

Taiwan Society of Cardiovascular Interventions

臺灣介入性 心臟血管醫學會

83期 會訊 2021年10月



110年10月23日 Contemporary Approaches to Bifurcation Stenting 講師合影

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臺灣介入性心臟血管醫學會會訊(第八十三期, Oct., 2021)

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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

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各位親愛的會員好友們:

時序入秋,秋意漸濃,這兩個月來 COVID-19 疫情依舊處於緊張之中,但學會仍舉辦了數場活動。

包括與心臟學會聯合甄審介入性心臟血管專科醫師考試(筆試及口試),教育訓練委員會舉辦了分叉病灶(Bifurcation Lesion)的最新治療研討會,醫事人員委員會舉辦了繼續教育研討會,學會也協辦了北榮及振興醫院的 Live Demonstration Course。另外,學



術委員會持續開會準備明年 TTT 會議的節目,編輯委員會也在積極邀稿完成每 年本會學術期刊能出刊兩次的目標。凡此種種,皆是有賴大家的幫忙,讓學會 的會務在疫情之下仍然可以正常的運作。

期待疫情的陰霾能夠早日煙消雲散,大家能夠恢復正常的生活,各位會員在辛苦工作、照顧患者之餘,也要注意自身的安全及健康,感恩!

理事長

謝宜璋

2021.10

會務活動-入會申請書

臺灣介入性心臟血管醫學會 入會申請表

填表日期: 年 月 日 名 性 別 □男 □女 貼相片處 身分證 英文姓名 (實貼一張) 號碼 省(市) 出生日期 年 月 日 出生地 縣(市) 最高學歷 學校 科系(所) 單位/職務 現任醫院 O: 户籍地址 電 H: 話 M:1. □同戶籍地址 通訊地址 必 □通訊地址 填 E-mail(必填) Fax: (a)______ 期間: ___ 年 ___ 月至 ___ 年 ___ 月 (1) 醫院:_____ 醫師主管姓名: 列印後主管簽名:_____ 介入性 醫師主管姓名:_____ 列印後主管簽名:_____ 工作經歷 列印後主管簽名:_____ 醫師主管姓名: 名:____ 名:____ 推薦會員 推薦會員 (1)(2) 列印後簽名:_____ 列印後簽名:_____ □ 同意入會 審查結果 □普通會員 □ 不同意入會 □ 準會員 (此欄由審 員 會員證 □ 名譽會員 查人員填 號碼 類 審查人員: □ 贊助會員 寫)

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

地址:10041 台北市中正區忠孝西路一段 50 號 16 樓之 18

TEL: 02-23811698 FAX: 02-23815198

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

臺灣介入性心臟血管醫學會 第八屆第七次學術委員會會議紀錄

一、時 間:110年10月8日(星期五)PM6:30

二、地 點:視訊 Google Meet

三、出席人員:主委:曹殿萍

委員:李文領、徐中和、張其任、蔡政廷、顧博明

四、請假人員:王怡智、施俊明、高憲立、郭風裕、黃啟宏、鄭正一、羅秉漢

五、列席人員:謝官璋理事長

秘書處:許榮城秘書長

秘 書:賴瑋儀、陳詠潔、黃玉卉、劉子瑄(記錄)

六、報告事項:

七、議程:

提案一:討論年度國際研討會 TTT 2022 籌備及節目規劃。

說明:1.討論節目時段及內容規劃

- (1) 請參閱螢幕 TTT2022 簡表
- (2) 請參閱螢幕各節目表規劃
- (3) TTT 2022 外賓邀請名單
- 2. TTT 2022 Case Competition 徵稿截至目前投稿篇數如下,截稿日期為 10 月 20 日,討論是否需延長徵稿時間:
 - A. Coronary CTO: 0 篇
 - B. CHIP: 0 篇
 - C. Coronary Complications: 2 篇
 - D. Image/Physiology: 0 篇
 - E. Structural Heart (Including Structural Heart Disease Complication): 0 篇
 - F. Carotid-EVT (Including EVT Complication): 0 篇
- 3. 依據衛福部疾病管制署規定,目前會議會場防疫管理措施如附件(目前二級 警戒管制措施期間為10月5日至10月18日,待10月19日後會再持續追 蹤)。
 - 10月6日詢問過台大國際會議中心,目前維持室內80人,超過80人須維持1.5公尺距離:只有201能容納100人,301、401容納80人。
- 4. 預錄方式:

第八屆第七次學術委員會會議

外賓演講預錄方式,是否如秋季會(國外 Faculties 採用預錄方式,當天會議上一起參與討論)

- ※決議: 1. A. 中榮及中國的 Demo Live 配合學會,請學會安排 Lectures。
 - B. 因 APSIC 不 參加 TTT 2022, 曹主委請張其任委員協助安排替代 Symposium。
 - 2. Case Competition 再請各位委員協助宣傳並踴躍投稿及邀稿。
 - 3. TTT Faculty 網站正在加憑證中,憑證完成後可以再請醫師測試完,約一星期後(約10月底)正式上線。
 - 4. 晚宴部分先請秘書處進行規劃,屆時再視疫情而定。
 - 5. 再請秘書處規劃兩種授課呈現方式:
 - A. 國內外皆採用預錄方式。
 - B. 國外預錄、國內實體課程。

提案二:討論 2022 夏季會及 TTT 2023 之日期及地點。

※決議: A. 2022 夏季會地點及日期: 因 2021 年疫情嚴峻,原本應於台中舉辦的秋季會 改為線上;因此決定 2022 年仍在台中舉辦,日期為 Jul. 30~31, 2022。

B. TTT 2023 日期: Jan. 7~8, 2023。

提案三:討論下次召開委員會會議日期。

※決議:預計於12月召開視訊會議,請秘書處再調查。(調查時間以12月1~15日為主。)

八、臨時動議

九、散會

臺灣介入性心臟血管醫學會 第八屆第七次編輯暨登錄委員會會議紀錄

一、時間:110年10月19日(星期二)PM6:30

二、地點:線上會議

三、出席人員:主委:李文領

委員: 盧怡旭、呂信邦、徐國基、謝明哲、吳卓鍇、邱昱偉、陳冠群

四、請假人員:顧博明、林肇鋒、蘇河名、王宇澄、謝敏雄

五、列席人員:理事長:謝宜璋

秘書長: 許榮城副秘書長: 黃慶昌

秘 書 處:賴瑋儀、陳詠潔、劉子瑄、黃玉卉(記錄)

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. ROTA 計畫進度說明 --- 完成度進度

- 2. RDN 計畫進度說明 ---- 收案進度
- 3. CHIP 計畫進度說明 ---- 收案進度
- ※決議:1. ROTA 已完成 161 位, 還差 14 位。
 - 2. RDN 已收案 110 位, 還可以收案 40 位。
 - 3. CHIP 已收案 285 位, 還可以收案 123 位。

提案二:登錄資料使用規範。

說明: 附件 TSOC HF Paper 發表規則

- ※決議:1. ROTA 登錄計畫及 CHIP 登錄計畫已有足夠數據可以統計分析,預計明年7 月第13期雜誌推薦醫師投稿
 - 2. 收案最多的醫院投稿第一篇
 - 3. 收案醫院皆可使用 Data 發表 Paper
 - 4. 統計分析各自處理
 - 5. 提案內容須要有針對性
 - 6. Paper 發表時所有收案中心的 PIs 皆要列名
 - 7. 文章末在 Acknowledgement 中感謝內容再擬

第八屆第七次編輯暨登錄委員會會議

提案三:第八屆雜誌稿件第十二期交稿進度。

說明:1.第十二期稿件:預計2021年10月30日交稿。

- 王宇澄 Review Article (TSOC STEMI Guideline P2Y12 Inhibitors Update Highlight)
- 盧怡旭 Review Article
- 呂信邦 Original Article
- 盧澤民 Case Report
- 陳冠群 Case Report ---- 已交稿
- 新光 Case Report ---- 已交稿
- 謝宜璋(諾華) Review Article --- 已交稿
- 李文領 Original Article --- 已交稿

※決議:持續提醒稿件繳交

提案四:TTT Faculty網頁:

說明:https://www.tscimd.org.tw/ttt/

※決議:1.已加上 SSL 安全憑證

2. 弱點測試後,可發給所有副秘書長測試

八、臨時動議:

第13期稿件邀稿名單

※決議:1. 兩篇 Original Article 可用 ROTA 及 CHIP 登錄計畫的資料

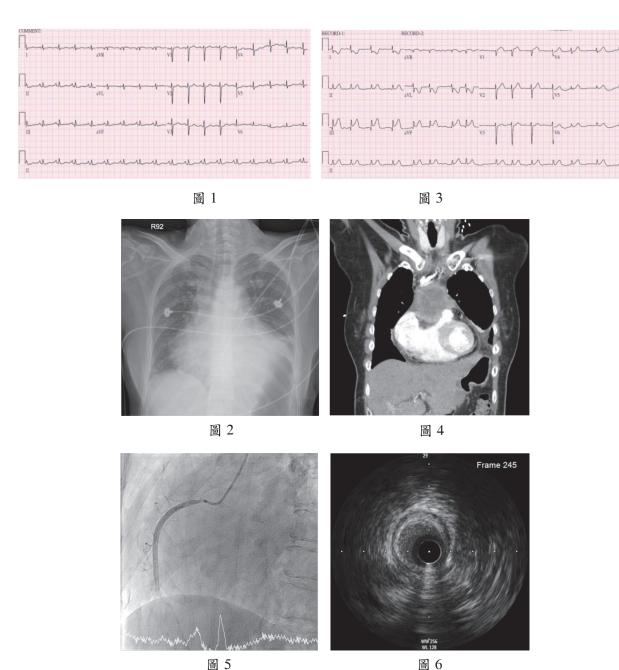
2. 第八屆未投稿的委員 ---- 顧博明醫師

九、散會

本期案例

【案例】

54 歲女性,因間歇性胸痛及氣促至急診,心電圖(圖1)及胸部X光(圖2)如圖所示,執行 心包穿刺術後病人發生急性胸痛,心電圖(圖3)如圖所示,服用 NTG 後症狀緩解,胸部電 腦斷層(圖4)及心導管(圖5,圖6)如圖所示。



【試問】 引發下壁心肌缺氧的原因?

