以減少出血風險。

在特定情況下，如高出血風險或同時使用抗凝血劑時，DAPT 的降階也可以是從較強效的 P2Y12 Inhibitors (Ticagrelor or Prasugrel)，轉換成 Clopidogrel。但應避免在 ACS 或心導管術後一個月內降階，因上述情況一個月內血栓事件的風險較高 (如圖 1)。

抗凝血劑的治療 Anticoagulant Therapy

目前臨床指引建議 ACS 的急性期治療除了 DAPT 以後尚包括抗凝血劑的治療。Enoxaparin, Bivalirudin, Fondaparinux, 或 Unfractionated Heparin 是 Class I Recommendation (使用到 ACS 後 48 小時或 PCI 前)。選擇哪一種抗凝血劑則需依據臨床情況及預計介入治療的時機來決定。若決定短時間內就會施行心導管，則選擇 UFH 或 Bivalirudin。若決定先藥物治療，則可選擇 Enoxaparin 或 Fondaparinux。而出院後需使用多久的抗凝劑尚無清楚的規範。

Direct Oral Anticoagulants (DOACs) 在 ACS 出院後長期治療的角色。APPRAISE-2 Trial 比較標準劑量的 Apixaban 及安慰劑在此情況下的療效，發現 Apixaban 顯著增加出血風險且無法降低 MACCE[9]。ATLAS ACS 2–TIMI 51 Trial 則比較低劑量的 Rivaroxaban (2.5 mg or 5 mg Daily) 和安慰劑 (大多數患者有使用 DAPT)，結果顯示 Rivaroxaban 可減少死亡、心肌梗塞及中風風險，但增加主要出血風險[10]。COMPASS Trial 也支持低劑量 Rivaroxaban (2.5 mg Twice Daily) 加上低劑量 Aspirin，可改善曾住院過的 Stable CAD 或周邊動脈疾病患者的預後[11]。總結來說，目前証據支持 DOACs 可減少 MACCE，而其劑量與出血風險有關，因此低劑量 DOACs 加上 DAPT 的治療僅建議使用在高缺血事件風險的患者。

心房顫動患者接受心導管術後的三合一治療 Triple Therapy

PIONEER AF-PCI Trial 將接受過 PCI 術後的心房顫動患者隨機分成三組，一組使用低劑量 Rivaroxaban (15 mg Daily) 加上 P2Y12 Inhibitor (治療 12 個月)，一組使用極低劑量

Rivaroxaban (2.5 mg Twice Daily) 加上 DAPT (1, 6, 12 個月)，一組使用 Warfarin 加上 DAPT (1, 6, 12 個月)，結果顯示使用 Rivaroxaban 的二個組別，都可降低出血風險，優於 Warfarin 加 DAPT[12]。

RE-DUAL PCI Trial 將患者分為二組，一組使用 Dabigatran + P2Y12 Inhibitor，另一組使用 Warfarin + DAPT，結果也顯示 Dabigatran 組有較低的出血風險[13]。

AUGUSTUS Trial 則是將 ACS 或 PCI 術後患者分為四組，分別為 Apixaban + P2Y12 Inhibitor + Aspirin, Apixaban + P2Y12 Inhibitor + Placebo, Warfarin + P2Y12 Inhibitor + Aspirin 以及 Warfarin + P2Y12 Inhibitor + Placebo。結果發現 Apixaban 比 Warfarin 有較低的出血風險，而 Aspirin 又比 Placebo 有較高的出血風險[14]。

ENTRUST-AF PCI Trial 是將 ACS 或 PCI 術後患者分二組，一組接受 Edoxaban + P2Y12 Inhibitors，另一組 Warfarin + P2Y12 Inhibitors + Aspirin，結果顯示 Edoxaban 組的出血風險不劣於 Warfarin 組，而缺血性事件的發生風險相等[15]。

總結來說，目前證據建議在 AF 合併 ACS 患者，使用短期的 Triple Therapy，之後使用 P2Y12 Inhibitors 加上 DOACs 直到 ACS 後一年。

個人化的治療 Individualizing Treatment Decisions

臨床指引主要是根據隨機對照試驗而來，但隨機對照試驗有嚴格的 Inclusion Criteria，實際上臨床患者的條件不一定和試驗中的相同，因此臨床上治療患者需要個人化。

關於 ACS 後的抗血栓藥物的治療，有些可得的工具可以幫助醫師和患者做醫病共享決策。

DAPT Score (表 1) 可幫忙決定 DAPT 治療是否要持續超過 12 個月。依據表 1 計算分數，若一分以下 (含一分)，則建議 ACS 一年後，單用 Aspirin 即可。若二分以上 (含二分)，延長 DAPT 大於一年，可以減少缺血性事件的風險。此外，目前尚無較有證據的出血風險評估工具。臨床醫師還是需要評估缺血事件和出血的風險，來做治療的決定。

表 2 總結了在 ACS 事件後，抗血栓藥物治療的建議。

結論

一體適用的治療策略並不適合 ACS 後的治療。醫師應仔細評估血栓和出血風險 , 和患者溝通後，給予每位患者個人化的治療。

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表一、DAPT Score 的計算

總和 2 分或以上，DAPT 治療持續超過 12 個月所得的好處（減少血栓）大於壞處（出血風險）。

Table 1. Calculation of the DAPT Score.*

Variable	Points
Age (yr)	
≥75	−2
65–74	−1
≤64	0
Diabetes mellitus	1
Current cigarette smoker	1
Prior MI or PCI	1
MI at presentation	1
CHF or left ventricular ejection fraction <30%	2
Stent diameter <3 mm	1
PCI of vein graft	2
Paclitaxel-eluting stent	1

* The score for dual antiplatelet therapy (DAPT) ranges from −2 to 10. A score of 2 or higher suggests that the magnitude of the benefit from a reduction in ischemic events is greater than the risk of bleeding with DAPT continued for more than 12 months. CHF denotes congestive heart failure, MI myocardial infarction, and PCI percutaneous coronary intervention.

