静岡医療センター研究業績集 (27) (2019 年度)

静岡医療センター臨床研究部

2019年の静岡医療センター臨床研究部業績集が完成いたしました。田邊臨床研究部長ならびに臨床研究部の職員の方々のご努力に感謝申し上げます。

本年も、英文論文の多さには驚くばかりで、臨床診療で忙しい中、数多くの英語論文を発表されている心臓血管外科の高木部長には、頭の下がる思いです。また、受託研究なども多く、静岡医療センターの実力を改めて実感しております。 国立病院機構共同臨床研究も開始され、今後、NHO内の共同研究が盛んにおこなわれていくこととなることが期待されます。

2019年の静岡医療センターの研究業績は、従来の心臓血管外科、循環器内科、消化器内科の業績に加え、内科系、そしてリハビリテーション科などの業績も報告され、静岡医療センターの臨床研究がさらに発展していく予感がいたします。

今後も静岡医療センター臨床研究部の活動をご支援くださるようお願い申し あげます。

2020年9月

独立行政法人国立病院機構静岡医療センター 院長 中野 浩

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臨床研究部の活動状況

臨床研究部の活動状況

はじめに

国立病院機構の使命として質の高い臨床研究と治験の推進を掲げています。静岡医療センターもその基本指針に健康科学の推進を挙げており、当臨床研究部がその責務を担っています。 2019年度の臨床研究部活動をまとめましたのでご報告いたします。

1. 臨床研究部の概要

(1) 設置年度

設置年度:平成3年10月

(2)組 織

5研究室および治験管理室

0 奶儿里40 6 0 旧歌自往里				
	氏 名	専任・併任の別	備考	
臨床研究部長	田邊 潤	専任	治験管理室長併任	
循環動態機能研究室長	小鹿野道雄	併任	循環器内科部長	
病因病態研究室長	欠			
治療開発研究室長	黒田勝宏	併任	脳神経外科部長	
人工臟器研究室長	高木寿人	併任	心臟血管外科部長	
神経難病治療研究室長	本間 豊	併任	脳神経内科診療部長	

2. 施設の機能付与及び特徴

臨床機能上は循環器・がん・救急・総合診療を4本柱とする急性期医療と神経、筋疾患、 重症心身障害を中心に脳血管障害以外の疾患も積極的に診療をおこなっています。 独立行政法人国立病院機構の東海北陸地方における循環器病の基幹施設に指定されており ます。2019年3月に静岡県東部で初めて補助循環器用ポンプカテーテル、インペラの実施施 設として認定されました。地域支援病院として、広域での連携強化とともに大型医療機器 の共同利用についても引き続き推進していくこととしています。

3. これまでの臨床研究部の主な活動状況

臨床研究部は主として循環器病およびその関連疾患に関する病因、病態、診断、治療、予防対策、社会復帰を含む予後調査等についての系統的研究を行なってきましたが、独立行政法人化に伴う病院機能の見直しとともに、循環器に限定せず、がん・総合診療を始め看護部門等での臨床研究にも幅広く支援を行っています。

これまでの主な研究テーマは循環器系では(1)動脈硬化性疾患の危険因子への対策に関する研究(2)虚血性心疾患、脳卒中、大動脈瘤、末梢血管疾患の病態及び先進的治療に関する研究(3)循環器病の予後調査に関する研究です。がんでは消化器内科、外科を中心に肝胆膵での業績が多くあげられています。臨床研究部での研究は、これらの臨床活動により得られた資料を有効に活用しながら診療の水準を向上させることを目的としています。今後も社会・医療に貢献する質の高い臨床研究を目指します。

4. 2019年度活動の概要

本年度は昨年度と比べて学会発表は横ばいでしたが、論文発表は増加しています。欧文での論文発表数の増加が目立っています。

平成27年4月に『人を対象とする医学系研究に関する倫理指針』が施行され、指針に則って臨床研究審査委員会で臨床研究の倫理審査をおこなっています。静岡を拠点とするファルマバレーセンターや日本医師会、その他の紹介も利用して、より多くの試験を受託するべく、体制を整えています。本年度はPMDAより監査を受けております。

5. 2019年度に獲得した研究費

(1) 国立病院機構共同臨床研究

課題名	研究者	研究費
膵がん切除後の補助化学療法における S-1 単独療法と S-1 とメトホルミンの併用療法 の非盲検ランダム化第Ⅱ相比較試験 (ASMET)	中野浩(外科)	19 万円

6. 受託研究に関する実績

件 数	受託金額	実施率	治験審査委員会登録の有無
17件	29, 156 千円	55.5%	有

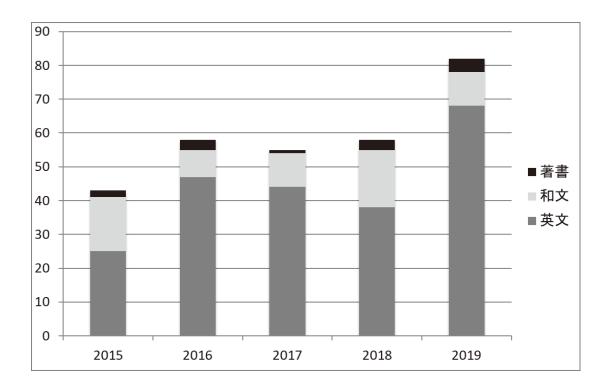
7. 2019年度の研究発表

(1) **学会発表:**国内 98件、国際 2件、 合計 100件 (2) **論文発表:**邦文 10編、欧文 68編、 合計 78編

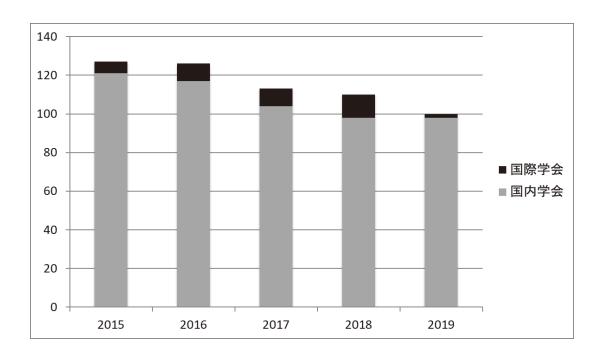
※ ただし、学会抄録、研究班報告書は含まない。

※ 欧文はLetterも含む

論文発表数の推移



学会発表数の推移



8. 受託研究審查委員会

委員長 : 田邊 潤 (臨床研究部長)

副委員長: 溝口 功一 (副院長)

外部委員: 杉村 伸一 (社会福祉法人静岡恵明学園赤ちゃんセンター静岡恵明学園園長)

青木 千賀子 (日本大学国際関係学部非常勤講師)

高橋 和彦 (静岡県立東部特別支援学校副校長)

委員: 小澤 章子 (統括診療部長)

委 員 : 本間 豊 (医局長) 委 員 : 松下 恒久 (副医局長) 委 員 : 森 元春 (事務部長) 髙木 亮 委 員 : (薬剤部長) 井上 淳子 委 員 : (看護部長) 委員: 宮嶋 由晴 (企画課長) 委員:棚田良之 (業務班長)

9. 2019年度新規受託研究一覧

(1)治験

研究課題	依頼者	責任医師
中等症から重症の活動期のクローン病患者を 対象とする JNJ-64304500 の安全性及び有効性 の評価を目的とした第 2b 相,ランダム化,二重 盲検,プラセボ対照,並行群間,多施設共同試験	ヤンセンファーマ株式会社	消化器内科 部長 大西佳文
日本人の中等症又は重症の活動性潰瘍性大腸 炎患者を対象として OZANIMOD を経口投与 したときの有効性及び長期安全性を評価する 第 2/3 相多施設共同ランダム化二重盲検プラ セボ対照試験	セルジーン株式会社	消化器内科 部長 大西佳文