上期解答

【案例】

A 66-year-old woman visited our hospital with complaining of near syncope episode with chest tightness. She had a history of breast cancer and received surgical treatment. Coronary angiography showed slow flow in right coronary artery. The angiography showed totally occlusion in left anterior descending artery (LAD) mid site (Figure 1). During the angiography procedure, the patient complained of chest tightness with concomitant unstable hemodynamic and ST elevation in ECG monitor immediately. When we prepared for balloon angioplasty, repeated coronary angiography five minutes later showed non-obstructive LAD with a TIMI III flow (Figure 2). The patient's symptom was progressively subsided with stable hemodynamic and there was no more ST change in ECG monitoring.

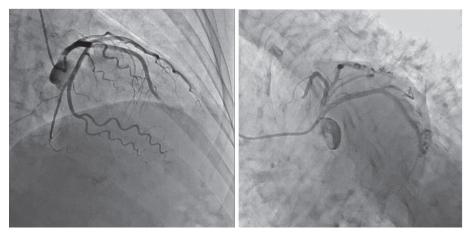


Figure 1

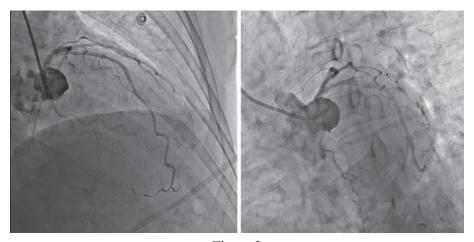


Figure 2

[Question]

What is the diagnosis?

12 介入影像專欄

【解答】

Most of the no-reflow phenomenon was found in patients with ST segment elevation myocardial infarction receiving primary balloon angioplasty. Distal embolization of the obstructive plaque or thrombus after ballooning angioplasty in the genesis of no-flow phenomenon was observation and evidenced. Other mechanisms as prolonged ischemia, extensive myocardial injury, and reperfusion injury led to microvascular damage could be the potential theory. No-flow phenomenon in diagnostic coronary angioplasty is rare. In spite the true mechanism could be complex and multi-factorial. It could be potentially life-threatening condition during diagnostic coronary angiography.¹

References

1. Zavala-Alarcon E, Cecena F, Little R, Bant A, Van Poppel S, Patel R. The no-flow phenomenon during diagnostic coronary angiography. Cardiovasc Revasc Med. 2005 Jul-Sep;6(3):126-32.

Impact of Transcatheter Mitral Valve Repair on Preprocedural and Postprocedural Hospitalization Rates

Andrew Czarnecki, MD, MSC, Lu Han, PHD, Wael Abuzeid, MD, MSC, Warren J.Cantor, MD, Vincent Chan, MD, MPH, Eric A. Cohen, MD, Gideon N. Cohen, MD, PHD, Neil Fam, MD, Pallav Garg, MD, Benjamin Hibbert, MD, PHD, Shamir R. Mehta, MD, MSC, Geraldine Ong, MD, MSC, Mark Osten, MD, Dennis T. Ko, MD, MSC

J Am Coll Cardiol Intv 2021;14:2274-2281

ABSTRACT

OBJECTIVES

The objective of this study was to determine the effect of transcatheter mitral valve repair (TMVr) on hospitalization rates by assessing pre- and postprocedural hospitalization patterns.

BACKGROUND

TMVr has emerged as the treatment of choice for selected patients with mitral regurgitation, but the impact of these procedures on hospital utilization remains unclear.

METHODS

All patients who underwent TMVr in Ontario, Canada, between 2011 and 2017 were included in this observational study using population-based data. Hospitalization person-year rates were assessed in the years before and after TMVr and 4 predefined intervals: 1 to 30, 31 to 90, 91 to 182, and 183 to 365 days. Main outcomes of interest were all-cause and heart failure (HF) hospitalizations. Poisson regression models were used to compare incidence rates across all time periods.

RESULTS

The study cohort included 523 patients. In the year preceding TMVr, 66.2% of patients were hospitalized compared with 47.4% in the year following. There were stepwise increases in both all-cause and HF hospitalization rates in the periods preceding the index procedure, and all postprocedural periods had significantly lower hospitalization rates. The adjusted rate ratios for all-cause and HF-related hospitalization in the year after TMVr were 0.65 (95% CI: 0.56-0.76) and 0.38 (95% CI: 0.29-0.51), respectively. All time periods had significant reductions in all-cause and HF hospitalization in the adjusted analysis.

44 醫學新知(I)

CONCLUSIONS

In this population-based study, significant reductions were observed in both all-cause and HF-related hospitalizations in all time periods after TMVr compared with the year prior. This suggests that TMVr has a sustained effect on hospitalization rates despite a high-risk population.

經導管二尖瓣膜修補術在術前與術後對於住院率之影響

编譯:台大醫院心臟內科 張皓雲醫師

二尖瓣逆流 (MR) 是最常見的瓣膜性心臟疾病。在75歲以上族群中,盛行率更高達百分之十。二尖瓣逆流常導致心衰竭、住院、甚至是死亡等不良的預後。然而,嚴重二尖瓣逆流病人常因高齡、多重共病症、與左心室收縮功能不良等原因有著較高之手術風險,進而使得病人會不願意接受手術治療。經導管二尖瓣膜修補術 (Transcatheter Mitral Valve Repair, TMVr) 屬侵入性的治療,提供了這群高手術風險之病患另一個安全的治療方法。在 COAPT 試驗中,將功能性二尖瓣逆流 (Functional MR) 隨機分配至藥物治療與藥物治療再加上經導管二尖瓣膜修補術的這組在二年內可以大幅減少因心衰竭而住院與死亡率。但此試驗是否可以代表真實的臨床照護與退化性二尖瓣逆流 (Degenerative MR) 就還有著疑問。在 MITRA-FR 試驗中,結果無法證實經導管二尖瓣膜修補術能減少住院率與死亡率。在 TVT (Transcatheter Valve Therapy) 登錄的資料中,接受經導管二尖瓣膜修補術能減少位衰竭住院,卻增加全因住院率 (All-cause Hospitalization)。因此,在實際的臨床照護上,經導管二尖瓣膜修補術是否能對住院率有著明顯的改善就是此篇研究想要探討的主題。

方法

此觀察性研究分析所有於 2011 至 2017 年間,在加拿大安大略省接受經導管二尖瓣膜修補 術之病人,比較手術前一年與手術後一年住院率的差異。總共分析了手術前 1-30 天、31-90 天、91-182 天、183-365 天與手術後 1-30 天、31-90 天、91-182 天、183-365 天的全原因住 院率與心衰竭住院率之差異。分母是以人年 (Person-year) 去分析並使用泊松回歸 (Poisson Regression Models) 來比較不同區間之發生率。

結果

此研究總共分析了 523 個病人。詳細的病人特徵如表一。在接受經導管二尖瓣膜修補術的前一年,66.2% 的病人有住院過;相較之下,術後一年內只有 47.4% 的病人有住院的紀錄。隨著時間越接近手術日,在全因住院率(圖一)與心衰竭住院率(圖二)上皆呈現階梯狀上升(Step-wise Increase)。而在手術後,隨著區間離手術日越遠,也皆呈現階梯狀下降。經校正後的發生比率(Rate Ratio),全因住院率為 0.65 (95% 信賴區間為 0.56-0.76),而心衰竭住院率為 0.38 (95% 信賴區間為 0.29-0.51)(表二)。

討論

在這個研究中,作者清楚的呈現出在接受經導管二尖瓣膜修補術之病人,在術前一年與術後

一年不管是全因住院率或者是心衰竭住院率皆有大幅度的下降。在所有的區間,手術前的一個月有著最高的住院率,其可能暗示著這群二尖瓣逆流之病患整體狀況是會隨著時間越來越差,變差到一定程度後才接受了經導管二尖瓣膜修補術。相較之下,在所有的區間中,手術後半年到一年間有著最低的住院率,表示手術能改善住院率,而改善的效果是隨著時間有著持續性的進步。