表二、急性冠心症後抗血栓治療的建議

急性冠心症後，在不同的三個時間點（一個月以內；一個月至 12 個月；大於 12 個月），根據患者的缺血風險及出血風險高低，來選擇藥物。患者若合併有心房顫動，需考慮使用 DOAC。

Table 2. Suggested Approaches to Antithrombotic Treatment after an ACS Event.*

Time after ACS Event	Default Strategy	Patients with High Ischemic Risk	Patients with High Bleeding Risk	Patients with Concomitant Atrial Fibrillation†
≤1 mo	Aspirin and newer-generation $P2Y_{12}$ inhibitor	Aspirin and newer-generation $P2Y_{12}$ inhibitor	Aspirin and newer-generation $P2Y_{12}$ inhibitor	Aspirin, clopidogrel, and DOAC‡
>1 mo to 12 mo	Aspirin and newer-generation $P2Y_{12}$ inhibitor	Aspirin and newer-generation $P2Y_{12}$ inhibitor	Any $P2Y_{12}$ inhibitor alone	Clopidogrel and DOAC
>12 mo	Any $P2Y_{12}$ inhibitor alone	Aspirin and newer-generation $P2Y_{12}$ inhibitor, or switch to aspirin and low-dose rivaroxaban	Any $P2Y_{12}$ inhibitor or aspirin	DOAC

* Aspirin is given at a dose of less than 100 mg. In this table, prasugrel and ticagrelor are considered newer-generation $P2Y_{12}$ inhibitors. ACS denotes acute coronary syndrome, and DOAC direct oral anticoagulant.
† Recommendations are for patients with nonvalvular atrial fibrillation (those who do not have mechanical heart valves and do not have moderate-to-severe mitral stenosis).
‡ Consider withdrawing aspirin before hospital discharge for patients who are at high risk for bleeding.

Aspirin Versus Clopidogrel for Chronic Maintenance Monotherapy after Percutaneous Coronary Intervention (HOST-EXAM): An Investigator-initiated, Prospective, Randomised, Open-label, Multicentre Trial

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ABSTRACT

BACKGROUND

Optimal antiplatelet monotherapy during the chronic maintenance period in patients who undergo coronary stenting is unknown. We aimed to compare head to head the efficacy and safety of aspirin and clopidogrel monotherapy in this population.

METHODS

We did an investigator-initiated, prospective, randomised, open-label, multicentre trial at 37 study sites in South Korea. We enrolled patients aged at least 20 years who maintained dual antiplatelet therapy without clinical events for 6-18 months after percutaneous coronary intervention with drug-eluting stents (DES). We excluded patients with any ischaemic and major bleeding complications. Patients were randomly assigned (1:1) to receive a monotherapy agent of clopidogrel 75 mg once daily or aspirin 100 mg once daily for 24 months. The primary endpoint was a composite of all-cause death, non-fatal myocardial infarction, stroke, readmission due to acute coronary syndrome, and Bleeding Academic Research Consortium (BARC) bleeding type 3 or greater, in the intention-to-treat population. This trial is registered with ClinicalTrials.gov, NCT02044250.

FINDINGS

Between March 26, 2014, and May 29, 2018, we enrolled 5530 patients. 5438 (98.3%) patients were randomly assigned to either the clopidogrel group (2710 [49.8%]) or to the aspirin group (2728 [50.2%]). Ascertainment of the primary endpoint was completed in 5338 (98.2%) patients. During 24-month follow-up, the primary outcome occurred in 152 (5.7%) patients in the clopidogrel group and 207 (7.7%) in the aspirin group (hazard ratio 0.73 [95% CI 0.59-0.90]; p=0.0035).

INTERPRETATION

Clopidogrel monotherapy, compared with aspirin monotherapy during the chronic maintenance period after percutaneous coronary intervention with DES significantly reduced the risk of the composite of all-cause death, non-fatal myocardial infarction, stroke, readmission due to acute coronary syndrome, and BARC bleeding type 3 or greater. In patients requiring indefinite antiplatelet monotherapy after percutaneous coronary intervention, clopidogrel monotherapy was superior to aspirin monotherapy in preventing future adverse clinical events.

於經皮冠狀動脈介入治療後，比較單用 Asprin 或 Clopidogrel 長期治療的效用 (HOST-EXAM)：一項多中心前瞻性隨機開放式研究

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目前接受冠狀動脈支架置入術的患者在長期維持期間的最佳單一抗血小板藥物治療尚無定論。本研究目的是在該群患者中比較 Aspirin 和 Clopdogrel 單一抗血小板藥物治療的有效性和安全性。

方法

在韓國的 37 個研究地點進行了一項由研究者發起的、前瞻性、隨機、開放試驗。招募年齡大於 20 歲，且排除任何缺血性和嚴重出血併發症的患者 (表一)。這些患者在使用塗藥支架 (DES) 進行經皮冠狀動脈介入治療後，在 6-18 個月內使用雙重抗血小板治療而沒有出現臨床事件。

患者被一比一隨機分配接受 Clopdogrel 75 mg 每天一次或 Aspirin 100 mg 每天一次，持續 24 個月。主要試驗指標是治療人群中全因死亡、非致命性心肌梗塞、中風、急性冠心症再入院和 BARC Type 3 型或以上出血的複合性終點。

結果

2014 年 3 月 26 日至 2018 年 5 月 29 日期間，共招募 5530 名患者。有 5438 (98.3%) 名患者被隨機分配到 Clopdogrel 組 (2710 人 [49.8%]) 或 Aspirin 組 (2728 人 [50.2%]) (圖一)。 其中 5338 名 (98.2%) 患者確定完成主要試驗指標評估。在 24 個月的隨訪期間，主要試驗指標在 Clopidogrel 組有 152 名 (5.7%) 而在 Aspirin 組有 207 名 (7.7%) (風險比 0.73 [95% CI 0.59-0.90]；p=0.0035)。(表二)

結論

在使用塗藥支架 (DES) 經皮冠狀動脈介入治療後長期維持期間的單藥治療中，Clopdogrel 單藥治療相比 Aspirin 來說顯著降低了全因死亡、非致死性心肌梗塞、中風、急性冠心症導致的再入院和 BARC Type 3 或以上出血的複合風險 (圖二、三)。在經皮冠狀動脈介入治療後需要長期單一抗血小板藥物治療的患者中，Clopidogrel 單一抗血小板藥物治療在預防未來不良臨床事件方面優於 Aspirin。

表一、研究族群的基本資料

	Clopidogrel (n=2710)	Aspirin (n=2728)
Age, years	63·5 (10·7)	63·4 (10·7)
Sex		
Female	695 (25·6%)	689 (25·3%)
Male	2015 (74·4%)	2039 (74·7%)
Diabetes*	925 (34·1%)	935 (34·3%)
Insulin-dependent diabetes	55 (2·0%)	62 (2·3%)
Hypertension	1664 (61·4%)	1674 (61·4%)
Dyslipidaemia	1884 (69·5%)	1883 (69·0%)
Current smoker	545 (20·1%)	581 (21·3%)
Chronic kidney disease	356 (13·1%)	337 (12·4%)
Previous myocardial infarction	437 (16·1%)	435 (15·9%)
Previous cerebrovascular accident	120 (4·4%)	133 (4·9%)
Clinical indication of PCI		
Silent ischaemia	58 (2·1%)	70 (2·6%)
Stable angina	688 (25·4%)	701 (25·7%)
Unstable angina	975 (36·0%)	959 (35·2%)
NSTEMI	526 (19·4%)	528 (19·4%)
STEMI	463 (17·1%)	470 (17·2%)
Laboratory results		
White blood cells, cells per µL	6·7 (1·9)	6·8 (1·9)
Haemoglobin, g/dL	13·7 (1·7)	13·8 (1·6)
Creatinine, mg/dL	1·0 (0·7)	1·0 (0·7)
Total cholesterol, mg/dL	136·8 (29·)8	138·2 (30·5)
Triglyceride, mg/dL	126·8 (86·5)	125·2 (70·8)
HDL cholesterol, mg/dL	46·3 (12·0)	46·5 (12·2)
LDL cholesterol, mg/dL	70·7 (23·7)	72·1 (23·2)
HbA_{1c}	6·5 (1·1)	6·5 (1·2)
Days from PCI to randomisation	383 (357–424)	380 (358–421)