(2) 製造販売後臨床試験・使用成績調査

研究課題	依頼者	責任医師
オノアクト点滴静注用 50 mg 一般使用成績調査	小野薬品工業株式会社	循環器內科 臨床研究部長 田邊 潤
IMPELLA 補助循環用ポンプカテーテルおよび IMPELLA 制御装置 使用成績調査	日本アビオメッド 株式会社	心臓血管外科 波里陽介
IMPELLA 補助循環用ポンプカテーテルおよび IMPELLA 制御装置 使用成績調査	日本アビオメッド 株式会社	循環器内科 医長 川中秀和
アデムパス錠使用成績調査 (肺動脈性肺高血圧症)	バイエル薬品株式会社	循環器內科 臨床研究部長 田邊 潤
ジーンプラバ®点滴静注 625mg 一般使用成績調査	MSD 株式会社	循環器內科 臨床研究部長 田邊 潤

ソリリス®点滴静注 300 mg 視神経脊髄炎スペクトラム障害に関する特定使用成績調	アレクシオンファーマ 合同会社	脳神経内科 診療部長 本間 豊
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(3) 副作用·感染症報告

研究課題	依頼者	責任医師
レボフロキサシン錠 250 mg「杏林」の投与後に	キョーリンリメディオ	内科
発現した「低血糖疑い」症例の詳細調査	株式会社	殿岡久美子
トラクリア 62.5mg 錠 副作用詳細調査	アクテリオンファーマ シューティカルズ ジャパン 株式会社	循環器内科 西郡 卓
プラザキサカプセル 75mg 副作用・感染症詳細	日本ベーリンガー	脳神経外科
報告書	インゲルハイム株式会社	高橋照男

(4) 医療機器

· / - / - / - / - / - / - / - / - / - /		
研究課題	依頼者	責任医師
経皮的補助循環システム使用実態調査	テルモ株式会社	心臓血管外科 部長 高木寿人
SJM OCT イメージングカテーテルに関する使用成績調査	アボットバスキュラー ジャパン株式会社	循環器内科 臨床研究部長 田邊 潤
体外式膜型人工肺キャピオックス FX プレコネクト回路使用実態調査	テルモ株式会社	心臓血管外科 部長 高木寿人
JLL 食道温モニタリングシステム性能に関する 使用実態調査	日本ライフライン 株式会社	循環器内科 部長 小鹿野道雄
アルチマスター及びアルチマスタータンセイ 市場実態調査	テルモ株式会社	循環器内科 臨床研究部長 田邊 潤

10. 臨床研究審査委員会

委員長 : 田邊 潤 (臨床研究部長)

副委員長: 溝口 功一 (副院長)

外部委員: 杉村 伸一 (社会福祉法人静岡恵明学園赤ちゃんセンター静岡恵明学園園長)

外部委員: 青木 千賀子 (日本大学国際関係学部非常勤講師) 外部委員: 高橋 和彦 (静岡県立東部特別支援学校副校長)

委員: 小澤 章子 (統括診療部長)

委 員 : 本間 豊 (医局長) 委 員 : 松下 恒久 (副医局長) 委 員 : 古山 雅博 (事務部長) 委 員 : 髙木 亮 (薬剤部長) 委 員 : 井上 淳子 (看護部長) 委 員 : 宮嶋 由晴 (企画課長) 委員:棚田良之 (業務班長)

(1) 当院で実施の研究

研究課題	研究責任者
アロマセラピーを使用した 16 時間夜勤を行う看護師の疲労軽減について	看護師 加藤 潤
手術室看護師の抱えるストレスについて	看護師 梅原朋世
退院支援退院調整に対する当病棟看護師の認識	看護師 飯田順子
がん化学療法における HBV 再活性化対策に関する検討	薬剤部 彦坂麻美
当院におけるプレアボイド報告事例と副作用報告事例	薬剤部 田代 匠
施設間・地域連携が必要な疾患の急性期(一般)病棟における栄養管理	栄養管理室 丹羽正人
心不全患者の意思決定を支えるために〜領域・分野をこえて考えよう〜	看護師 市川智子
高齢心不全患者の心不全の急性増悪による再入院に関する因子の検討	リハビリテーション科 鬼頭和也
循環器病棟で勤務する看護師の職務に対するストレッサ―と職務満足度	看護師 細野奈々
頭部の除圧の必要性と頭部の圧測定 〜耳介の褥瘡が軽快・治癒に至った経緯から〜	看護師 杉本香織
申し送りが長くなることに看護師個人の申し送りに対する考えは影響して いるのか	看護師 河口真菜美
当院における術後訪問定着化に向けての取り組み	看護師 土屋奈津美
笑いによる仕事へのモチベーション向上の検証	看護師 大庭美緒
当病棟看護師の退院支援・退院調整に対する認識変化の実態調査	看護師 千田舞子

急性期病院内での病棟内認知症カフェ「みかんカフェ」を開催して	看護師 塩川幸子
弾性ストッキング装着時に活動した場合の有効性 - 弾性ストッキング のズレと装着圧の検討 -	看護師 勝又美樹
病棟災害マニュアルに対する病棟看護師の意識調査	看護師 羽石麻穂
心房細動症例に対する右肺静脈拡大隔離における右肺静脈分岐部への右房 経由心外膜伝導と心外膜脂肪織との関連についての検討	循環器内科 坪井一平
ジゴキシン血中濃度上昇に関する背景因子の検討	薬剤部 市川竜太郎
外来患者へ限られた時間での説明を視覚・色覚の視認性と合わせて考えて みた効率的な手段について	看護師 吉田典子
CAM-ICU 導入に向けた ICU 看護師のせん妄に対する現状の意識調査	看護師 大兼ことみ
基礎看護教育における一時吸引の教授方法の検討	看護学校 青木裕子
実習指導者と学生が看護を語りあう効果	看護学校 荻澤英幸
転倒・転落予防を目的とした対策方法選択のためのフローチャート作成の 効果	看護師 武井麻紀
静岡医療センターに移転したことで治療の幅が広がった患者に対するアプローチ~副鼻腔癌、脳腫瘍に罹患した患者の看護~	看護師 望月美絵

(2) 受託研究

研究課題	研究責任者
消化器内視鏡に関連した偶発症の全国調査	消化器内科 部長 大西佳文
ダプトマイシン投与による CK への影響に関する検討	薬剤部 上田真也
AI解析に基づく十二指腸乳頭分類と ERCP におけるアウトカムとの相関性 に関する検証	消化器内科 診療部長 松田浩二

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【薬剤部】

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【歯科】

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循環器科医が喉頭上エアウエイと静脈麻酔薬を用いて深鎮静を行っている 〜我々は、未来に向けて、今、何をすべきか〜 日本麻酔科学会第66回学術集会 2019.6.1 (神戸)

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声門上器具で救命できた挿管困難・換気困難事例 第3回気道管理学会学術集会 2020.1.18 (東京)

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救急救命士気管挿管実習-気管挿管実習から気道管理実習へ 第3回気道管理学会学術集会 2020.1.18 (東京)

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- 4) <u>神野恭輔、一瀬あずさ、小鹿野道雄、阿部彰子、中嶋貴志、杉山 彰</u>、 田邊 潤

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抗菌薬と AMR

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【栄養管理室】

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基調講演:令和時代を豊かに勝ち抜く勤務医とは キャリア支援シンポジウム「医師として働く未来を考えよう」 浜松医科大学女性医師支援センター/静岡県医師会/ふじのくに女性医師支援センター 2019.12.14 (静岡)

【放射線科】

1) 阿部彰子

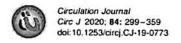
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発表論文集

原著ならびに症例報告の原文抄録を掲載しました。



JCS 2017 Guideline on Management of Vasculitis Syndrome

Digest Version —

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JCS Joint Working Group (consists of 12 groups): Japanese Circulation Society, Japan Radiological Society, Japanese Ophthalmological Society, The Japanese Association for Thoracic Surgery, The Japanese Society for Vascular Surgery, Japanese Society for Cardiovascular Surgery, Japanese College of Cardiology, Japanese Society of Nephrology, The Japanese Society of Pathology, Japanese College of Angiology, Japan College of Rheumatology, and The Japan Research Committee of the Ministry of Health, Labour and Welfare for Intractable Vasculitis (JPVAS)

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The Pathologic and Genetic Characteristics of the Intestinal Subtype of Intraductal Papillary Neoplasms of the Bile Duct

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Abstract

The present study aimed to identify the pathologic and genetic characteristics of intestinal subtype of intraductal papillary neoplasm of the bile duct (iIPNB) showing columnar cells with pseudostratified, cigar-shaped nuclei, and basophilic or amphophilic cytoplasm with the diffuse immunohistochemical expression of CK20 and/or CDX2. A total of 34 cases of iIPNB were pathologically examined according to their anatomic location (the bile duct) and were then compared with the intestinal subtype of intraductal papillary mucinous neoplasm (iIPMN) of the pancreas (n=22). Mutations of 26 somatic genes were examined in formalin-fixed paraffin-embedded tissue specimens from 21 cases of iIPNB using the TruSight Tumor 26 gene panel and next-generation sequencing. iIPNB cases were divided into intrahepatic (n=6) and extrahepatic (n=28) categories. Intrahepatic IPNBs showed a less-complicated villous-papillary pattern, while extrahepatic IPNBs showed a papillary pattern with tubular and/or villous components and predominant high-grade dysplasia with complicated architectures. MUC5AC was Eur J Prev Cardiol . 2019 Dec;26(18):1931-1940. doi: 10.1177/2047487319859974. Epub 2019 Jul 5.