在之前的幾個大型研究中,有著不同的研究結果,Rymer 等研究者藉由分析 TVT 登錄資料,發現經導管二尖瓣膜修補術能降低心衰竭住院率,卻無法改善全因住院率。而在其他兩個研究中卻有著與本研究相同的結果。有著這樣不一樣的結果推測可能原因有幾點:第一,在本研究的族群裡,病人年紀相對較年輕、衰弱程度較低、較高比例有左心室收縮功能不良(暗示著有較高的比率為功能性二尖瓣逆流)。這些差異暗示著選擇特定的病人族群接受經導管二尖瓣膜修補術,對於結果似乎有著一定的影響。第二,在研究的期間,安大略省只有六家醫學中心能進行經導管二尖瓣膜修補術。MitraClip 這種高技術性的手術,病人多集中在特定的醫學中心進行,醫師對於手術的熟悉度也會增高,進而有著較好的預後。本研究與之前的COAPT 研究有著相同的結果,表示經導管二尖瓣膜修補術確實在真實的臨床治療上,不管是功能性還是退化性二尖瓣逆流皆可以改善二尖瓣逆流病人的住院率。

觀察此研究的結果,可以看到在手術前一年中,越接近手術時有著越高的住院率,在手術前的一個月達到高峰。此現象很有可能是反應了大多數的病人是在疾病已經進展到後期,頻繁的住院後才開始接受介入性治療如經導管二尖瓣膜修補術。而在手術後可以看到在這群高齡、常合併多重共病的族群中能明顯的改善住院率。這兩個現象皆暗示在更早期即進行經導管二尖瓣膜修補術,而不是等到病人已經症狀明顯反覆住院後才介入,是否會有著更好的預後,就有待更多的研究來證實。

結論

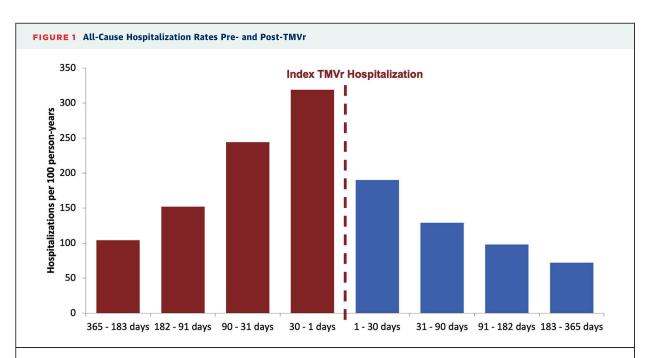
在這個特定族群觀察性的研究中,全因住院率與心衰竭住院率在經導管二尖瓣膜修補術後每個區間,皆與術前相對應的區間有著顯著的下降(核心圖示)。此結果表示,儘管須接受經導管二尖瓣膜修補術之病人是一群常需要住院接受治療的高危險族群,經導管二尖瓣膜修補術對於此高住院風險族群的住院率還是有著持續性的改善。

表一

TABLE 1 Baseline Characteristics of Study Co	Mort (N = 323)
Demographics	70 (71 04)
Age (y)	78 (71-84)
Female	208 (39.8)
Income quintile	
Low	176 (33.6)
Medium	209 (40.0
High	134 (25.6)
Rural residence	58 (11.1)
Clinical characteristics	
NYHA functional class	
1	31 (5.9)
II	111(21.2)
III	285 (54.5)
IV	65 (12.4)
Left ventricular ejection fraction	
≥50%	211 (40.3)
35%-49%	90 (17.2)
20%-34%	117 (22.4)
<20%	37 (7.1)
Cardiac risk factors	
Diabetes	164 (31.4)
Hypertension	364 (69.6)
Dyslipidemia	407 (77.8)
Comorbidities	
Myocardial infarction	201 (38.4)
Heart failure	442 (84.5)
Atrial fibrillation	361 (69.0)
Cerebrovascular disease	66 (12.6)
Peripheral vascular disease	42 (8.0)
Chronic obstructive lung disease	123 (23.5)
Liver disease	13 (2.5)
Frailty	189 (39.6)
Chronic kidney disease	104 (19.9)
Dialysis	33 (6.3)
Anemia	152 (29.1)
Dementia	13 (2.5)
Cancer	42 (8.0)
Charlson comorbidity score	2.50 (1-4)
•	2.50 (1-4)
Prior cardiac procedures	262 (66.4)
Cardiac catheterization within 1 y	363 (69.4)
Percutaneous coronary intervention within 1 y	69 (13.2)
Coronary artery bypass graft surgery	112 (21.4)
Permanent pacemaker	45 (8.6)
Cardiac resynchronization therapy	12 (2.3)
Implantable cardioverter-defibrillator	71 (13.6)
Values are median (interquartile range) or n (%).	
values are median (interquartite range) or ft (%).	

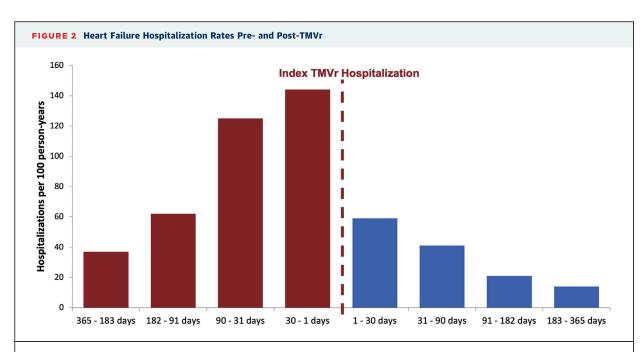
表二

			Time Period		
	1 y	1-30 d	31-90 d	91-182 d	183-365 d
All-cause hospitalization ^a	0.65 (0.56-0.76)	0.59 (0.45-0.77)	0.53 (0.41-0.68)	0.67 (0.51-0.86)	0.73 (0.57-0.94)
Heart failure hospitalization ^a	0.38 (0.29-0.51)	0.41 (0.26-0.66)	0.33 (0.22-0.51)	0.36 (0.22-0.59)	0.40 (0.24-0.64

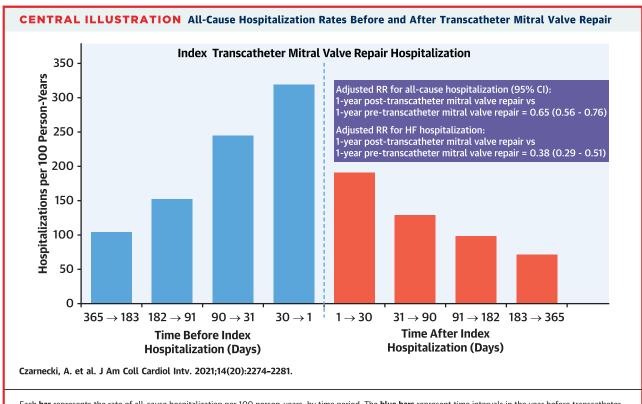


Each **bar** represents the rate of all-cause hospitalization per 100 person-years, by time period. The **red bars** represent time intervals in the year pre-TMVr, and the **blue bars** represent the corresponding time intervals in the year post-TMVr. TMVr = transcatheter mitral valve repair.

圖一



Each **bar** represents the rate of heart failure hospitalization per 100 person-years, by time period. The **red bars** represent time intervals in the year pre-TMVr, and the **blue bars** represent the corresponding time intervals in the year post-TMVr. TMVr = transcatheter mitral valve repair.



Each **bar** represents the rate of all-cause hospitalization per 100 person-years, by time period. The **blue bars** represent time intervals in the year before transcatheter mitral valve repair, and the **orange bars** represent the corresponding time intervals in the year after transcatheter mitral valve repair. HF = heart failure; RR = rate ratio.

核心圖示 (Central Illustration)

Impact of Intravascular Ultrasound on Long-Term Clinical Outcomes in Patients With Acute Myocardial Infarction

Ik Jun Choi, MD, PHD, Sungmin Lim, MD, PHD, Eun Ho Choo, MD, Byung-Hee Hwang, MD, Chan Joon Kim, MD, PHD, Mahn-Won Park, MD, PHD, Jong-Min Lee, MD, PHD, Chul Soo Park, MD, PHD, Hee Yeol Kim, MD, PHD, Ki-Dong Yoo, MD, PHD, Doo Soo Jeon, MD, PHD, Ho Joong Youn, MD, PHD, Wook-Sung Chung, MD, PHD, Min Chul Kim, MD, PHD, Myung Ho Jeong, MD, PHD, Youngkeun Ahn, MD, PHD, Kiyuk Chang, MD, PHD

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ABSTRACT

BACKGROUND

IVUS-guided PCI has been associated with improved cardiovascular outcomes. However, the beneficial effect of IVUS-guided PCI in patients with AMI in the drug-eluting stent era remains unclear.

METHODS

Patients who underwent PCI with drug-eluting stents were selected from 10,719 patients enrolled in a multicenter AMI registry. The included patients were classified into 2 groups according to the use or nonuse of IVUS. The primary outcome was a composite of major adverse cardiovascular events (MACE), including cardiovascular death, myocardial infarction, and target lesion revascularization, during long-term follow-up.