(Table 1 continues in next column)

	Clopidogrel (n=2710)	Aspirin (n=2728)
(Continued from previous column)		
DAPT at the randomisation		
Aspirin plus clopidogrel	2218 (81·8%)	2212 (81·1%)
Aspirin plus ticagrelor	266 (9·8%)	268 (9·8%)
Aspirin plus prasugrel	212 (7·8%)	235 (8·6%)
Aspirin plus clopidogrel plus cilostazol	14 (0·5%)	13 (0·5%)
Angiographic data per patient		
Extent of CAD		
One-vessel disease	1367 (50·4%)	1376 (50·4%)
Two-vessel disease	855 (31·5%)	844 (30·9%)
Three-vessel disease	488 (18·0%)	507 (18·6%)
Left main disease	142 (5·2%)	130 (4·8%)
PCI for bifurcation lesion	285 (10·5%)	295 (10·8%)
Two-stenting for bifurcation PCI	46 (1·7%)	42 (1·5%)
PCI for CTO lesion	257 (9·5%)	254 (9·3%)
Number of treated lesions†	1·3 (0·6)	1·3 (0·6)
Mean diameter of implanted stents, mm	3·1 (0·4)	3·1 (0·4)
Minimum diameter of implanted stents, mm	3·0 (0·5)	3·0 (0·5)
Total length of implanted stents, mm	36·1 (24·2)	35·7 (23·6)
Total number of implanted stents	1·5 (0·8)	1·5 (0·8)
Generation of DES		
First generation DES	54 (2·0%)	52 (1·9%)
Second generation DES	2627 (96·9%)	2651 (97·2%)
Unknown generation	29 (1·1%)	25 (0·9%)

Data are n (%), mean (SD), or median (IQR). CAD=coronary artery disease. CTO=chronic total occlusion. DAPT=dual antiplatelet therapy. DES=drug-eluting stent. HbA_{1c}=glycated haemoglobin. NSTEMI=non ST-segment elevation myocardial infarction. PCI=percutaneous coronary intervention. STEMI=ST-segment elevation myocardial infarction. *Diabetes was defined as any type of diabetes. †3562 lesions were treated in the clopidogrel group and 3565 in the aspirin group.

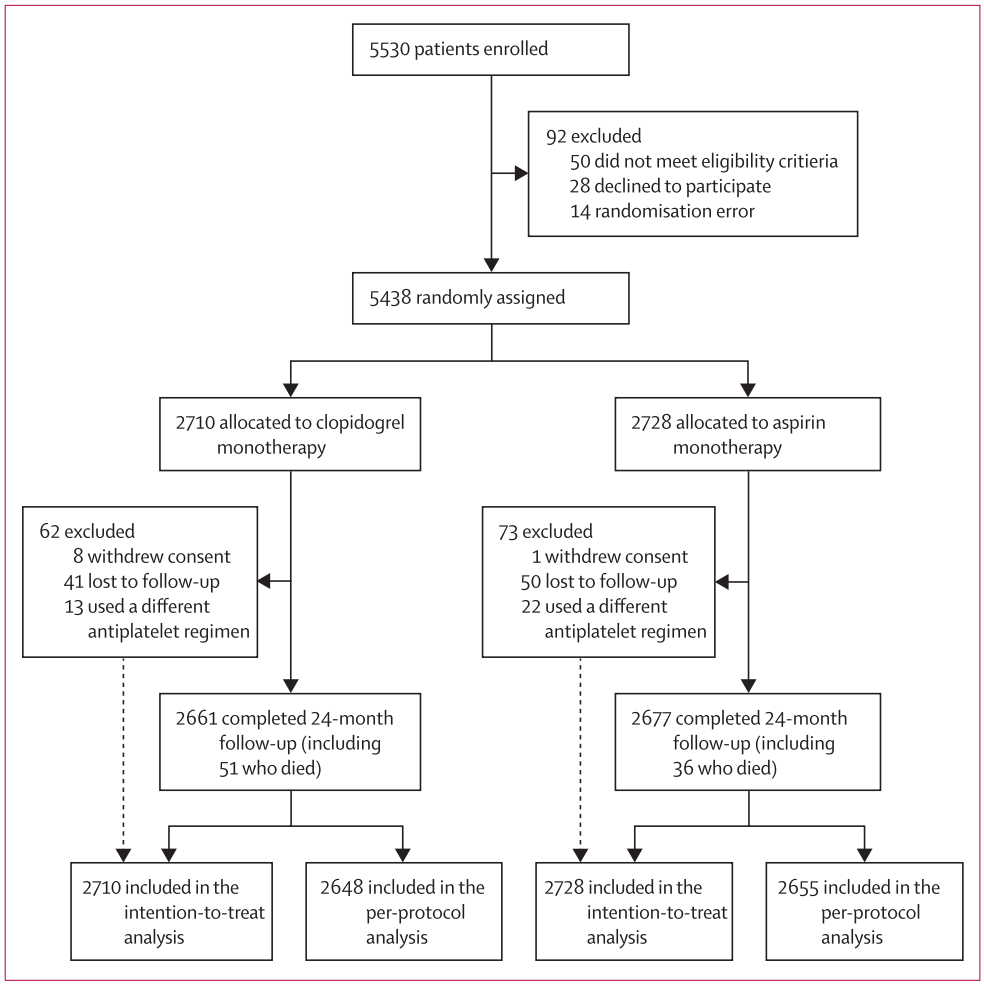
Table 1: **Baseline characteristics of the intention-to-treat population**