44

CHF-B290 を用いた経口胆道鏡診断の実際と 愛護的な操作方法のコツ

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大西 佳文 先生

新型経口胆道鏡 CHF-B290 は従来品 CHF-B260 と比較し、近点画質が強化され、血管の明瞭性が向上した。 CHF-B290 を用い胆道粘膜を直視下に評価することで、胆道内病変をより正確に診断することが可能となった。 当院では愛護的な操作方法により、新型経口胆道鏡を長期間使用することができている。そこで今回、手技のポイントと愛護的な操作方法のコツを紹介する。

愛護的な操作方法

1) 前処置

主乳頭(以下、乳頭)の処置としては、内視鏡的乳頭切開術(EST:Endoscopic sphincterotomy)で中切開を行った後に結石除去用バルーンを用い、乳頭開口部を大切開と同程度に拡張する(図1a)。バルーンを拡張したまま、胆管内から外へ2~3回掻き出す操作を行い、バルーンが滞りなく可動し十二指腸へ排出することを確認する。

乳頭開口部を拡張する理由は、①胆道内でのベビースコープ(CHF-B290)の可動性を良好にする ②胆道内洗浄による胆道内圧の上昇を抑える ③胆道内観察において、左右前後方向の広視野観察を可能にし、乳頭部近傍での観察を容易にするためである。乳頭とベビースコープに肉眼的な隙間(図1b)を生じる程度が適切で、胆管内を生理食塩水で洗浄した際に、乳頭開口部から生理食塩水が漏れ出る程度に乳頭処置を行う。流水が漏れ出ない場合には胆管内圧が上昇し胆管炎が問題となるし、過度な乳頭拡張を行った場合には出血や穿孔に繋がる(憩室内乳頭開口や傍乳頭憩室開口)ため、ともに注意が必要である。

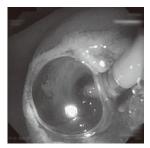


図1a: 結石除去用バルーンによる乳頭拡張



図1b:乳頭とベビースコープの

2) 挿入手技

基本的には、ガイドワイヤー0.025Inchを用いて挿入する。ベビースコープをガイドワイヤーに追従させ、マザースコープ(TJF-260V)の鉗子口に挿入する。その際、潤滑剤をマザースコープの鉗子口内に注入するか、ベビースコープの湾曲部に潤滑剤を十分塗布してマザースコープへ挿入する。ベビースコープをマザースコープの鉗子口内へ進める際に注意すべき点は、短いストロークで小刻みに押し進めていくことである。長いストロークで進める場合、押し込む力が効率よく伝達できず、不均衡な力の加重によりベビースコープの蛇管が座屈する可能性がある。地道ではあるが、焦らず同じ動作を小刻みに繰り返すことが、ベビースコープの愛護的な取り扱いとして重要である。マザースコープ内から鉗子チャンネルの外へ出す操作としては、マザースコープの鉗子レバーを UP 方向にロックし、鉗子台にベビースコープが軽く突き当たるところで、鉗子レバーをフリーにし、ベビースコープを 2cm 程度押し出す(図2a)。マザースコープの UP アングルを使用し、乳頭開口部になるべく近接し、頭側に見上げるように、胆管内へガイドワイヤー誘導下で押し進めながら挿入する(図2b)。その際、鉗子台を使いながら、安易に

ベビースコープを胆道内へ推し進めるとベビースコープの故障に繋がるため、注意が必要である。つまり、鉗子台の起上は全可動の6分の1までとし、マザースコープを水平にした場合30°~60°までの起上に留めるべきである。ただし、鉗子起上装置を使わずに挿入が可能であれば、ベビースコープに負荷は掛けない。CHF-B290の湾曲部は、従来のCHF-B260と比較して、ゴム厚を約2倍にする事で耐久性を向上させたが、デリケートである事に変わりはない為、以前と同様に愛護的な操作を行う事が最善である。当院では、CHF-Y0012(プロトタイプ)による142例の使用まで破損なく使用可能であったことから、CHF-B290は愛護的な操作により長期間の使用が可能で、従来のCHF-B260と比較しても耐久性は向上したといえる。



図2a: ベビースコープを2cm程度

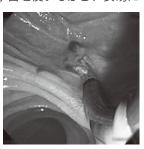


図2b: 乳頭開口部に近接し見上げる。鉗子起上台ではなく、マザースコープのUPアングルのみを使用する

Exercise-based Cardiac Rehabilitation for Patients With Catheter Ablation for Persistent AtrialFibrillation: A Randomized Controlled Clinical Trial

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Abstract

Aims: The efficacy and safety of cardiac rehabilitation for patients with persistent atrial fibrillation who restored sinus rhythm after catheter ablation remains unclear. The aim of the present study was to evaluate the effects of cardiac rehabilitation on exercise capacity, inflammatory status, cardiac function, and safety in patients with persistent atrial fibrillation who had catheter ablation.

Methods: In this randomized controlled study, 61 patients treated with catheter ablation for persistent atrial fibrillation (male, 80%; mean age, 66 ± 9 years) were analyzed. Thirty patients underwent cardiac rehabilitation (rehabilitation group), whereas the remaining 31 patients received usual care (usual care group). The rehabilitation group underwent endurance and resistance training with moderate intensity, at least three times per week for six months. Six-minute walk distance, muscle strength, serum high-sensitivity C-reactive protein, plasma pentraxin 3, left ventricular ejection fraction and atrial fibrillation recurrence were assessed at baseline and at six-month follow-up.

Results: In the rehabilitation group, significant increases in the six-minute walk distance, handgrip strength, leg strength and left ventricular ejection fraction and significant decreases in high-sensitivity C-reactive protein and plasma pentraxin 3 concentrations were observed at six-month follow-up compared with baseline (all p < 0.05). No significant changes were observed in the usual care group. During the six-month follow-up period, the number of patients with atrial fibrillation recurrence was six (21.4%) in the rehabilitation group and eight (25.8%) in the usual care group (risk ratio, 0.83; 95% confidence interval, 0.33 to 2.10).



解 説

遺伝性不整脈に対する デバイス治療の適応と有効性*

小鹿野道雄**

Key Words: long QT syndrome, Brugada syndrome, subcutaneous implantable cardioverter defibrillator(S-ICD), wearable cardioverter defibrillator(WCD), implantable cardiac monitor(ICM)

はじめに

多くの遺伝性不整脈は突然死の可能性がある ため、生活習慣の改善や薬物治療・デバイス治療などが行われる.本稿ではまず各遺伝性不整 脈疾患に対するデバイス治療の適応・有効性に ついて述べ、その後遺伝性不整脈に対する最新 のデバイス治療についての話題に触れる.