RESULTS

A total of 9,846 patients were treated with IVUS-guided PCI (n = 2,032) or angiography-guided PCI (n = 7,814). IVUS-guided PCI was associated with reduced MACE (HR: 0.779; 95% CI: 0.689-0.880; P < 0.001). The results were consistent after multivariable regression and propensity score matching. One-year landmark analysis showed a lower risk for MACE within 1 year (HR: 0.766; 95% CI: 0650-0.903; P = 0.002) and beyond 1 year (HR: 0.796; 95% CI: 0663-0.956; P = 0.014) after index PCI.

CONCLUSIONS

The use of IVUS was associated with better long-term cardiovascular outcomes. The clinical benefit of IVUS was maintained both within and beyond 1 year after index PCI. The use of IVUS in PCI should be considered for patients with AMI.

血管內超音波的使用對於急性心肌梗塞病人長期預後的 影響

編譯:台大醫院心臟內科 連朕緯醫師

許多研究顯示,於心導管手術中使用血管內超音波輔助可以改善病人的心血管預後。然而, 在塗藥支架的年代,目前尚未有明確的證據支持「於心導管手術中使用血管內超音波輔助對 於急性心肌梗塞病人能帶來好處」。

方法

COREA-AMI為韓國首爾聖瑪麗醫院主導的一個多中心真實世界的數據蒐集資料庫,收納了 2004 年 1 月至 2014 年 8 月有接受心導管冠狀動脈介入手術的急性心肌梗塞病人。此篇研究於資料庫篩選出 10,719 位接受心導管手術的急性心肌梗塞病人,將病人分為於心導管手術中有使用血管內超音波輔助 (IVUS-guided PCI) 或單純使用冠狀動脈攝影作為治療指引 (Angiography-guided PCI) 的兩個不同組別,去比較兩個組別之間的重大心血管事件(包括心血管相關的死亡、心肌梗塞、目標病兆再重建)在長期追蹤下的發生率。

結果

在篩選出的 9,846 位病人當中,有 2,032 位病人於心導管手術中接受了血管內超音波的輔助,有 7,814 位病人在心導管手術中單純以冠狀動脈攝影作為治療指引。在平均追蹤時間 1,690 天 (四分位距: 966-2,563 天)之下,使用血管內超音波輔助的病人有較低的重大心血管事件發生率 (HR: 0.779; 95% CI: 0.689-0.880; P < 0.001)。這樣的結果在使用多變相回歸分析及傾向分數配對 (Propensity Score Matching) 後仍然有統計學上的意義。在距離指標心導管冠狀動脈介入手術 (Index PCI) 後第一年的定點分析 (Landmark Analysis) 顯示使用血管內超音波輔助的病人在一年內有較低的重大心血管事件發生 (HR: 0.766; 95% CI: 0650-0.903; P = 0.002),這樣顯著的差異在超過一年的後續追蹤下仍然持續 (HR: 0.796; 95% CI:0663-0.956; P = 0.014)。

討論

在這篇大規模多中心的世代研究中,收錄了9,846 位接受心導管手術並置放塗藥支架的急性 心肌梗塞病人,於術中有使用血管內超音波輔助的病人相比於單純以血管攝影為治療指引的 病人有著較佳的長期預後。

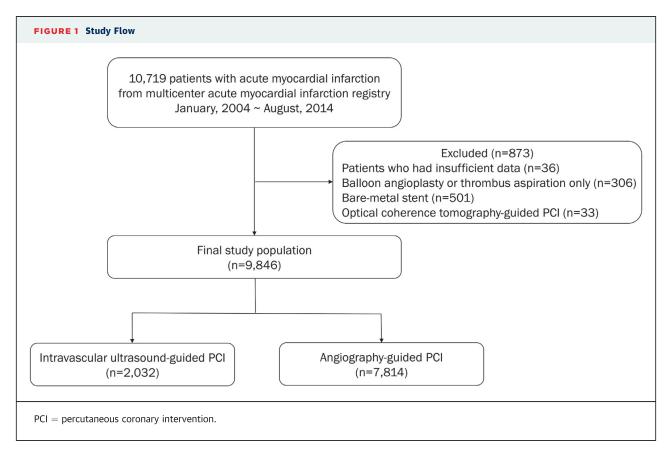
這個研究的結果可以簡單歸納為三點:(1)兩組在手術併發症的發生並沒有差異,相反的,有接受血管內超音波輔助的病人會接受較多、較大且較長的支架置放。這樣的結果可能影響

了所有血管內病兆的涵蓋率及支架位置的最佳化,進而避免了不佳的臨床預後。(2) 使用血管內超音波輔助帶來的好處包含較低的重大心血管事件發生、心血管死亡、心肌梗塞及目標病兆的再重建率。這樣的好處不只在第一年出現,並在後續的長期追蹤仍然存在。然而,預期之外的是,統計結果上並沒有看到使用血管內超音波輔助的病人和單純血管攝影的病人相比有著較低的支架血栓發生率。(3) 在次族群的分析當中,使用血管內超音波輔助對於慢性腎臟疾病的病人及有左主幹冠狀動脈病兆的病人有最顯著的好處。過去認為血管內超音波的輔助對於複雜性經皮冠狀動脈介入手術 (Complex PCI) 會有幫助,不過在次族群分析當中並沒有看到這方面統計學上的差異。

此篇研究有一些侷限。首先,這是一篇回溯性的世代研究,雖然已使用傾向分數配對分析來降低存在的干擾因子,然而未知的干擾因子仍然可能存在且影響到統計的結果。再者,於手術中是否使用血管內超音波是由臨床醫師決定,對於為何使用血管內超音波的原因無法在這篇研究中被闡明。因為是回溯性的研究,無法事先訂定血管內超音波輔助的支架置放的標準,所以每個臨床醫師經驗上的差異也可能影響到研究結果。第三,研究數據並沒有蒐集到血管內超音波的細項參數,例如最小面積 (Minimal Area)、斑塊特性 (Plaque Characteristic)等。所以無法進一步分析哪一項參數會和長期臨床於後有所相關。

結論

急性心肌梗塞的病人於心導管手術中接受血管內超音波的輔助是安全且沒有增加手術相關的併發症。使用血管內超音波輔助的病人接受了較多、較大且較長的支架置放。血管內超音波輔助在急性心肌梗塞並接受塗藥支架置放的病人有較低的心血管事件發生率。這樣的好處在長期追蹤超過一年以後仍然持續存在。對於急性心肌梗塞的病人,在心導管手術中應考慮使用血管內超音波輔助。



表一

TABLE 1 Baseline Clinical and Procedural Characteristics in Patients With Acute Myocardial Infarction Undergoing PCI According to the Use of IVUS Angiography IVUS (n = 7,814)(n = 2,032)P Value Demographic characteristics < 0.001 Age, y $63.8\,\pm\,12.6$ $61.4\,\pm\,12.5$ 5,565 (71.2) < 0.001 Male 1,533 (75.4) Body mass index, kg/m² $24.1\pm3.2\,$ $24.3\,\pm\,3.1$ 0.016 Initial vital signs Systolic blood pressure, mm Hg 128.7 ± 27.1 128.5 ± 25.7 0.727 Diastolic blood pressure, mm Hg $78.6\,\pm\,16.7$ 78.1 ± 16.0 0.251 Heart rate, beats/min $79.0\,\pm\,19.1$ $78.9\,\pm\,18.6$ 0.836 Killip class < 0.001 5,923 (75.8) 1,724 (84.8) ı 92 (4.5) Ш 674 (8.6) 484 (6.2) 94 (4.6) Ш IV 733 (9.4) 122 (6.0) Clinical diagnosis 0.003 STEMI 4,337 (55.5) 1,053 (51.8) **NSTEMI** 3,477 (44.5) 979 (48.2) Hypertension 4,097 (52.4) 1,009 (49.7) 0.027 Diabetes mellitus 2,496 (31.9) 595 (29.3) 0.023 < 0.001 Dyslipidemia 1,288 (16.5) 225 (11.1) Chronic kidney disease 474 (23.3) 0.022 2,011 (25.8) 1,139 (56.1) 0.091 Smoking 4,214 (53.9) Family history of coronary artery 239 (3.1) 60 (3.0) 0.861 disease Previous myocardial infarction 270 (3.5) 87 (4.3) 0.088 124 (6.1) Previous PCI 0.739 495 (6.3) Previous CABG 32 (0.4) 9 (0.4) 0.988 Previous cerebrovascular events 576 (7.4) 137 (6.7) 0.354 Year of enrollment < 0.001 2004-2009 3,353 (42.9) 1,182 (58.2) 2010-2014 4,461 (57.1) 850 (41.8) Tertiary centers 3,658 (46.8) 531 (26.1) < 0.001 Laboratory characteristics Hemoglobin, g/dL 13.6 (12.2-15.1) 14.2 (12.7-15.4) < 0.001 Total cholesterol, mg/dL 0.782 175 (151-201) 175 (152-201) Triglyceride, mg/dL 102 (71-146) 102 (73-149) 0.194 HDL, mg/dL 40 (34-46) 40 (34-46) 0.674 LDL, mg/dL 111 (90-134) 111 (92-133) 0.715 Estimated glomerular filtration 79.2 (59.4-95.2) 79.0 (61.4-94.7) 0.781 rate, mL/min Initial CK-MB, ng/mL 7.6 (3.0-26.4) 6.7 (2.9-22.9) 0.016 Peak CK-MB, ng/mL 63.0 (16.7-181.5) 61.3 (15.4-200.5) 0.510