表二、研究族群的臨床結果

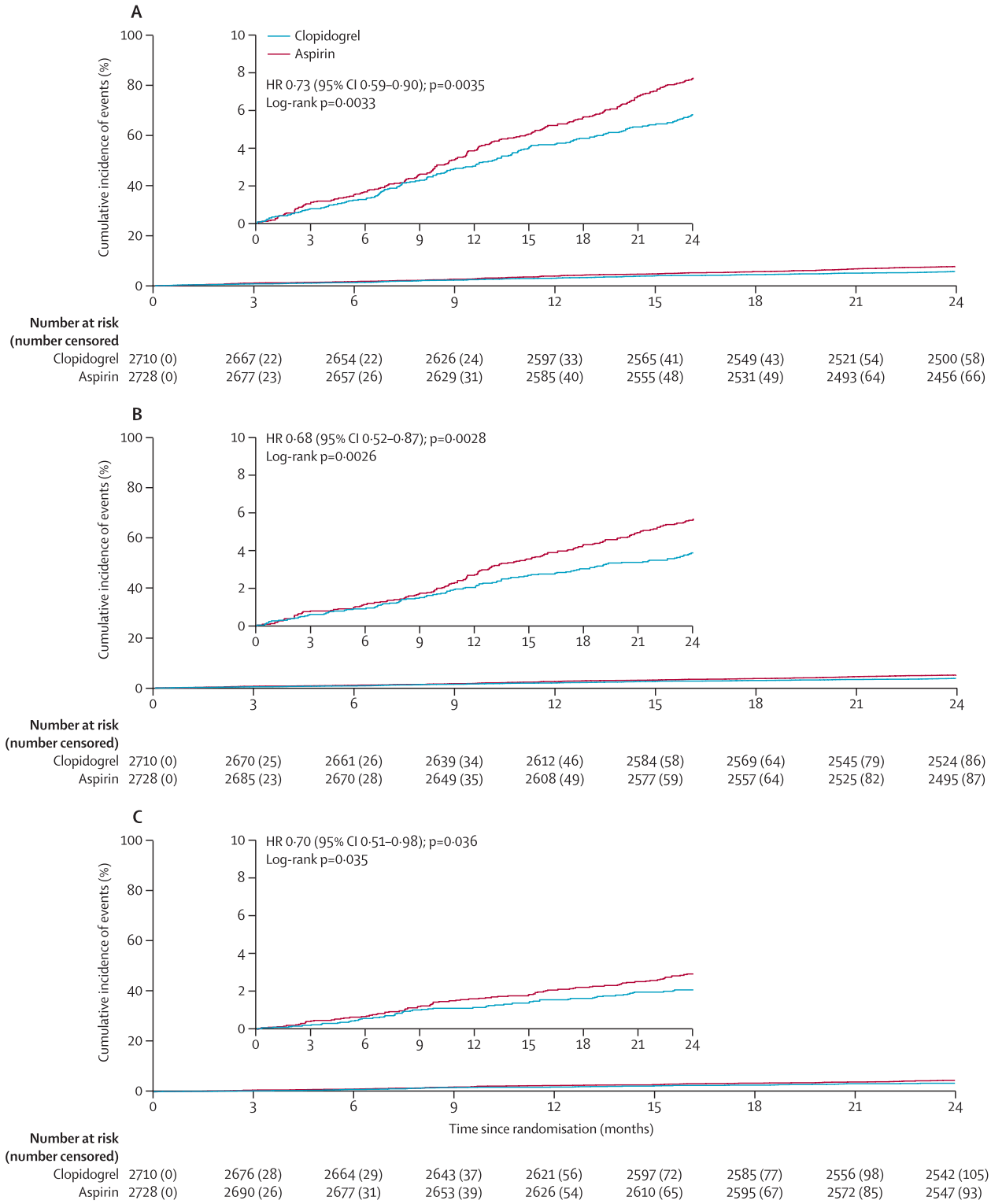
	Clopidogrel (n=2710)	Aspirin (n=2728)	Hazard ratio (95% CI)*	p value
Primary composite endpoint†	152 (5·7%)	207 (7·7%)	0·73 (0·59–0·90)	0·003
Thrombotic composite endpoint‡	99 (3·7%)	146 (5·5%)	0·68 (0·52–0·87)	0·003
Any bleeding (BARC type ≥2)§	61 (2·3%)	87 (3·3%)	0·70 (0·51–0·98)	0·036
All-cause death¶	51 (1·9%)	36 (1·3%)	1·43 (0·93–2·19)	0·101
Cardiac death	19 (0·7%)	14 (0·5%)	1·37 (0·69–2·73)	0·374
Non-cardiac death	32 (1·2%)	22 (0·8%)	1·47 (0·85–2·52)	0·167
Non-fatal myocardial infarction	18 (0·7%)	28 (1·0%)	0·65 (0·36–1·17)	0·150
Stroke	18 (0·7%)	43 (1·6%)	0·42 (0·24–0·73)	0·002
Ischaemic stroke	14 (0·5%)	26 (1·0%)	0·54 (0·28–1·04)	0·064
Haemorrhagic stroke	4 (0·2%)	17 (0·6%)	0·24 (0·08–0·70)	0·010
Readmission due to ACS	66 (2·5%)	109 (4·1%)	0·61 (0·45–0·82)	0·001
Major bleeding (BARC type ≥3)	33 (1·2%)	53 (2·0%)	0·63 (0·41–0·97)	0·035
Any revascularisation	56 (2·1%)	69 (2·6%)	0·82 (0·57–1·16)	0·261
Target lesion revascularisation	24 (0·9%)	36 (1·4%)	0·67 (0·40–1·12)	0·130
Target vessel revascularisation	37 (1·4%)	48 (1·8%)	0·78 (0·50–1·19)	0·245
Definite or probable stent thrombosis	10 (0·4%)	16 (0·6%)	0·63 (0·29–1·39)	0·251
Any minor gastrointestinal complications	272 (10·2%)	320 (11·9%)	0·85 (0·72–1·00)	0·048

Data are n (%), unless otherwise specified. Clinical endpoints were assessed in the intention-to-treat population at 24 months after randomisation. The percentages shown are Kaplan-Meier estimates. All primary and secondary endpoints and their associated definitions are listed in the appendix (pp 13–18). ACS=acute coronary syndrome. BARC=Bleeding Academic Research Consortium. *The 95% CIs for secondary endpoints have not been adjusted for multiple testing and therefore no clinical inferences can be made from these analyses. †The primary composite endpoint was defined as a composite of all-cause death, non-fatal myocardial infarction, stroke, readmission due to ACS, and major bleeding events (BARC type ≥3). ‡The thrombotic composite endpoint was defined as cardiac death, non-fatal myocardial infarction, ischaemic stroke, readmission due to ACS, and definite or probable stent thrombosis. §The specific types of bleeding events are described in the appendix (p 26). Any bleeding event was defined as BARC type bleeding of 2 or more. ¶The specific causes of death are described in the appendix (p 25).