先天性QT延長症候群

先天性QT延長症候群は,QT時間の延長と torsade de pointes(TdP)と呼ばれる多形性心室 頻拍を認め, 失神や突然死をひき起こす症候群 である¹⁾. 先天性QT延長症候群は, 難聴を伴 い常染色体劣性遺伝を示す Jervell and Lange-Nielsen 症候群と, 難聴を伴わず常染色体優性遺 伝を示す Romano-Ward 症候群に分けられる. 分 子遺伝学的研究により,遺伝性不整脈の多くが 心筋の活動電位を形成するイオンチャネルとこれ に関連する細胞膜蛋白などをコードする遺伝子上 の変異によって発症することが判明しているが, 先天性QT延長症候群の診断がついた患者の半 数以上で原因遺伝子上に変異が同定される2). 主な遺伝子型である Romano-Ward 症候群の 1型 (LQT1), 2型(LQT2), 3型(LQT3)では, 遺伝 子型と臨床所見(表現型)との関連の詳細な検討 がなされ,遺伝子型別,遺伝子変異別の臨床症状 や特異的治療がすでに実施されている11.

先天性QT延長症候群の臨床診断には古くか らSchwartzの診断基準3)が用いられてきた(表 1). 2012年に改訂があり、新たに運動負荷試験 回復期4分における QTc≥480 msec に1点を加 算する項目が追加され、合計スコアが3.5以上の 場合に先天性QT延長症候群と診断される4). 2013年に発表された Heart Rhythm Society (HRS), European Heart Rhythm Association (EHRA), およびAsia Pacific Heart Rhythm Society (APHRS) による3学会合同ステートメント の先天性QT延長症候群の臨床診断では、上記 の先天性QT延長症候群リスクスコア≥3.5以外 に, 先天性QT延長症候群関連遺伝子に明らか な病的変異を認める, あるいは QTc≥500 msec, のいずれかを認める場合でも先天性QT延長症候 群と診断する,となった5). また,先天性QT延 長症候群関連遺伝子に変異を認めず, 説明のつ かない失神を認める患者において、QTcが480~ 499 msecを示す場合も先天性QT延長症候群と 診断しうるとなった.

先天性QT延長症候群では、無治療の場合40歳までに半数以上の患者で心イベントを発症し、また初発症状として突然死あるいは心停止を認める患者も5%未満であるが存在する. 先天性QT延長症候群に対する治療は一般的に生活指導と薬物治療になるが、このような治療を十分行っ

^{*} Indication and efficacy of device therapies for inherited arrhythmia.

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▶ 循環器集中治療のエビデンス更新─検証と課題─

重症心不全における CRT、CRT-D ─適応と課題

小鹿野道雄*1

要約

心臓再同期療法(cardiac resynchronization therapy: CRT)は心臓内非同期を有する症候性慢性心不全患者に対する確立された治療法である。近年、わが国でも CRT のガイドラインが改訂され、左脚ブロック、Wide QRS 患者への推奨度が高くなった。その背景として、CRT が是正するのは"機械的心臓内非同期"ではなく"電気的心臓内非同期"であり、左脚ブロックや Wide QRS の症例では CRT に適した"電気的心臓内非同期"が存在していることがあげられる。また、左室リード留置時には Q-LV 時間を指標とした留置法が注目されており、CRT が"電気的心臓内非同期"を是正する治療であることが再認識されている。植込み後は確実に左室ペーシングが心筋を捕捉していることをフォローする必要がある。"電気的心臓内非同期"を合併する心不全患者に対する治療効果は十分に確立されており、近い将来心不全パンデミックが予想されるわが国には必須の治療法である。

🔾 はじめに

心臓再同期療法(cardiac resynchronization therapy: CRT)は症候性慢性心不全患者に対して心室内の非同期を是正し、心機能・心不全症状を改善させる治療である。

CRT は 1) 植込み前の患者選定、2) 植込み中の電極リード位置、3) 植込み後のフォロー、すべてにおいて十分な配慮が必要であり、上記 1) ~3) のいずれが欠けていても十分な効果は得られない。逆に 1)~3) がしっかりと把握されていれば、軽症~重症まで幅広い心不全患者に対して効果が得られる。本稿ではより臨床に即して、上記 1)~3) までの過程を踏まえながら CRT の機序とその期待される効果について記していく。

Q

I. 植込み前の患者選定

1. 心臓内非同期の質を評価する

CRT は"心臓内非同期"を是正する治療である。 そのため、植込み前の患者条件を考慮する際、"心 臓内非同期"が存在しない患者には CRT の適応 は無いことを熟知する必要がある。ではどのよう に"心臓内非同期"を評価するべきか?

2008年に発表された PROSPECT 試験 ¹⁾ では 心臓超音波検査を用いて、いくつかの "心臓内非同期" を示す指標 (SPWMD や IVMD, 組織ドップラーでの Ts-SD など)を計測し、"心臓内非同期"の有無で CRT のレスポンダーを予測した。しかし、超音波検査で得られた "心臓内非同期"を示すいくつかの指標は CRT のレスポンダー予測に有用ではなかったことが報告されている。心臓超音波検査で測定できる "心臓内非同期" は壁

Cardiac Resynchronization Therapy with Pacemaker and with Defibrillator for Severe Heart Failure Patients: Indication and Issue

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Meta-analysis of impact of liver disease on mortality after transcatheter aortic valve implantation

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Aims To evaluate whether liver disease is associated with increased mortality after transcatheter aortic valve implantation (TAVI) and whether TAVI is associated with decreased mortality compared to surgical aortic valve replacement (SAVR) in patients with liver disease, we performed meta-analyses of currently available studies.

Methods Studies reporting mortality in TAVI patients with liver disease versus those without liver disease and mortality after TAVI versus SAVR in patients with liver disease were eligible to be included. A relative risk (RR) or hazard ratio of mortality for TAVI patients with versus without liver disease and mortality for TAVI versus SAVR in patients with liver disease was extracted from each individual study. Study-specific estimates were combined in the random-effects model.

Results We identified nine studies of TAVI patients with versus without liver disease and four studies of TAVI versus SAVR in patients with liver cirrhosis. Pooled analyses demonstrated no association of liver disease with early (inhospital/30-day) mortality (P = 0.28), but a statistically significant association of liver disease with increases midterm (1-2-year) mortality (hazard ratio 1.87, P < 0.00001) in

TAVI patients, and no statistically significant difference in inhospital mortality between TAVI and SAVR in patients with cirrhosis (RR 0.60, P = 0.12).

Conclusion There may be no impact of liver disease on early mortality in TAVI patients, negative impact of liver disease on mid-term mortality in TAVI patients, and no difference in in-hospital mortality between TAVI and SAVR in patients with liver cirrhosis.

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Keywords: cirrhosis, liver disease, meta-analysis, mortality, surgical aortic valve replacement, transcatheter aortic valve implantation

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Introduction

Liver dysfunction adversely affects outcomes of open heart surgery such as coronary artery bypass grafting (CABG) and valvular surgery even in an elective situation. In patients with liver cirrhosis compared with those without cirrhosis undergoing open heart surgery, outcomes such as mortality and readmission for reasons of hepatic or cardiac failure are poorer, and a tendency toward liverrelated mortality (predominantly due to hepatocellular carcinoma) is still higher even after successful heart surgery.² Also in patients undergoing surgical aortic valve replacement (SAVR), cirrhosis brings about increased mortality, complications, length of stay, and cost, whereas, in patients with mild to moderate chronic liver disease undergoing transapical (TA) and transfemoral (TF) transcatheter aortic valve implantation (TAVI), postprocedural complication rates are low and late complication rates are acceptable. Even in candidates with cirrhosis for hepatic transplantation, TAVI may be considered a valid alternative treatment.5 However, it remains unclear how liver disease plays a negative role in TAVI. In the present article, to evaluate whether liver disease is associated with increased mortality after TAVI and whether TAVI is associated with decreased mortality compared with SAVR in patients with liver disease, we performed meta-analyses of currently available studies.