表一(接續)

表一(續)

TABLE 1 Continued			
	Angiography $(n = 7,814)$	IVUS (n = 2,032)	P Value
Left ventricular ejection fraction, %	53.4 ± 11.0	53.0 ± 10.4	0.144
Procedural characteristics			
Early invasive strategy	5,154 (66.0)	1,194 (58.8)	< 0.001
Door-to-balloon time, min	$1,217 \pm 6,953$	$1,567 \pm 3,612$	0.002
STEMI	73.5 ± 24.4	76.7 ± 26.1	0.241
NSTEMI	$1,971 \pm 4,511$	$2,324 \pm 3,395$	0.008
Disease extent			0.002
1-vessel disease	3,586 (45.9)	844 (41.5)	
2-vessel disease	2,535 (32.4)	700 (34.4)	
3-vessel disease	1,693 (21.7)	488 (24.0)	
Multivessel disease	4,228 (54.1)	1,188 (58.5)	< 0.001
Culprit lesion			< 0.001
Left main coronary artery	164 (2.1)	157 (7.7)	
LAD	3,696 (47.3)	1,073 (52.8)	
LCx	1,378 (17.6)	249 (12.3)	
RCA	2,571 (32.9)	552 (27.2)	
Stent generation			0.049
First-generation drug-eluting stent	2,242 (28.7)	629 (31.0)	
Second-generation drug-eluting stent	5,572 (71.3)	1,403 (69.0)	
Restenosis	126 (1.6)	47 (2.3)	0.041
Chronic total occlusion	313 (4.0)	74 (3.6)	0.491
Bifurcation	300 (3.8)	121 (6.0)	< 0.001
Timing of IVUS use	0 (0)		< 0.001
Pre-PCI only		178 (8.8)	
Post-PCI only		328 (16.1)	
Pre- and post-PCI		1,526 (75.1)	
Procedural complications			
No reflow	263 (3.4)	82 (4.0)	0.163
Coronary artery dissection	94 (1.2)	34 (1.7)	0.099
Distal embolization	14 (0.2)	2 (0.1)	0.550
Acute coronary thrombosis	11 (0.1)	3 (0.1)	0.999
Coronary artery perforation	3 (0.0)	2 (0.1)	0.276
Medications at discharge			
Aspirin	7,296 (98.3)	1,947 (98.8)	0.159
Clopidogrel	6,734 (86.2)	1,817 (89.4)	< 0.001
Potent P2Y ₁₂ inhibitor	1,048 (13.4)	207 (10.2)	< 0.001
Statin	7,105 (90.9)	1,867 (91.9)	0.193
Beta-blocker	6,162 (83.0)	1,629 (82.6)	0.719
ACE inhibitor or ARB	6,163 (78.9)	1,558 (76.7)	0.034

Values are mean \pm SD, n (%), or median (interquartile range).

ACE = angiotensin-converting enzyme; ARB = angiotensin receptor blocker; CABG = coronary artery bypass grafting; CK-MB = creatinine kinase-MB; HDL = high-density lipoprotein; IVUS = intravascular ultrasound; LAD = left anterior descending coronary artery; LCx = left circumflex coronary artery; LDL = low-density lipoprotein; NSTEMI = non-ST-segment elevation myocardial infarction; PCI = percutaneous coronary intervention; RCA = right coronary artery; STEMI = ST-segment elevation myocardial infarction.

表二

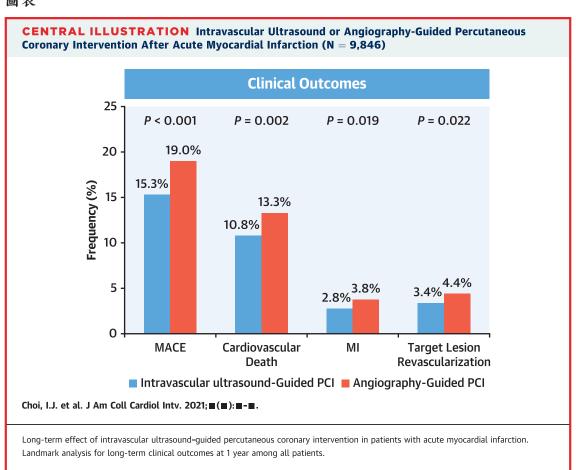
 TABLE 2
 Comparison of Clinical Outcomes Between IVUS-Guided and Angiography-Guided Percutaneous Coronary Intervention

	Unadjusted			Multivariate ^a		Propensity Score Matched		
	IVUS (n = 2,032)	Angiography (n = 7,814)	HR (95% CI)	P Value	HR (95% CI)	P Value	HR (95% CI)	P Value
MACE	311 (15.3)	1,484 (19.0)	0.779 (0.689-0.880)	< 0.001	0.800 (0.706-0.907)	< 0.001	0.762 (0.652-0.891)	< 0.001
Cardiovascular death	219 (10.8)	1,036 (13.3)	0.793 (0.686-0.913)	0.002	0.822 (0.709-0.954)	0.010	0.805 (0.668-0.971)	0.023
MI	56 (2.8)	295 (3.8)	0.709 (0.533-0.944)	0.019	0.766 (0.572-1.027)	0.075	0.600 (0.417-0.862)	0.006
Culprit MI	33 (1.6)	190 (2.4)	0.650 (0.449-0.940)	0.022	0.646 (0.443-0.942)	0.023	0.500 (0.320-0.782)	0.002
Nonculprit MI	24 (1.2)	113 (1.4)	0.795 (0.511-1.234)	0.306	1.016 (0.645-1.600)	0.947	0.852 (0.461-1.575)	0.610
TLR	70 (3.4)	347 (4.4)	0.737 (0.568-0.956)	0.022	0.738 (0.565-0.963)	0.025	0.686 (0.500-0.942)	0.020
Stent thrombosis	26 (1.3)	108 (1.4)	0.906 (0.590-1.390)	0.652	0.942 (0.607-1.464)	0.792	0.766 (0.450-1.305)	0.327
All-cause death	263 (12.9)	1,323 (16.9)	0.745 (0.635-0.850)	< 0.001	0.804 (0.702-0.920)	0.002	0.775 (0.655-0.919)	0.003

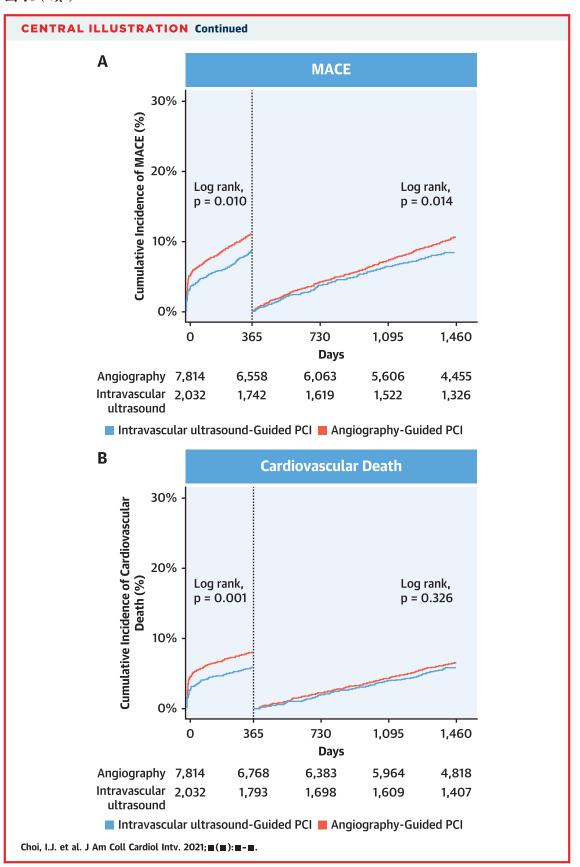
Values are n (%), unless otherwise indicated. ^aAdjusted variables included age, sex, body mass index, hypertension, diabetes, dyslipidemia, smoking, chronic kidney disease, end-stage renal disease, stroke, family history of coronary artery disease, prior MI, clinical diagnosis, Killip class, left ventricular ejection fraction, multivessel disease, culprit lesion, stent generation, restenosis, bifurcation, clopidogrel, potent P2Y₁₂ inhibitor, and angiotensin-converting enzyme inhibitor or angiotensin receptor blocker.

IVUS = intravascular ultrasound; MACE = major adverse cardiovascular event (a composite of cardiovascular death, myocardial infarction, or target lesion revascularization); MI = myocardial infarction; TLR = target lesion revascularization.