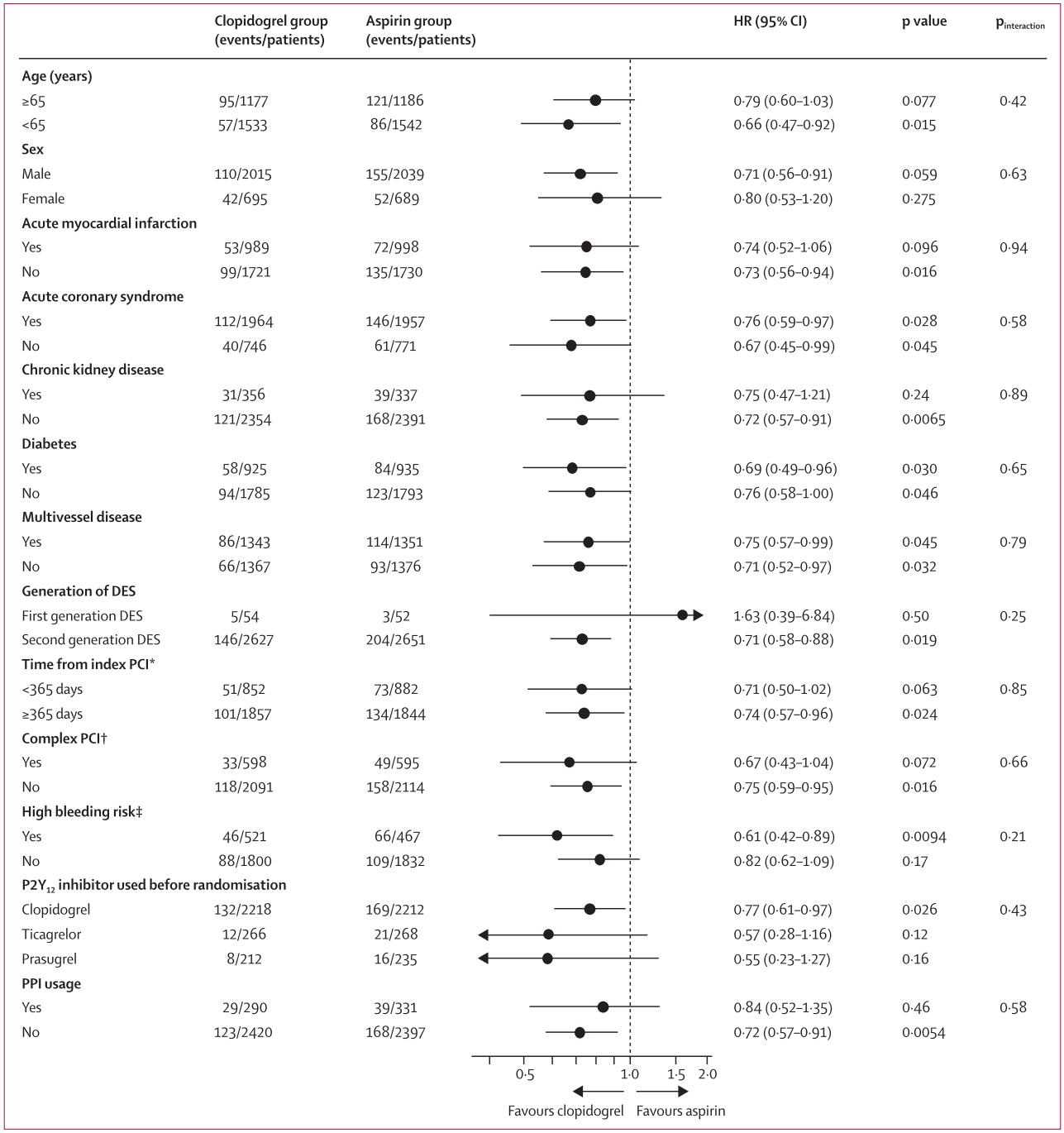
Table 2: **Clinical outcomes in the intention-to-treat population**



圖一、共招募 5530 名患者。有 5438 (98.3%) 名患者被隨機分配到 Clopdogrel 組 (2710 人 [49.8%]) 或 Aspirin 組 (2728 人 [50.2%])，意向分析 (Intention-to-Treat) 臨床結果。



圖二、A. 主要療效終點的累積發生率，包含全因死亡、非致死性心肌梗塞、中風、急性冠心症導致的再入院和 BARC Type 3 或以上出血的複合風險。B. 次要（血栓相關）終點的累積發生率，包括心因性死亡、非致命性心肌梗塞、缺血性中風、急性冠心症導致的再入院、或支架血栓形成。C. 任何出血事件的累積發生率。



圖三、 主要療效終點 (包含全因死亡、非致死性心肌梗塞、中風、急性冠心症導致的再入院和 BARC Type 3 或以上出血) 的次族群分析。

Very Short vs. Long Dual Antiplatelet Therapy after Second Generation Drug-eluting Stents in 35785 Patients Undergoing Percutaneous Coronary Interventions: Ameta-analysis of Randomized Controlled Trials

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ABSTRACT

AIM

To provide an updated assessment of the efficacy-safety profile of very short (1 or 3 months) dual antiplatelet therapy (DAPT) compared with long (12 months) DAPT in patients undergoing percutaneous coronary interventions (PCIs).

METHODS AND RESULTS

Seven randomized controlled trials (RCTs) comparing very short vs. long DAPT in 35785 patients undergoing PCI were selected. The primary efficacy endpoint was major adverse cardiovascular events (MACE) and the primary safety endpoint trial-defined major bleeding through at least 1 year. Compared with longer duration, very short DAPT yielded comparable rates of MACE [odds ratio (OR) 0.93, 95% confidence interval (CI) 0.84-1.03, P = 0.19], all-cause mortality (OR 0.92, 95% CI 0.80-1.06, P = 0.25), myocardial infarction (OR 1.01, 95% CI 0.88-1.15, P = 0.91), stroke (OR 1.04, 95% CI 0.72-1.50, P = 0.83), stent thrombosis (OR 1.05, 95% CI 0.80-1.37, P = 0.73), target vessel revascularization (OR 0.99, 95% CI 0.82-1.18, P = 0.89), and comparable net clinical benefit (OR 0.92, 95% CI 0.84-1.01, P = 0.08). Very short DAPT was associated with reduced rates of major bleeding (OR 0.61, 95% CI 0.40-0.94, P = 0.03) or any bleeding (OR 0.65, 95% CI 0.47-0.90, P = 0.009). Subgroup analyses showed consistent results for 1 vs. 3 month DAPT and for aspirin vs. P2Y12 inhibitor monotherapy following very short DAPT.

CONCLUSIONS

Compared with long DAPT, very short DAPT did not increase the odds of ischaemic complications, while reducing the odds of major or any bleeding by over 30%.

Keywords: Acute coronary syndrome; Drug-eluting stent; Dual antiplatelet therapy; Long term; Very short.