Methods

We identified all studies evaluating the impact of liver disease including cirrhosis on mortality after TAVI and comparing mortality after TAVI versus SAVR in patients with liver disease by means of the following two-level search strategy. First, we searched databases (MED-LINE, EMBASE, and the Cochrane Central Register of Controlled Trials) through July 2018 by use of Webbased search engines (PubMed and OVID). We used the following search terms: percutaneous, transcatheter, transluminal, transarterial, transapical, transaortic, transcarotid, transaxillary, transsubclavian, transiliac, transfemoral, or transiliofemoral; aortic valve; liver or hepatic; and disease, diseases, dysfunction, failure, insufficiency, or cirrhosis. Second, to identify relevant studies, we

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ORIGINAL STUDIES

WILEY

Impact of concurrent tricuspid regurgitation on mortality after transcatheter aortic-valve implantation

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Abstract

Objectives: To determine whether concomitant tricuspid regurgitation (TR) is associated with increased mortality in patients with severe aortic stenosis (AS) undergoing transcatheter aorticvalve implantation (TAVI), we performed a meta-analysis of currently available studies.

Methods: MEDLINE and EMBASE were searched through May 2018. We included comparative or cohort studies enrolling patients with AS undergoing TAVI and reporting early (in-hospital or 30-day) and late (including early) all-cause mortality in patients stratified by baseline TR grade. An odds ratio (OR) of early mortality and a hazard ratio (HR) of late mortality with its 95% CI for significant versus non-significant (typically, >moderate versus <moderate) TR was extracted. Study-specific estimates were combined in the random-effects model.

Results: Our search identified 12 eligible studies enrolling a total of 41,485 TAVI patients. The meta-analysis for early mortality combining 3 ORs demonstrated a significant 1.80-fold increase in mortality with significant TR (OR, 1.80; 95% CI, 1.01 to 3.19; P = 0.05). The primary metaanalysis for midterm (6-month to 30-month) mortality combining all the 12 HRs/ORs indicated a significant 1.96-fold increase in mortality (HR/OR, 1.96; 95% CI, 1.35 to 2.85; P = 0.0004). The secondary meta-analysis for midterm mortality combining 7 homogeneous HRs (adjusted HRs for ≥moderate versus <moderate TR) showed a significant 2.25-fold increase in mortality (HR, 2.25; 95% CI, 1.20-4.24; P = 0.01).

Conclusions: Concurrent significant (typically, >moderate) TR is associated with an approximately two-fold increase in both early and midterm all-cause mortality in patients with AS undergoing TAVI.

KEYWORDS

meta-analysis, mortality, transcatheter aortic valve implantation, tricuspid regurgitation

1 | INTRODUCTION

Several meta-analyses¹⁻⁴ suggest that concurrent ≥moderate mitral regurgitation (MR) is associated with increased early and late mortality in patients with severe aortic stenosis (AS) undergoing transcatheter aortic-valve implantation (TAVI), though a trend toward decreased MR grade is identified⁴ and MR severity is significantly improved in half of patients after TAVI². Impact of concomitant tricuspid regurgitation (TR) on mortality after TAVI, however, has been less investigated. Although only a meta-analysis⁵ of three studies including a total of 1,328 patients suggests that coexisting ≥moderate TR may be a

predictor of midterm (1- to 2-year) mortality in patients undergoing TAVI, association of concurrent TR with mortality after TAVI remains unclear. In the present article, to determine whether concomitant TR is associated with increased mortality in patients with AS undergoing TAVI, we performed a meta-analysis of currently available studies.

2 | MATERIALS AND METHODS

All studies which investigated impact of concurrent TR on mortality in patients with AS undergoing TAVI were identified using a two-level

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Meta-analysis of Valve-in-Valve Transcatheter versus Redo Surgical Aortic Valve Replacement

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Abstract

transcatheter aortic valve implantation (VIV-TAVI) is associated with better survival than redo surgical aortic valve replacement (SAVR) in patients with degenerated aortic valve bioprostheses, and we performed a meta-analysis of comparative studies. **Methods** To identify all comparative studies of VIV-TAVI versus redo SAVR; MEDLINE, Embase, and the Cochrane Central Register of Controlled Trials were searched through October 2017. For each study, data regarding all-cause mortality in both the VIV-TAVI and redo SAVR groups were used to generate odds ratios (ORs). To assess selection bias, we generated ORs and (standardized) mean differences (MDs) for baseline characteristics. Study-specific estimates were combined in the random-effects model. **Results** Of 446 potentially relevant articles screened initially, 6 reports of retrospective comparative studies enrolling a total of 498 patients were identified. Pooled analyses of baseline characteristics demonstrated no statistically significant differences in the proportion of women, patients with diabetes mellitus, patients with coronary artery disease, and patients with baseline New York Heart Association functional class of ≥III; baseline ejection fraction; and predicted mortality between the VIV-TAVI and redo SAVR groups. Patients in the VIV-TAVI group, however, were significantly older (MD, 4.20 years) and had undergone prior coronary artery bypass grafting more frequently (OR, 2.19) than those in the redo SAVR group. Main pooled analyses demonstrated no statistically significant differences in early (30 days or inhospital) (OR, 0.91; p = 0.83) and midterm (180 days-3 years) all-cause mortalities (OR, 1.42; p = 0.21) between the VIV-TAVI and redo SAVR groups.

Objective The objective of this study was to determine whether valve-in-valve

meta-analysis hospital) (OR, 0.91; p = 0.83) and midterm (180 redo surgical aortic valve replacement hospital) (OR, 0.91; p = 0.83) and midterm (180 (OR, 1.42; p = 0.21) between the VIV-TAVI and response to the valve replacement of the valve replacement.

 valve-in-valve transcatheter aortic valve implantation

degenerated aortic

valve bioprostheses

Conclusion In patients with degenerated aortic valve bioprostheses, especially elderly or high-risk patients, VIV-TAVI could be a safe, feasible alternative to redo SAVR. The lack of randomized data and differences in baseline characteristics in the present analysis emphasize the need for prospective randomized trials.

Introduction

Keywords

The use of valve-in-valve (VIV) transcatheter aortic valve implantation (TAVI) (VIV-TAVI) for the treatment of high-risk patients with degenerated aortic bioprostheses is associated with relatively low rates of mortality and major complica-

tions, improved hemodynamics and excellent improvement in functional and quality of life outcomes at 1 year, ¹ whereas redo surgical aortic valve replacement (SAVR) is now performed with acceptable operative mortality of 4.6%.² Although mortality and morbidity are high compared with primary SAVR, the rates of stroke, vascular complications,

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Original article

Meta-analysis of transcatheter aortic valve implantation for bicuspid versus tricuspid aortic valves



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ABSTRACT

Background: We performed meta-analysis and meta-regression of transcatheter aortic valve implantation (TAVI) for the bicuspid aortic valve (B-AV) versus the tricuspid aortic valve (T-AV).

Methods: MEDLINE and EMBASE were searched through June 2018 using PubMed and OVID. We included comparative studies of TAVI patients with B-AV versus T-AV reporting at least one of postprocedural transcatheter valve regurgitation (TVR)/pacemaker implantation (PMI) incidence and early (30-day or in-hospital)/late (including early) mortality. For each study, crude (unadjusted) data regarding TVR/PMI incidence and early/late mortality in both the B-AV and T-AV groups were used to generate risk ratios (RRs). Study-specific estimates were combined in the random-effects model. Using meta-regression, we assessed potential confounders identified in preliminary meta-analysis.

Results: We identified 12 eligible studies including a total of 1045 B-AV and 4069 T-AV patients. Pooled analysis demonstrated an association of B-AV with a statistically significant increase in TVR incidence (RR, 1.42; p = 0.006) but no statistically significant difference in PMI incidence (p = 0.54) and 30-day (p = 0.11)/midterm (1-year to 2-year) mortality (p = 0.99) between patients with B-AV and those with T-AV. All meta-regression coefficients of 6 identified potential confounders (age, mean aortic valve gradient, aortic valve area, left ventricular ejection fraction, aortic calcification, and B-AV types) for the outcomes (TVR/PMI incidence and early/late mortality) were statistically non-significant.

Conclusions: Postprocedural PMI incidence and 30-day/midterm (1-year to 2-year) mortality after TAVI may be similar between patients with B-AV and those with T-AV despite the significant association of B-AV with increased postprocedural TVR incidence.