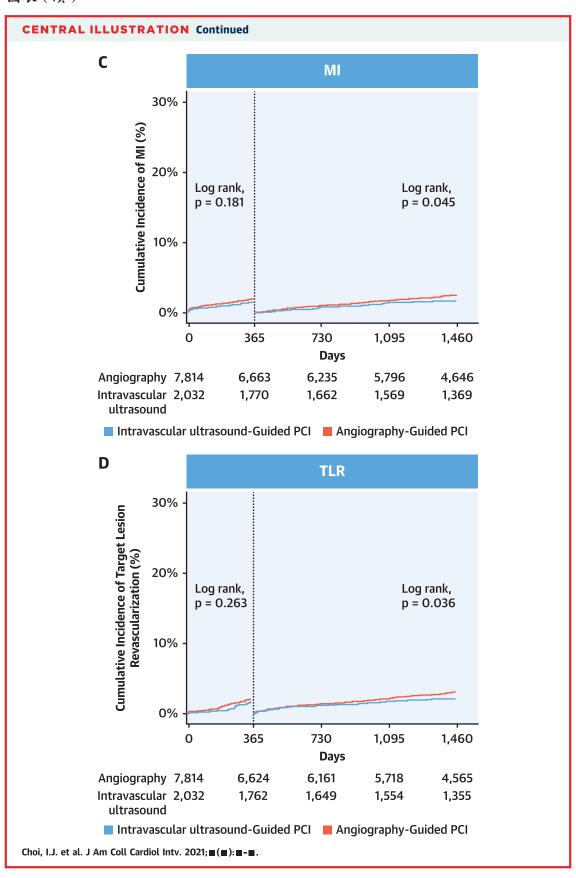
圖表

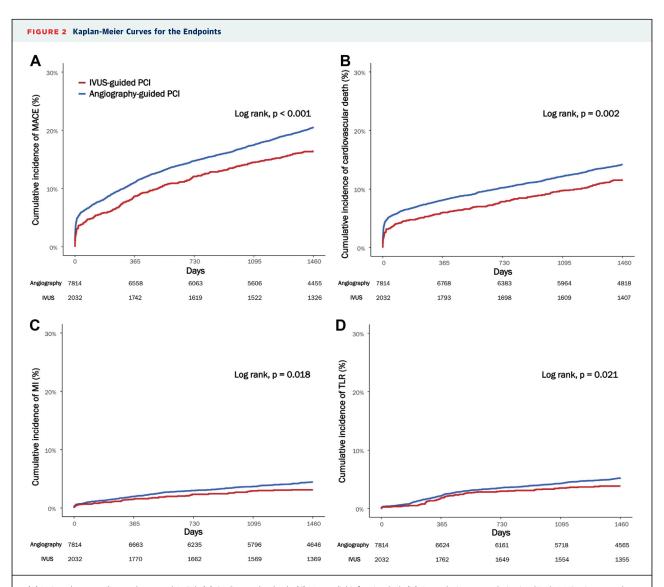


圖表(續)



圖表(續)





(A) Major adverse cardiovascular event (MACE). (B) Cardiovascular death. (C) Myocardial infarction (MI). (D) Target lesion revascularization (TLR). IVUS = intravascular ultrasound; PCI = percutaneous coronary intervention.

表三

	Unadjusted		Multivariate ^a	Multivariate ^a		ntched
	HR (95% CI)	P Value	HR (95% CI)	P Value	HR (95% CI)	P Value
Within 1 y						
MACE	0.766 (0.650-0.903)	0.002	0.808 (0.683-0.956)	0.013	0.793 (0.642-0.979)	0.031
Cardiovascular death	0.724 (0.595-0.881)	0.001	0.785 (0.643-0.959)	0.018	0.745 (0.580-0.957)	0.021
MI	0.762 (0.512-1.136)	0.183	0.809 (0.537-1.218)	0.309	0.657 (0.400-1.079)	0.097
Culprit MI	0.735 (0.450-1.202)	0.220	0.748 (0.453-1.235)	0.256	0.559 (0.308-1.013)	0.055
Nonculprit MI	0.805 (0.407-1.592)	0.532	0.944 (0.467-1.907)	0.872	0.987 (0.392-2.486)	0.978
TLR	0.807 (0.554-1.175)	0.264	0.775 (0.527-1.140)	0.195	0.805 (0.501-1.293)	0.369
Stent thrombosis	0.966 (0.568-1.646)	0.900	0.916 (0.527-1.592)	0.755	0.782 (0.397-1.539)	0.476
All-cause death	0.730 (0.609-0.874)	< 0.001	0.822 (0.683-0.989)	0.038	0.793 (0.628-1.002)	0.052
After 1 y						
MACE	0.796 (0.663-0.956)	0.014	0.796 (0.660-0.960)	0.017	0.728 (0.578-0.916)	0.007
Cardiovascular death	0.896 (0.720-1.115)	0.326	0.883 0.706-1.104)	0.274	0.890 (0.671-1.179)	0.416
MI	0.660 (0.438-0.994)	0.047	0.721 (0.474-1.098)	0.128	0.542 (0.318-0.923)	0.024
Culprit MI	0.561 (0.320-0.984)	0.044	0.535 (0.302-0.950)	0.033	0.435 (0.221-0.860)	0.017
Nonculprit MI	0.788 (0.442-1.402)	0.417	1.076 (0.592-1.954)	0.811	0.759 (0.333-1.732)	0.513
TLR	0.681 (0.475-0.977)	0.037	0.688 (0.475-0.994)	0.046	0.605 (0.395-0.928)	0.021
Stent thrombosis	0.810 (0.394-1.667)	0.567	0.916 (0.434-1.932)	0.818	0.741 (0.312-1.758)	0.496
All-cause death	0.764 (0.629-0.927)	0.007	0.792 (0.649-0.966)	0.021	0.757 (0.591-0.968)	0.026

^aAdjusted variables included age, sex, body mass index, hypertension, diabetes, dyslipidemia, smoking, chronic kidney disease, prior MI, clinical diagnosis, left ventricular ejection fraction, door-to-balloon time, multivessel disease, culprit lesion, stent generation, restenosis, bifurcation, clopidogrel, angiotensin-converting enzyme inhibitor or angiotensin receptor blocker, tertiary hospital, and year of enrollment.

Abbreviations as in Table 2.

	Angiography	IVUS		HR (95% CI)	P value	P for interaction
Overall	1484/7814 (19.0%)	311/2032 (15.3%)	 ■ 	0.783 (0.693-0.885)	<0.001	
Age <65	449/3878 (11.6%)	121/1175 (10.3%)	⊢= 1	0.885 (0.724-1.082)	0.232	0.492
Age ≥65	1035/3936 (26.3%)	190/857 (22.2%)	H = 1	0.810 0.694-0.945)	0.008	0.492
Female	559/2249 (24.9%)	93/499 (18.6%)	H=	0.723 (0.581-0.901)	0.004	0.278
Male	925/5565 (16.6%)	218/1533 (14.2%)	⊢= ⊣	0.836 (0.721-0.969)	0.017	0.276
Hypertension (-)	547/3717 (14.7%)	127/1023 (12.4%)	⊢=	0.831 (0.685-1.008)	0.061	0.515
Hypertension (+)	937/4097 (22.9%)	184/1009 (18.2%)	H=-1	0.765 (0.653-0.896)	0.001	0.515
Diabetes mellitus (-)	853/5318 (16.0%)	186/1437 (12.9%)	⊢=-1	0.786 (0.671-0.922)	0.003	0.844
Diabetes mellitus (+)	631/2496 (25.3%)	125/474 (26.4%)	H=	0.807 (0.666-0.977)	0.028	0.844
Chronic kidney disease (-)	740/5770 (12.8%)	186/1557 (11.9%)	⊢= 1	0.927 (0.789-1.089)	0.355	0.005
Chronic kidney disease (+)	737/2011 (36.6%)	125/474 (26.4%)	H=-1	0.653 (0.540-0.789)	<0.001	0.003
NSTEMI	672/3477 (19.3%)	162/979 (16.5%)	⊢ ■	0.844 (0.711-1.002)	0.053	0.218
STEMI	812/4337 (18.7%)	149/1053 (14.2%)	 -1	0.727 (0.610-0.865)	<0.001	
LVEF ≥40%	1163/6917 (16.8%)	247/1824 (13.5%)	⊢= ⊣	0.787 (0.686-0.903)	0.001	0.874
LVEF <40%	321/897 (35.8%)	64/208 (30.8%)		0.806 (0.616-1.054)	0.115	0.074
Multivessel disease (-)	564/3586 (15.7%)	110/844 (13.0%)	⊢=	0.808 (0.659-0.991)	0.041	0.574
Multivessel disease (+)	920/4228 (21.8%)	201/1188 (16.9%)	H=-1	0.752 (0.645-0.875)	<0.001	
Non-left main disease	1392/7616 (18.3%)	266/1815 (14.7%)	H = 1	0.778 (0.682-0.887)	<0.001	<0.001
Left main disease	92/198 (46.5%)	45/217 (20.7%)	-	0.361 (0.253-0.516)	<0.001	10.001
1 st DES	441/2242 (18.3%)	104/629 (16.5%)	⊢	0.818 (0.660-1.012)	0.065	0.621
2 nd DES	1043/5572 (18.7%)	207/1403 (14.8%)	H=-1	0.766 (0.660-0.889)	<0.001	
Complex PCI (-)	918/4917 (18.7%)	146/1064 (13.7%)	⊢=	0.709 (0.595-0.844)) <0.001	0.135
Complex PCI (+)	566/2897 (19.5%)	165/968 (17.0%)	├─	0.855 (0.719-1.017)	0.077	0.133