經皮冠狀動脈介入第二代塗藥支架使用後超短期和長期雙重抗血小板治療：隨機對照試驗的統合分析

編譯：中山醫學大學附設醫院 心臟內科 羅健賢醫師

前言

雙重抗血小板治療（Dual Antiplatelet Therapy, DAPT）是急性冠心症或接受經皮冠狀動脈介入治療（Percutaneous Coronary Intervention, PCI）後的患者的基石治療藥物，來降低支架血栓形成（Stent Thrombosis, ST）和其他缺血性事件的發生率。之前隨機對照試驗（Randomized, Controlled Trials, RCT）已顯示雙重抗血小板治療超過標準 12 個月扔然有缺血性益處。但支架內血栓發病率的下降（主要原因是 PCI 材料和技術的進步），並且越來越關注出血事件的不利影響，也提示了隨機對照試驗探索越來越短的 DAPT 持續時間的影響。許多統合分析（Meta Analysis）顯示了缺血 / 缺血後的淨獲益，對於低缺血風險患者使用 DAPT ≦ 6 月比 ≦ 12 個月有利於出血平衡。最近的 RCT 研究了在高風險人群使用非常短的 DAPT 方案。這系統文獻回顧和薈萃分析，評估患者接受 PCI 第二代塗藥支架（Drug Eluting Stent, DES）放置後超短（1 或 3 個月）與 12 個月的 DAPT 治療結果。

方法

本篇於 2019 年 10 月使用 Medline/PubMed, Embase, Cochrane Library, Web of Science Database 等網路資料庫搜尋了 5983 篇裡篩選了 7 篇隨機對照試驗 (RCT) 並進行系統性文獻回顧與統合分析。主要研究療效終點為主要不良心血管事件（Major Adverse Cardiovascular Events, MACE）以及和主要安全終點試驗定義的大出血追蹤至少 1 年。

結果

7 篇隨機對照試驗 (RCT) 共 35785 名接受 PCI 的患者中比較了使用超短與長 DAPT。與標準長 DAPT 的持續時間相比，超短 DAPT 產生了可比較的 MACE 率 [優勢比 (OR) 0.93，95% 信賴區間 (CI) 0.84-1.03，P = 0.19]，全因死亡率（OR 0.92，95% CI 0.80-1.06，P = 0.25），心肌梗塞（OR 1.01，95% CI 0.88-1.15，P = 0.91)（圖一）、中風 (OR 1.04，95% CI 0.72-1.50，P = 0.83)、支架內血栓形成 (OR 1.05，95% CI 0.80-1.37，P = 0.73)，靶血管血流重建處理 Target Vessel Revascularization（OR 0.99，95% CI 0.82-1.18，P = 0.89）（圖二）和淨臨床獲益 Net Clinical Benifit（OR 0.92，95% CI 0.84-1.01，P = 0.08）。超短 DAPT 與大出血率降低相關（OR 0.61，95% CI 0.40-0.94，P = 0.03）或有任何出血（OR 0.65，95% CI 0.47-0.90，P = 0.009）（圖三）。亞組分析 1 個月 vs. 3 個月 DAPT 和阿司匹林 vs. P2Y12 抑製劑單藥治療後的結果也顯示一致。

重點討論

這篇分析表明對使用第二代 DES 進行 PCI 的患者，1 或 3 個月的 DAPT 與 12 個月的 DAPT 具有可比的缺血危害。縮短療程後，大出血或任何出血的機率降低了 1/3。初始 DAPT 後阿司匹林與 P2Y12 抑製劑單藥治療以及 1 個月與 3 個月 DAPT 的療效和安全性結果一致。迄今，國際共識和指引支持患者收短 DAPT 方案的概念，衡量個人出血和缺血風險。儘管如此，可靠的數據仍然缺乏，歐洲心臟病學會分別給出了 3 個月 DAPT 的 IIa 等級證據水平 (LOE) A 建議，和 1 個月 DAPT 的 IIb 級 LOE C 建議，分別針對 CCS 患者與高和非常高的出血風險。前年發表的 TWILIGHT 結果，將混合隊列的患者隨機分配至單獨使用 Ticagrelor 與最初 3 個月的 DAPT 後 Ticagrelor 加阿司匹林，單獨使用 Ticagrelor 顯示減少 44% BARC 2-5 出血，主要風險幾乎減半出血，並且缺血事件沒有增加。根據這篇的發現，不同的 DAPT 後治療方案沒有在安全性方面具有任何優勢，並且使用 P2Y12 抑製劑單藥治療，即使是 Ticagrelor，似乎與單用阿司匹林一樣安全。相信這些結果與當前 ESC 對 CCS 患者的建議一致，考慮在臨床情況需要時縮短 DAPT。另一方面，讓臨床醫師安心，這超短 DAPT 治療針對缺血風險是可接受，或更長的 DAPT 認為不合適的急性患者可行選擇。

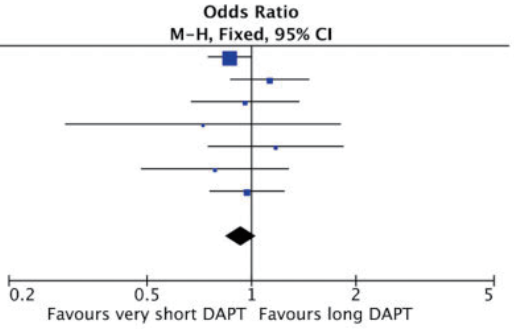
結論

與長 (12 個月) DAPT 相比，超短 (1 或 3 個月) DAPT 不會增加缺血性並發症的機率，同時將大出血或任何出血的機率降低 30% 以上。總而言之，研究結果支持在冠心症 - PCI 患者中使用非常短的 DAPT，但持續時間應根據個人風險收益情況進行調整。

MACE

Study or Subgroup	very short DAPT Events	Total	long DAPT Events	Total	Weight	Odds Ratio M-H, Fixed, 95% CI
GLOBAL LEADERS	362	7980	416	7988	51.6%	0.86 [0.75, 1.00]
OPTIMIZE	128	1563	114	1556	13.6%	1.13 [0.87, 1.47]
REDUCE	64	733	66	727	7.9%	0.96 [0.67, 1.37]
RESET	8	1059	11	1058	1.4%	0.72 [0.29, 1.81]
SMART-CHOICE	42	1495	36	1498	4.5%	1.17 [0.75, 1.84]
STOPDAPT-2	29	1500	37	1509	4.7%	0.78 [0.48, 1.28]
TWILIGHT	126	3555	130	3564	16.3%	0.97 [0.76, 1.25]
Total (95% CI)		**17885**		**17900**	**100.0%**	**0.93 [0.84, 1.03]**
Total events	759		810			