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Introduction

Transcatheter aortic valve implantation (TAVI) may bring about less favorable results in aortic stenosis due to the bicuspid aortic valve (B-AV) than in that due to the tricuspid aortic valve (T-AV) because of the following theoretical concerns: geometric mismatch between the ovoid B-AV annulus and the circular transcatheter prosthesis due to increases in annular ellipticity

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and asymmetric calcification [1] may result in paravalvular leakage or leaflet asymmetry, and questionable B-AV annulus strength may potentially lead to annular rupture or aortic dissection [2]. Post-procedural ≥moderate transcatheter valve regurgitation (TVR) and pacemaker implantation (PMI) occur respectively in approximately 12% and 18% of TAVI patients with B-AV [2], which are more frequent than in the PARTNER [Placement of Aortic Transcatheter Valves] II SAPIEN 3 trial [3] (3.4% and 11.2%) and the CoreValve Evolut R study [4] (3.4% and 11.7%) and may be associated with increased early and late mortality. Focusing postprocedural TVR/PMI incidence and early/late mortality, we performed meta-analysis and meta-regression analysis of TAVI for patients with B-AV versus those with T-AV.

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Meta-analysis of prognostic impact of blood transfusion on survival after transcatheter aortic valve implantation

Periprocedural blood transfusion is suggested to be associated with increased mortality after transcatheter aortic valve implantation (TAVI) for patients with severe aortic stenosis. ^{1, 2} The association of periprocedural blood transfusion with increased post-procedural mortality, however, is complicated, not simple. First, preprocedural anemia and periprocedural bleeding complications are probable predictors of increased incidence of periprocedural blood transfusion. Second, preprocedural anemia, ³ periprocedural bleeding complications, ⁴ and periprocedural blood transfusion ^{4, 5} is associated with increased incidence of periprocedural acute kidney injury (AKI) which is a predictor of increased postprocedural mortality. ^{4, 6} Third, as well as periprocedural blood transfusion, pre-

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procedural anemia *per se*⁹, 8 may be and periprocedural bleeding complications *per se*⁹ is associated with increased postprocedural mortality. These complexities have made it difficult for us to assess prognostic impact of periprocedural blood transfusion on survival after TAVI. In the present article, to determine whether periprocedural blood transfusion affects survival after TAVI, especially, independently of preprocedural anemia and/or periprocedural bleeding complications, we performed meta-analysis of currently available studies.

All studies investigating prognostic impact of periprocedural blood transfusion on mortality after TAVI were identified through an electronic search of MEDLINE and EMBASE and a manual search of secondary sources including references of initially identified articles, reviews, and commentaries. Studies considered for inclusion met the following criteria: the design was a comparative study of patients undergoing periprocedural blood transfusion versus those not undergoing periprocedural blood transfusion or a cohort study investigating periprocedural blood transfusion as one of prognostic factors of postprocedural mortal-

ity; the study population was patients undergoing TAVI; and main outcomes included an relative risk (odds ratio [OR] or hazard ratio [HR]) of early (30-day or in-hospital) or late (including early) all-cause mortality for periprocedural blood transfusion by means of the multivariable logistic or Cox proportional hazards regression analysis adjusting for at least one of preprocedural anemia (or hemoglobin/hematocrit levels) and periprocedural bleeding complications as well as other covariates. All study-specific estimates were combined using inverse variance-weighted averages of logarithmic ORs/HRs in the random-effects model (primary meta-analysis). As sensitivity analysis, we exclusively pooled ORs/HRs adjusted for both preprocedural anemia and periprocedural bleeding complications as well as other covariates (secondary meta-analysis). Publication bias for the primary meta-analysis was assessed graphically using a funnel plot and mathematically using the adjusted rank-correlation test. All analyses were conducted using Review Manager version 5.3 (available from http:// tech.cochrane.org/revman) and Comprehensive Meta-Analysis version 3 (Biostat, Englewood, NJ).

Table I.—Study characteristics.

Study	Baseline patient characteristics					Predicted surgical mortality (%)		Procedural characteristics (%)		
	Number	Age (years)	Men (%)	Anemia (%)	Hemoglobin (g/dL)	Hematocrit (%)	Logistic EuroSCORE	STS-PROM	Transfemoral	Balloon- expandable valve
Czerwińska-	178	80.07±7.47	33.15	60.67	N/A	N/A	22.35±12.42	8.43±8.26	73.60	N/A
Jelonkiewicz 2017 ¹⁰										
Escárcega 201511	332	82	51.2	N/A	11.4	35.0	N/A	9.4	100	N/A
Kleczynski 2017 ¹²	101	81.0 (76.0-84.0)	39.6	N/A	N/A	N/A	14.0 (10.0-22.5)	12.0 (5.0-24.0)	77.2	76.2
Konigstein 2016 ¹³	597	82.6	42.2	N/A	N/A	N/A	16.3	N/A	100	N/A
Koster 201614	639	83	45.6	N/A	N/A	38.3	18.8	N/A	0	N/A
Nuis 20137	1696	81±7	52.1	57.1	12.1±1.7	N/A	19.0 (11.0-30.7)	N/A	75.7	39.3
PRAGMATIC Plus	943	81.0 ± 7.0	53.8	56.2	12.13±1.69	N/A	20.9 (12.9-28.8)	N/A	84.1	N/A
(Tchetche) 201215										
Seiffert 20178	1201	82.0 (76.7-85.5)	48.5	58.9	N/A	N/A	16.9 (10.7-26.2)	5.6 (3.8-8.9)	47.4	N/A
Souza 201616	136	83 (80-87)	50.7	N/A	N/A	N/A	19.1 (11.4–31.1)	9.3 (4.8-22.3)	N/A	N/A
Wessely 201217	183	81.1±6.1	44.8	N/A	12.2±1.7	N/A	23.5±11.5	N/A	100	0

BEV: balloon-expandable valve; EuroSCORE: European System for Cardiac Operation Risk Evaluation; DA: direct aortic approach; N/A: not available; PRAGMATIC: Pooled-RotterdAm-Milano-Toulouse In Collaboration; STS-PROM: Society of Thoracic Surgeons-Predicted Risk of Mortality. Continuous variables are expressed as number, mean, mean ± standard deviation, and median (interquartile range).

A Contemporary Meta-Analysis of Antegrade versus Retrograde Cerebral Perfusion for **Thoracic Aortic Surgery**

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Abstract

Objective To determine which of antegrade and retrograde cerebral perfusion (ACP and RCP) surpasses for a reduction in postoperative incidence of neurological dysfunction and all-cause death in thoracic aortic surgery, we performed a metaanalysis of contemporary comparative studies.

Methods MEDLINE, EMBASE, and the Cochrane Central Register of Controlled Trials were searched from January 2010 to June 2017. For each study, data regarding the endpoints in both the ACP and RCP groups were used to generate odds ratios (ORs) and 95% confidence intervals (CIs). Study-specific estimates were combined using inverse variance-weighted averages of logarithmic ORs in the fixed-effect model.

Results We identified and included 19 eligible studies with a total of 15,365 patients undergoing thoracic aortic surgery by means of ACP (a total of 7,675 patients) or RCP (a total of 7,690 patients). Pooled analysis demonstrated no statistically significant differences in postoperative incidence of stoke (17 studies enrolling a total of 9,421 patients; OR, 0.92; 95% CI, 0.79–1.08; p = 0.32) and mortality (16 studies including a total of 14,452 patients; OR, 1.07; 95% CI, 0.90–1.26; p = 0.46) between ACP and RCP, whereas a trend toward a significant reduction in incidence of temporary neurological dysfunction (TND) for ACP (12 studies enrolling a total of 7922 patients; OR, 0.85; 95% CI, 0.69-1.04; p = 0.12) was found.

Conclusion In thoracic aortic surgery, postoperative incidence of stroke and mortality was similar between ACP and RCP, whereas a trend toward a reduction of TND incidence existed in ACP.