 $DES = drug-eluting \ stent; \ LVEF = left \ ventricular \ ejection \ fraction; \ NSTEMI = non-ST-segment \ elevation \ myocardial \ infarction; \ PCI = percutaneous \ coronary \ intervention; \ STEMI = ST-segment \ elevation \ myocardial \ infarction.$

Fractional Flow Reserve – Guided PCI as Compared with Coronary Bypass Surgery

W.F. Fearon, F.M. Zimmermann, B. De Bruyne, Z. Piroth, A.H.M. van Straten, L. Szekely, G. Davidavičius, G. Kalinauskas, S. Mansour, R. Kharbanda, N. Östlund Papadogeorgos, A. Aminian, K.G. Oldroyd, N. Al Attar, N. Jagic, J. H.E. Dambrink, P. Kala, O. Angerås, P. MacCarthy, O. Wendler, F. Casselman, N. Witt, K. Mavromatis, S.E.S. Miner, J. Sarma, T. Engstrøm, E.H. Christiansen, P.A.L. Tonino, M.J. Reardon, D. Lu, V.Y. Ding, Y. Kobayashi, M.A. Hlatky, K.W. Mahaffey, M. Desai, Y.J. Woo, A.C. Yeung, and N.H.J. Pijls, for the FAME 3 Investigators*

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ABSTRACT

BACKGROUND

Patients with three-vessel coronary artery disease have been found to have better outcomes with coronary-artery bypass grafting (CABG) than with percutaneous coronary intervention (PCI), but studies in which PCI is guided by measurement of fractional flow reserve (FFR) have been lacking.

METHODS

In this multicenter, international, noninferiority trial, patients with three-vessel coronary artery disease were randomly assigned to undergo CABG or FFR-guided PCI with current-generation zotarolimus-eluting stents. The primary end point was the occurrence within 1 year of a major adverse cardiac or cerebrovascular event, defined as death from any cause, myocardial infarction, stroke, or repeat revascularization. Noninferiority of FFR-guided PCI to CABG was prespecified as an upper boundary of less than 1.65 for the 95% confidence interval of the hazard ratio. Secondary end points included a composite of death, myocardial infarction, or stroke; safety was also assessed.

RESULTS

A total of 1500 patients underwent randomization at 48 centers. Patients assigned to undergo PCI received a mean (±SD) of 3.7±1.9 stents, and those assigned to undergo CABG received 3.4±1.0 distal anastomoses. The 1-year incidence of the composite primary end point was 10.6% among patients randomly assigned to undergo FFR-guided PCI and 6.9% among those assigned to undergo CABG (hazard ratio, 1.5; 95% confidence interval [CI], 1.1 to 2.2), findings that were not consistent with noninferiority of FFR-guided PCI (P = 0.35 for noninferiority). The incidence of death, myocardial infarction, or stroke was 7.3% in the FFR-guided PCI group and 5.2% in the CABG group (hazard ratio, 1.4; 95% CI, 0.9 to 2.1). The incidences of major bleeding, arrhythmia, and acute kidney injury were higher in the CABG group than in the FFR-guided PCI group.

CONCLUSIONS

In patients with three-vessel coronary artery disease, FFR-guided PCI was not found to be noninferior to CABG with respect to the incidence of a composite of death, myocardial infarction, stroke, or repeat revascularization at 1 year. (Funded by Medtronic and Abbott Vascular; FAME 3 ClinicalTrials.gov number, NCT02100722.)

血流儲備分數導引之經皮冠狀動脈介入治療與冠狀動脈 繞道手術之比較

編譯:臺大醫院心臟內科 陳威霖醫師

背景

三條冠狀動脈疾病 (Three-vessel Coronary Artery Disease) 在過去的研究顯示接受冠狀動脈 繞道手術 (Coronary Artery Bypass Graft, CABG) 的病患其預後較經皮冠狀動脈介入治療 (Percutaneous Coronary Intervention, PCI) 者為佳。然過去研究卻未有對於「血流儲備分數 (Fractional Flow Reserve, FFR) 導引下的經皮冠狀動脈介入治療」與「冠狀動脈繞道手術」二 者治療結果相較之證據。本研究試圖比較兩者效果。

方法

本研究為一個多醫學中心、跨國際的不劣性試驗 (Non-inferiority Trials)。患有三條冠狀動脈疾病的病人被隨機分派接受冠狀動脈繞道手術或血流儲備分數導引之經皮冠狀動脈介入治療 (使用近代釋放 Zotarolimus 的支架)。

主要療效指標 (Primary Endpoint) 探討一年內重大心臟或腦血管事件的發生率(包含全因性死亡、心肌梗塞、中風或需反覆接受心肌再灌流治療)。實驗預設為不劣性試驗,其風險比 (Hazard Ratio) 95% 信賴區間之上界為 1.65。而次要療效指標 (Secondary Endpoint) 則包括死亡、心肌梗塞、中風與反覆接受心肌再灌流治療。

結果

總共1500名病人於48個醫學中心進行隨機分派。接受經皮冠狀動脈介入治療者平均置放了3.7±1.9隻支架(平均值±標準差),而接受冠狀動脈繞道手術者平均吻合了3.4±1.0條遠端血管。

追蹤一年總和主要療效指標,接受血流儲備分數導引之經皮冠狀動脈介入治療者發生率為10.6%,而接受冠狀動脈繞道手術者發生率為6.9%(風險比1.5,95%信賴區間1.1-2.2)。結果顯示流儲備分數導引之經皮冠狀動脈介入治療並未達到不劣性之標準(P=0.35)。

死亡、心肌梗塞或中風之發生率在接受血流儲備分數導引之經皮冠狀動脈介入治療組為7.3% 而於接受冠狀動脈繞道手術組為5.2%(風險比1.4,95%信賴區間0.9-2.1)。接受冠狀動脈繞道手術者發生大出血、心律不整與急性腎功能損傷之發生率則明顯高於接受血流儲備分數導引之經皮冠狀動脈介入治療組。

結論

於三條冠狀動脈疾病之患者,在追蹤一年的死亡、心肌梗塞、中風或反覆血管再灌流的總和發生率上,接受「血流儲備分數導引下的經皮冠狀動脈介入治療」劣於「冠狀動脈繞道手術」。

表一

Characteristic	PCI (N = 757)	CABG (N = 743)
Age — yr	65.2±8.6	65.1±8.3
Male sex — no. (%)	616 (81.4)	619 (83.3)
White race — no. (%)†	711 (93.9)	686 (92.3)
Body-mass index‡	28.6±4.5	28.7±4.3
Diabetes — no. (%)	214 (28.3)	214 (28.8)
Insulin-dependent	55 (7.3)	61 (8.2)
Non–insulin-dependent	159 (21.0)	153 (20.6)
Hypertension — no./total no. (%)	538/756 (71.2)	556/741 (75.0)
Dyslipidemia — no./total no. (%)	521/756 (68.9)	531/741 (71.7)
Smoking status — no./total no. (%)		
Current tobacco user	145/756 (19.2)	136/741 (18.4)
Previous tobacco user	296/756 (39.2)	296/741 (39.9)
Family history of coronary artery disease — no./total no. (%)	246/756 (32.5)	213/740 (28.8)
Previous myocardial infarction — no./total no. (%)	252/756 (33.3)	248/741 (33.5)
Previous PCI — no./total no. (%)	98/756 (13.0)	104/741 (14.0)
History of TIA or CVA — no./total no. (%)	49/756 (6.5)	56/741 (7.6)
Kidney disease — no./total no. (%)§	37/756 (4.9)	44/741 (5.9)
Noninvasive test for ischemia — no./total no. (%)	311/756 (41.1)	301/741 (40.6)
LVEF ≤50% — no./total no. (%)	137/753 (18.2)	130/740 (17.6)
Hospitalized with NSTE-ACS — no./total no. (%)	300/756 (39.7)	287/741 (38.7)

^{*} Plus-minus values are means ±SD. CABG denotes coronary-artery bypass grafting, CVA cerebrovascular accident, LVEF left ventricular ejection fraction, NSTE-ACS non-ST-segment elevation acute coronary syndrome, PCI percutaneous coronary intervention, and TIA transient ischemic attack.

[†] Race was reported by the patients.

[‡] The body-mass index is the weight in kilograms divided by the square of the height in meters.

[§] Kidney disease was defined as an estimated glomerular filtration rate (calculated with the Modification of Diet in Renal Disease Study equation) of less than 60 ml per minute per 1.73 m² of body-surface area.