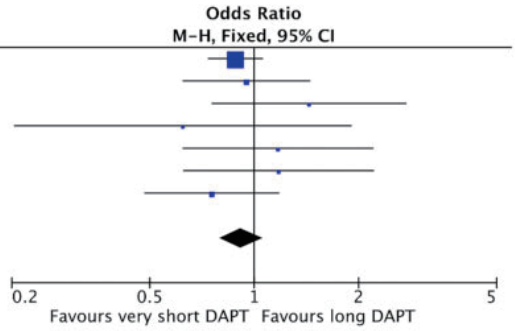
Heterogeneity: $Chi^2 = 4.95$, df = 6 (P = 0.55); $I^2 = 0\%$
Test for overall effect: Z = 1.32 (P = 0.19)



All-cause death

Study or Subgroup	very short DAPT Events	Total	long DAPT Events	Total	Weight	Odds Ratio M-H, Fixed, 95% CI
GLOBAL LEADERS	224	7980	253	7988	62.5%	0.88 [0.74, 1.06]
OPTIMIZE	43	1563	45	1556	11.2%	0.95 [0.62, 1.45]
REDUCE	23	733	16	727	4.0%	1.44 [0.75, 2.75]
RESET	5	1059	8	1058	2.0%	0.62 [0.20, 1.91]
SMART-CHOICE	21	1495	18	1498	4.5%	1.17 [0.62, 2.21]
STOPDAPT-2	21	1500	18	1509	4.5%	1.18 [0.62, 2.22]
TWILIGHT	34	3555	45	3564	11.3%	0.76 [0.48, 1.18]
Total (95% CI)		**17885**		**17900**	**100.0%**	**0.92 [0.80, 1.06]**
Total events	371		403			

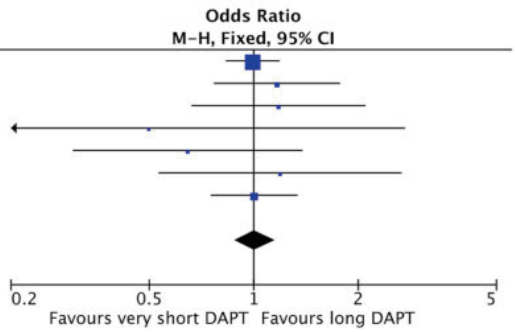
Heterogeneity: $Chi^2 = 4.41$, df = 6 (P = 0.62); $I^2 = 0\%$
Test for overall effect: Z = 1.16 (P = 0.25)



Myocardial infarction

Study or Subgroup	very short DAPT Events	Total	long DAPT Events	Total	Weight	Odds Ratio M-H, Fixed, 95% CI
GLOBAL LEADERS	248	7980	250	7988	56.5%	0.99 [0.83, 1.19]
OPTIMIZE	49	1563	42	1556	9.5%	1.17 [0.77, 1.77]
REDUCE	26	733	22	727	5.0%	1.18 [0.66, 2.10]
RESET	2	1059	4	1058	0.9%	0.50 [0.09, 2.73]
SMART-CHOICE	11	1495	17	1498	3.9%	0.65 [0.30, 1.38]
STOPDAPT-2	13	1500	11	1509	2.5%	1.19 [0.53, 2.67]
TWILIGHT	95	3555	95	3564	21.6%	1.00 [0.75, 1.34]
Total (95% CI)		**17885**		**17900**	**100.0%**	**1.01 [0.88, 1.15]**
Total events	444		441			

Heterogeneity: $Chi^2 = 2.92$, df = 6 (P = 0.82); $I^2 = 0\%$
Test for overall effect: Z = 0.11 (P = 0.91)

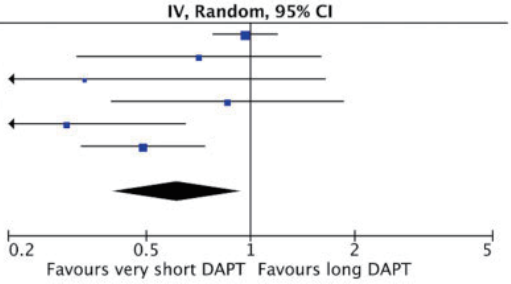


圖一、主要不良心血管事件 (MACE)、全因死亡和心肌梗塞。

Major bleeding

Study or Subgroup	very short DAPT Events	Total	long DAPT Events	Total	Weight	Odds Ratio IV, Random, 95% CI
GLOBAL LEADERS	163	7980	169	7988	27.3%	0.96 [0.78, 1.20]
OPTIMIZE	10	1563	14	1556	14.2%	0.71 [0.31, 1.60]
RESET	2	1059	6	1058	5.7%	0.33 [0.07, 1.65]
SMART-CHOICE	12	1495	14	1498	15.0%	0.86 [0.40, 1.86]
STOPDAPT-2	8	1500	27	1509	14.7%	0.29 [0.13, 0.65]
TWILIGHT	34	3555	69	3564	23.1%	0.49 [0.32, 0.74]
Total (95% CI)		**17152**		**17173**	**100.0%**	**0.61 [0.40, 0.94]**
Total events	229		299			

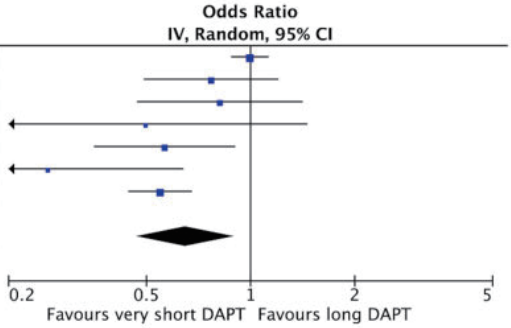
Heterogeneity: $Tau^2 = 0.16$; $Chi^2 = 15.58$, df = 5 (P = 0.008); $I^2 = 68\%$
Test for overall effect: Z = 2.24 (P = 0.03)



Any bleeding

Study or Subgroup	very short DAPT Events	Total	long DAPT Events	Total	Weight	Odds Ratio IV, Random, 95% CI
GLOBAL LEADERS	529	7980	532	7988	21.2%	1.00 [0.88, 1.13]
OPTIMIZE	35	1563	45	1556	15.5%	0.77 [0.49, 1.20]
REDUCE	24	733	29	727	13.5%	0.81 [0.47, 1.41]
RESET	5	1059	10	1058	6.5%	0.50 [0.17, 1.46]
SMART-CHOICE	28	1495	49	1498	15.1%	0.56 [0.35, 0.90]
STOPDAPT-2	6	1500	23	1509	8.2%	0.26 [0.11, 0.64]
TWILIGHT	141	3555	250	3564	20.1%	0.55 [0.44, 0.68]
Total (95% CI)		**17885**		**17900**	**100.0%**	**0.65 [0.47, 0.90]**
Total events	768		938			