Keywords

- ► antegrade cerebral perfusion
- ► meta-analysis
- retrograde cerebral perfusion

Introduction

Although deep hypothermic circulatory arrest (DHCA) has been used for thoracic aortic surgery as an effective cerebral protective technique for more than 3 decades and proven to be a feasible means of protection of any organ, a timedependent cascade of events resulting in brain cell injury is initiated. Antegrade and retrograde cerebral perfusion

(ACP and RCP) have become well-established techniques for cerebral protection during DHCA.² Both ACP and RCP, however, have their own pros and cons. On the one hand, although ACP can provide independent control of temperature and/or flow to the cerebral and systemic circulation, it has the potential for embolization; on the other hand, although RCP can flush potential embolus from the cerebral

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Meta-Analysis for Impact of Statin on Mortality After Transcatheter Aortic Valve Implantation



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To determine whether statin (hydroxymethylglutaryl-CoA reductase inhibitor) therapy is associated with better midterm survival after transcatheter aortic valve implantation (TAVI), the first meta-analysis of currently available studies was performed. To identify all observational comparative studies and randomized controlled trials (RCTs) of statin versus control (no statin) therapy or cohort studies investigating statin treatment as one of covariates in patients undergoing TAVI, PubMed, Web of Science, and Google Scholar were searched through March 2019. Adjusted (if unavailable, unadjusted) hazard ratios (HRs) with their confidence interval (CIs) of midterm (≥1 year) all-cause mortality after TAVI for statin therapy were extracted from each study. Study-specific estimates were combined by means of inverse variance-weighted averages of logarithmic HRs in the random-effects model. Eight eligible studies with a total of 5,170 TAVI patients were identified and included in the present meta-analysis. The primary meta-analysis (including HRs for high intensity statin from 3 studies together with other HRs) demonstrated that statin treatment was associated with significantly lower midterm mortality (HR, 0.74; 95% CI, 0.60 to 0.91; p = 0.005). The secondary meta-analysis (including HRs for low/moderate intensity statin from 3 studies together with other HRs) also indicated an association of statin therapy with significantly lower midterm mortality (HR, 0.80; 95% CI, 0.69 to 0.93; p = 0.005). No funnel plot asymmetry for the primary meta-analysis (p = 0.64) was identified, which suggested probably no publication bias. In conclusion, statin therapy is associated with better midterm survival after TAVI. © 2019 Elsevier Inc. All rights reserved. (Am J Cardiol 2019;124:920-925)

It has been well-known that statin (hydroxymethylglutaryl-CoA reductase inhibitor) therapy is associated with better survival after repair of abdominal aortic aneurysm. 1–5 Statin treatment also may be associated with lower early all-cause mortality 6–8 and midterm mortality from myocardial infarction (MI) after cardiac surgery and coronary artery bypass grafting. After surgical aortic valve replacement (SAVR), however, a metanalysis of only 4 studies demonstrated no significant difference in early all-cause mortality between statin and control groups. Impact of statin on mortality after transcatheter aortic valve implantation (TAVI) has been less investigated. Our aim was to determine whether statin therapy is associated with better midterm survival after TAVI, performing the first meta-analysis of currently available studies.

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Methods

To identify all studies reporting impact of statin on midterm mortality after TAVI, PubMed (https://www.ncbi.nlm. nih.gov/pubmed/), Web of Science (http://www.webof knowledge.com/wos), and Google Scholar (https://scholar. google.com) were searched through March 2019. Search terms included transcatheter; aortic valve; implantation or replacement; and statin, hydroxymethylglutaryl-CoA reductase inhibitor, atorvastatin, fluvastatin, lovastatin, pitavastatin, pravastatin, or simvastatin. Studies meeting the following criteria were included in the present meta-analysis: the design was an observational comparative study and a randomized controlled trial (RCT) of statin versus control (no statin) therapy or a cohort study investigating statin treatment as one of covariates; the study population was patients undergoing TAVI; outcomes included midterm (≥1 year) all-cause mortality.

Adjusted (if unavailable, unadjusted) hazard ratios (HRs) with their confidence interval (CIs) of mortality for statin therapy were extracted from each study. Study-specific estimates were combined by means of inverse variance-weighted averages of logarithmic HRs in the random-effects model. Funnel plot asymmetry (indicating publication bias) was mathematically assessed by use of the linear regression test. All analyses were performed using Review Manager version 5.3 (available from http://tech.cochrane.org/revman) and Comprehensive Meta-Analysis version 3 (Biostat, Englewood, New Jersey).

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See page 924 for disclosure information.

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Meta-Analysis of Relation of Skipping Breakfast With Heart Disease



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To determine whether skipping breakfast is associated with heart disease, the first metaanalysis of currently available epidemiological studies was performed. To identify casecontrol, cross-sectional, longitudinal, or cohort studies investigating the association of skipping breakfast with prevalence, incidence, or mortality of heart disease in adults, PubMed, and Web of Science were searched through April 2019. Adjusted (if unavailable, unadjusted) hazard ratios (HRs) or odds ratios (ORs) with their confidence interval (CIs) of prevalence, incidence, or mortality for skipping breakfast were extracted from each study. Study-specific estimates were combined using inverse variance-weighted averages of logarithmic HRs/ORs in the random-effects model. Eight eligible studies with a total of 284,484 participants were identified and included in the present meta-analysis. The primary meta-analysis combining HRs for Q1 (first quartile, most skipping breakfast) versus Q4 (fourth quartile, least skipping breakfast) from 3 studies together with other HRs/ORs demonstrated that skipping breakfast was associated with the significantly increased risk of heart disease (pooled HR/OR 1.24; 95% CI 1.09 to 1.40; p = 0.001). In sensitivity analyses combining HRs for Q2 (second quartile, second most skipping breakfast) versus Q4 or HRs for Q3 (third quartile, second least skipping breakfast) versus Q4 from 3 studies together with other HRs/ORs, the association of skipping breakfast with the increased risk of heart disease in the primary meta-analysis was confirmed. In conclusion, skipping breakfast is associated with the increased risk of heart disease. © 2019 Elsevier Inc. All rights reserved. (Am J Cardiol 2019;124:978-986)

Skipping breakfast is associated with cardiometabolic risk including metabolic risk profiles, overweight, obesity, hypertension, diabetes mellitus, and cardiovascular disease. A recent systematic review suggests the association of skipping breakfast with worse lipid profiles, blood pressure levels, insulin resistance, and metabolic syndrome. Large epidemiological studies reported that skipping breakfast was associated with the increased risk of type 2 diabetes mellitus in both females³ and males.⁴ Furthermore, a recent cross-sectional study⁵ provided the association of skipping breakfast with the increased risk of prevalent noncoronary and generalized atherosclerosis independently of conventional cardiovascular risk factors. However, the impact of skipping breakfast on the risk (i.e., prevalence, incidence, or mortality) of cardiovascular disease, especially heart disease, has been less investigated. In the present article, to determine whether skipping breakfast is

associated with heart disease, the first meta-analysis of currently available epidemiological studies was performed.

Methods

We conducted the present met-analysis in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Statement (http://www.prisma-statement.org). PubMed (https://www.ncbi.nlm.nih.gov/pubmed/) and Web of Science (http://www.webofknowledge.com/wos) were searched through April 2019. Search terms included breakfast; cardiac, cardiovascular, coronary artery, coronary heart, ischemic coronary, or ischemic heart; and disease, event, death, or mortality. Studies meeting the following criteria were included in the present meta-analysis: the design was a case-control, cross-sectional, longitudinal, or cohort study; the study population was adults; the study investigated the association of skipping breakfast with prevalence, incidence, or mortality of heart disease including coronary artery disease (CAD).

Adjusted (if unavailable, unadjusted) hazard ratios (HRs) or odds ratios (ORs) with their confidence interval (CIs) of prevalence, incidence, or mortality for skipping breakfast were extracted from each study. Study-specific estimates were combined using inverse variance-weighted averages of logarithmic HRs/ORs in the random-effects model. Funnel plot asymmetry (suggesting the presence of publication bias) was mathematically assessed using the linear regression test. All analyses were performed using

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A meta-analysis of impact of low-flow/low-gradient aortic stenosis on survival after transcatheter aortic valve implantation

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Aims To determine whether low-flow/low-gradient (LF/LG) aortic stenosis affects survival after transcatheter aortic valve implantation (TAVI), we performed a meta-analysis of currently available studies.