表二

Table 2. Angiographic and Procedural Characteristics.*		
Characteristic	PCI (N = 757)	CABG (N = 743)
Median time to procedure (IQR) — days	4 (1–13)	13 (6–26)
Median procedure duration (IQR) — min	87 (67–113)	197 (155–239)
Median length of hospital stay (IQR) — days	3 (1-7)	11 (7–16)
No. of lesions	4.3±1.3	4.2±1.2
At least one chronic total occlusion — no./total no. (%)	157/755 (20.8)	171/739 (23.1)
At least one bifurcation lesion — no./total no. (%)	522/755 (69.1)	491/739 (66.4)
SYNTAX score†	26.0±7.1	25.8±7.1
SYNTAX score category — no./total no. (%)†		
Low, 0 to 22	237/734 (32.3)	245/710 (34.5)
Intermediate, 23 to 32	365/734 (49.7)	343/710 (48.3)
High, >32	132/734 (18.0)	122/710 (17.2)
PCI characteristics		
Staged procedure — no./total no. (%)	166/750 (22.1)	NA
No. of stents	3.7±1.9	NA
Median total length of stents placed (IQR) — mm	80 (52–116)	NA
Intravascular imaging used — no./total no. (%)	87/744 (11.7)	NA
CABG characteristics		
Multiple arterial grafts — no./total no. (%)	NA	173/705 (24.5)
No. of distal anastomoses	NA	3.4±1.0
LITA used as graft — no./total no. (%)	NA	684/705 (97.0)
Off-pump surgery — no./total no. (%)	NA	168/698 (24.1)
FFR used before CABG — no./total no. (%)	NA	72/718 (10.0)

^{*} Plus—minus values are means ±SD. Data on time to procedure were missing for 11 patients in the PCI group and 37 in the CABG group, data on procedure duration were missing for 12 patients in the PCI group and 77 patients in the CABG group, data on length of hospital stay were missing for 8 patients in the PCI group and 15 patients in the CABG group, and data on number of lesions were missing for 2 patients in each group. In the PCI group, data on number of stents were missing for 12 patients, and data on total length of stents were missing for 30 patients. In the CABG group, data on the number of distal anastomoses were missing for 51 patients. FFR denotes fractional flow reserve, IQR interquartile range, LITA left internal thoracic artery, and NA not applicable.

[†] The Synergy between Percutaneous Coronary Intervention with Taxus and Cardiac Surgery (SYNTAX) score is an angiography-based score evaluating the severity of the coronary artery disease; lower scores indicate less complexity of coronary artery disease and predict a better outcome with PCI (the lowest score is 0, and there is no upper limit). Scores were calculated by the core laboratory. Data were missing for 23 patients in the PCI group and 33 patients in the CABG group.

表三

End Point	PCI (N = 757)	CABG (N = 743)	Hazard Ratio (95% CI)	P Value
	no. of patie	ents (%)*		
Primary end point				
Death from any cause, myocardial infarction, stroke, or repeat revascularization	80 (10.6)	51 (6.9)	1.5 (1.1–2.2)	0.35†
Secondary end points:				
Death	12 (1.6)	7 (0.9)	1.7 (0.7–4.3)	
Death from cardiac causes	6 (0.8)	4 (0.5)		
Myocardial infarction	39 (5.2)	26 (3.5)	1.5 (0.9–2.5)	
Spontaneous	25 (3.3)	17 (2.3)		
Procedural	13 (1.7)	9 (1.2)		
Stroke	7 (0.9)	8 (1.1)	0.9 (0.3–2.4)	
Death, myocardial infarction, or stroke	55 (7.3)	39 (5.2)	1.4 (0.9–2.1)	
Repeat revascularization	45 (5.9)	29 (3.9)	1.5 (0.9–2.3)	
PCI	39 (5.2)	26 (3.5)		
CABG	6 (0.8)	3 (0.4)		
Safety end points §				
BARC type 3–5 bleeding¶	12 (1.6)	28 (3.8)		< 0.01
Acute kidney injury∥	1 (0.1)	7 (0.9)		<0.04
Atrial fibrillation or clinically significant arrhythmia	18 (2.4)	105 (14.1)		<0.001
Definite stent thrombosis	6 (0.8)	NA		
Definite symptomatic graft occlusion	NA	10 (1.3)		
Rehospitalization within 30 days	42 (5.5)	76 (10.2)		< 0.001

^{*} Percentages are crude values based on an intention-to-treat analysis.

[†] This P value was obtained from a test of noninferiority with respect to the primary end point.

[‡] Confidence intervals (CIs) were not adjusted for multiplicity and should not be interpreted to inform definitive treatment effects.

[§] P values were obtained from chi-square or Fisher's exact tests. Patients who were lost to follow-up before the end of the first year were excluded from comparisons with respect to safety end points.

 $[\]P$ Bleeding Academic Research Consortium (BARC) type 3–5 indicates severe bleeding.

Acute kidney injury was defined as an increase in serum creatinine level by at least 0.3 mg per deciliter (\geq 26.5 μ mol per liter) within 48 hours, an increase in serum creatinine level to at least 1.5 times the baseline level that was known or presumed to have occurred within the previous 7 days, or a urine volume of less than 0.5 ml per kilogram of body weight per hour for 6 hours.

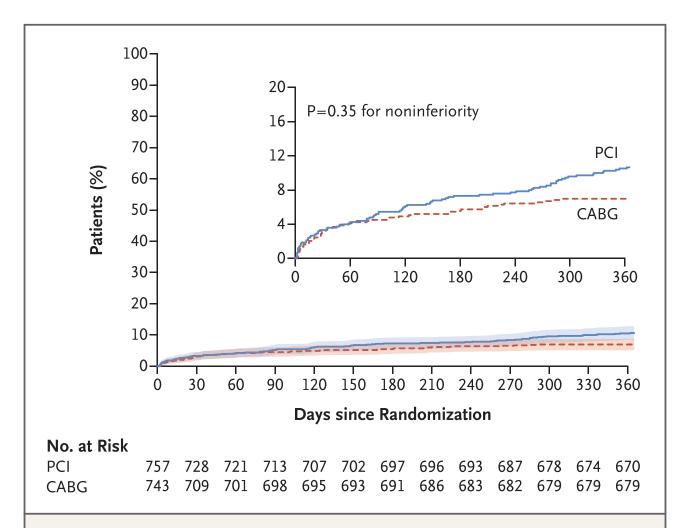


Figure 1. Kaplan-Meier Curves for the Primary End Point.

The primary end point was the occurrence within 1 year of a major adverse cardiac or cerebrovascular event, defined as death from any cause, myocardial infarction, stroke, or repeat revascularization. The inset shows the same data on an enlarged y axis. CABG denotes coronary-artery bypass grafting, and PCI percutaneous coronary intervention.

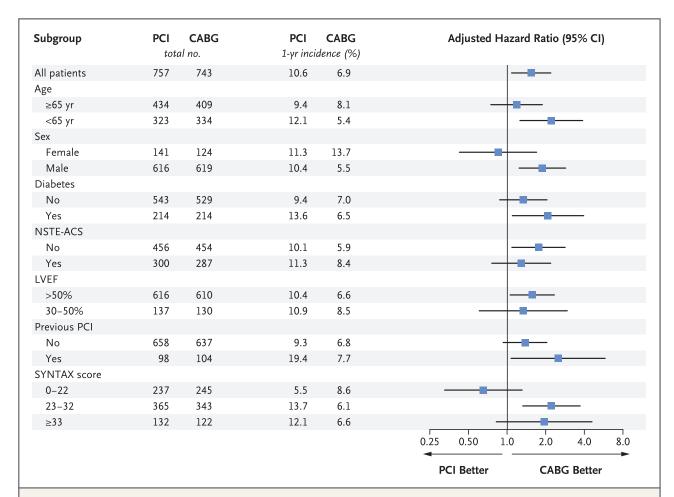
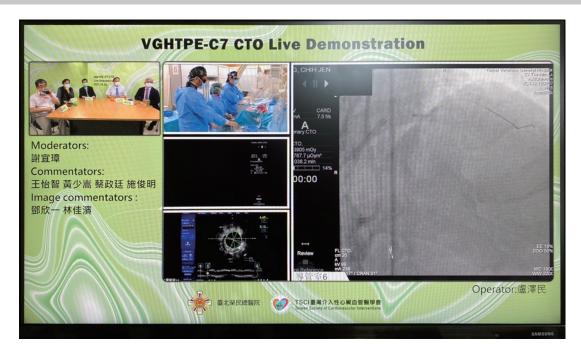


Figure 2. Subgroup Analyses of the Primary End Point.

The Synergy between Percutaneous Coronary Intervention with Taxus and Cardiac Surgery (SYNTAX) score is an angiography-based score evaluating the severity of coronary artery disease; lower scores indicate less complexity of coronary artery disease and predict a better outcome with PCI (the lowest score is 0, and there is no upper limit). Scores were calculated by the core laboratory. CI denotes confidence interval, LVEF left ventricular ejection fraction, and NSTE-ACS non–ST-segment elevation acute coronary syndrome.

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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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