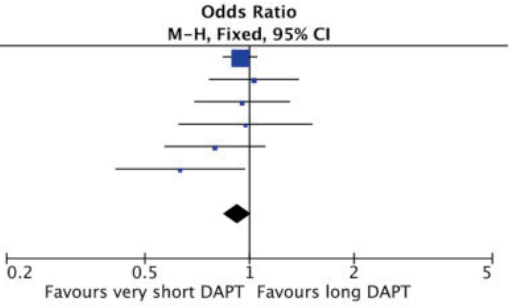
Heterogeneity: $Tau^2 = 0.13$; $Chi^2 = 32.82$, df = 6 (P < 0.0001); $I^2 = 82\%$
Test for overall effect: Z = 2.60 (P = 0.009)



Net clinical benefit

Study or Subgroup	very short DAPT Events	Total	long DAPT Events	Total	Weight	Odds Ratio M-H, Fixed, 95% CI
GLOBAL LEADERS	616	7980	653	7988	64.4%	0.94 [0.84, 1.05]
OPTIMIZE	93	1563	90	1556	9.1%	1.03 [0.76, 1.39]
REDUCE	85	733	88	727	8.3%	0.95 [0.69, 1.31]
RESET	40	1059	41	1058	4.2%	0.97 [0.62, 1.52]
SMART-CHOICE	65	1495	81	1498	8.3%	0.80 [0.57, 1.11]
STOPDAPT-2	35	1500	55	1509	5.7%	0.63 [0.41, 0.97]
Total (95% CI)		**14330**		**14336**	**100.0%**	**0.92 [0.84, 1.01]**
Total events	934		1008			

Heterogeneity: $Chi^2 = 4.46$, df = 5 (P = 0.49); $I^2 = 0\%$
Test for overall effect: Z = 1.75 (P = 0.08)

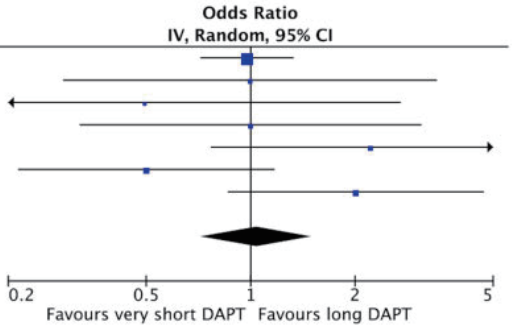


圖二、主要出血、任何出血和淨臨床獲益。

Stroke

Study or Subgroup	very short DAPT Events	Total	long DAPT Events	Total	Weight	Odds Ratio IV, Random, 95% CI
GLOBAL LEADERS	80	7980	82	7988	41.4%	0.98 [0.72, 1.33]
OPTIMIZE	5	1563	5	1556	7.6%	1.00 [0.29, 3.45]
REDUCE	2	733	4	727	4.3%	0.49 [0.09, 2.71]
RESET	6	1059	6	1058	8.8%	1.00 [0.32, 3.11]
SMART-CHOICE	11	1495	5	1498	9.9%	2.21 [0.77, 6.39]
STOPDAPT-2	8	1500	16	1509	14.0%	0.50 [0.21, 1.17]
TWILIGHT	16	3555	8	3564	14.1%	2.01 [0.86, 4.70]
Total (95% CI)		**17885**		**17900**	**100.0%**	**1.04 [0.72, 1.50]**
Total events	128		126			

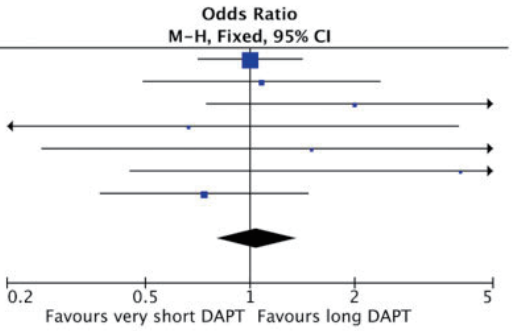
Heterogeneity: Tau² = 0.06; Chi² = 7.96, df = 6 (P = 0.24); I² = 25%
Test for overall effect: Z = 0.21 (P = 0.83)



Stent thrombosis

Study or Subgroup	very short DAPT Events	Total	long DAPT Events	Total	Weight	Odds Ratio M-H, Fixed, 95% CI
GLOBAL LEADERS	64	7980	64	7988	59.8%	1.00 [0.71, 1.42]
OPTIMIZE	13	1563	12	1556	11.2%	1.08 [0.49, 2.37]
REDUCE	12	733	6	727	5.6%	2.00 [0.75, 5.36]
RESET	2	1059	3	1058	2.8%	0.67 [0.11, 3.99]
SMART-CHOICE	3	1495	2	1498	1.9%	1.50 [0.25, 9.01]
STOPDAPT-2	4	1500	1	1509	0.9%	4.03 [0.45, 36.12]
TWILIGHT	14	3555	19	3564	17.8%	0.74 [0.37, 1.47]
Total (95% CI)		**17885**		**17900**	**100.0%**	**1.05 [0.80, 1.37]**
Total events	112		107			

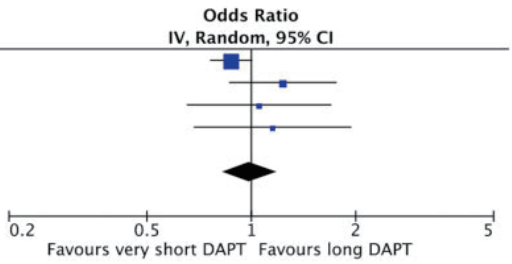
Heterogeneity: Chi² = 4.57, df = 6 (P = 0.60); I² = 0%
Test for overall effect: Z = 0.34 (P = 0.73)



TVR

Study or Subgroup	very short DAPT Events	Total	long DAPT Events	Total	Weight	Odds Ratio IV, Random, 95% CI
GLOBAL LEADERS	389	7980	442	7988	57.1%	0.87 [0.76, 1.01]
OPTIMIZE	70	1563	57	1556	20.0%	1.23 [0.86, 1.76]
REDUCE	36	733	34	727	12.3%	1.05 [0.65, 1.70]
RESET	31	1059	27	1058	10.6%	1.15 [0.68, 1.94]
Total (95% CI)		**11335**		**11329**	**100.0%**	**0.99 [0.82, 1.18]**
Total events	526		560			

Heterogeneity: Tau² = 0.01; Chi² = 4.02, df = 3 (P = 0.26); I² = 25%
Test for overall effect: Z = 0.14 (P = 0.89)



圖三、中風、支架內血栓形成和靶血管血流重建。

INFORMATION FOR AUTHORS

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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.

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