Methods MEDLINE and EMBASE were searched through January 2019 using PubMed and OVID. Observational studies comparing all-cause mortality after TAVI for patients with classical LF/LG (C/LF/LG) aortic stenosis versus normal-flow/high-gradient (NF/HG) aortic stenosis, paradoxical LF/LG (P/LF/LG) aortic stenosis versus NF/HG aortic stenosis, and (3) C/LF/LG aortic stenosis versus P/LF/LG aortic stenosis were included. Study-specific estimates, risk and hazard ratios of mortality, were combined in the random-effects model.

Results Our search identified nine eligible studies including a total of 5512 TAVI patients. Pooled analysis demonstrated significantly higher early mortality in C/LF/LG aortic stenosis than NF/HG aortic stenosis (risk ratio, 1.72; P=0.02) and no statistically significant difference in early mortality between P/LF/LG aortic stenosis and NF/HG aortic stenosis (P=0.67) and between C/LF/LG aortic stenosis and P/LF/LG aortic stenosis (P=0.51). Midterm mortality in C/LF/LG (risk ratio/hazard ratio, 1.73; P=0.0003) and P/LF/LG aortic stenosis (risk ratio/hazard ratio, 1.48; P<0.0001) was significantly higher than that in NF/HG aortic stenosis. There was no statistically significant

difference in midterm mortality between C/LF/LG aortic stenosis and P/LF/LG aortic stenosis (P = 0.63).

Conclusion After TAVI, C/LF/LG aortic stenosis is associated with increased early mortality compared with NF/HG, and C/LF/LG and P/LF/LG aortic stenosis is associated with increased midterm mortality compared with NF/HG aortic stenosis despite no difference in early mortality between P/LF/LG aortic stenosis and NF/HG aortic stenosis. There is no difference in early and midterm mortality between C/LF/LG aortic stenosis and P/LF/LG aortic stenosis.

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Keywords: low-flow/low-gradient aortic stenosis, meta-analysis, survival, transcatheter aortic valve implantation

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Introduction

Each of low stroke volume (SV) index (SVI) (low-flow), low aortic valve pressure gradient (low-gradient), and low left ventricular ejection fraction (LVEF) (low-ejection fraction) is associated with increased midterm mortality after transcatheter aortic valve implantation (TAVI) for patients with severe aortic stenosis, and the prognostic impact of individual low flow, low gradient, and low-ejection fraction on survival may be similar. Severe aortic stenosis is defined as aortic valve maximum velocity ($V_{\rm max}$) at least 4 m/s or mean aortic valve pressure gradient (MPG) at least 40 mmHg and typically aortic valve area (AVA) 1.0 cm² or less and classified into asymptomatic (corresponding to stage C) and symptomatic severe aortic stenosis (corresponding to stage D).² Although

symptomatic severe aortic stenosis is typically high-gradient (corresponding to stage D1), it can be present in patients with low-flow aortic stenosis leading to $V_{\rm max}$ less than 4 m/s or MPG less than 40 mmHg, which is usually called low-flow/low-gradient (LF/LG) aortic stenosis.³ Furthermore, symptomatic LF/LG aortic stenosis is divided into classical LF/LG aortic stenosis and paradoxical LF/LG aortic stenosis. The definition of classical LF/LG aortic stenosis is AVA of $1.0\,{\rm cm}^2$ or less with $V_{\rm max}$ less than 4 m/s or MPG less than 40 mmHg and ejection fraction less than 50% (low-ejection fraction) (corresponding to stage D2), and that of paradoxical LF/LG aortic stenosis is AVA of $1.0\,{\rm cm}^2$ or less with $V_{\rm max}$ less than 4 m/s or MPG less than 40 mmHg and ejection fraction at least 50% (normal-ejection fraction) (corresponding to

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ORIGINAL ARTICLE



A meta-analysis of impact of mitral stenosis on outcomes after transcatheter aortic valve implantation

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Abstract

Objectives: To determine whether concomitant mitral stenosis (MS) impairs outcomes after transcatheter aortic valve implantation (TAVI) in patients with severe aortic stenosis (AS), we performed a meta-analysis of currently available evidence.

Methods: To identify all observational comparative studies of outcomes after TAVI for AS in patients with MS vs patients with no-MS, we searched databases (MEDLINE and EMBASE) using web-based search engines (PubMed and OVID). Studies meeting the following criteria were included; the design was an observational study; the study population was patients undergoing TAVI for AS; outcomes in patients with MS were compared with those in patients with no-MS. Study-specific estimates were then pooled using inverse variance-weighted averages of logarithmic odds and hazard ratios in the random-effects model.

Results: We identified six eligible studies including 111 621 patients undergoing TAVI. In pooled analyses, postprocedural incidence of \geq moderate paravalvular aortic regurgitation (PAR) (P = .02), early all-cause mortality (P = .008), early incidence of myocardial infarction (MI) (P = .01), and midterm all-cause mortality (P = .03) after TAVI were significantly higher in patients with MS than in patients with no-MS. There were no significant differences in early incidence of stroke, major bleeding, acute kidney injury, and new permanent pacemaker implantation after TAVI between patients with MS and patients with no-MS. When the study for mitral annular calcification was excluded in the pooled analyses, no results except for MI were substantially altered but the significance for early incidence of MI disappeared (P = .10).

Conclusion: Postprocedural incidence of ≥ moderate PAR, early all-cause mortality, early incidence of MI, and midterm all-cause mortality after TAVI are higher in patients with MS than in patients with no-MS.

KEYWORDS

meta-analysis, mitral stenosis, transcatheter aortic valve implantation

1 | INTRODUCTION

Concomitant mitral regurgitation (MR) affects early and midterm mortality after transcatheter aortic valve implantation (TAVI) in patients with severe aortic stenosis (AS). A recent meta-analysis¹

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Comparison of early and midterm outcomes after transsubclavian/axillary versus transferoral, transapical, or transaortic transcatheter aortic valve implantation



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Transapical transcatheter aortic valve implantation
Transfemoral transcatheter aortic valve implantation
Transsubclavian/transaxillary transcatheter aortic valve implantation

ABSTRACT

Background: Outcomes after transsubclavian/transaxillary (TSc/TAx)-transcatheter aortic valve implantation (TAVI) have been unclear.

Objectives: To compare outcomes after TSc/TAx-TAVI versus transfemoral (TF)-TAVI, transapical (TAp)-TAVI, or transaortic (TAo)-TAVI, we performed meta-analysis of currently available studies.

Methods: Studies considered for inclusion met the following criteria: the study population was patients undergoing TAVI; patients were assigned to TSc/TAx-TAVI and TF-TAVI, TAp-TAVI, or TAo-TAVI; and at least one of postprocedural early (30-day or in-hospital) or late (including early) outcomes was reported. An odds or hazard ratio of each early or late outcome with its 95% confidence interval for TSc/TAx-TAVI versus the other approach was extracted from each individual study and combined in the random-effects model.

Results: Our search identified 15 eligible reports from 12 studies including 10,528 patients. Pooled analysis of early all-cause mortality demonstrated a statistically significant reduction after TSc/TAx-TAVI compared with TAp-TAVI (P = 0.003) or TAo-TAVI (P = 0.03). Pooled analysis of early pacemaker implantation demonstrated a statistically significant increase after TSc/TAx-TAVI compared with TAp-TAVI (P = 0.0001) or TAo-TAVI (P < 0.00001). Pooled analysis of midterm all-cause mortality demonstrated a statistically significant increase after TSc/TAx-TAVI compared with TF-TAVI (P = 0.007).

Conclusions: Early all-cause mortality was lower after TSc/TAx-TAVI than TAp-TAVI or TAo-TAVI, early pace-maker implantation was more frequent after TSc/TAx-TAVI than TAp-TAVI or TAo-TAVI, and midterm all-cause mortality was higher after TSc/TAx-TAVI than TF-TAVI.

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Introduction

In transcatheter aortic valve implantation (TAVI), the transfemoral (TF) approach has been the most commonly used with the lowest incidence of postprocedural complications. Due to concomitant peripheral artery disease such as unpassable stenosis, severe tortuosity, or small calibers of the iliofemoral arteries, however, 10%–15% of patients are unable to undergo TF-TAVI. Alternative approaches include transsubclavian (synonym for transaxillary) (TSc/TAx),

Abbreviations: TAo, transaortic; TAp, transapical; TAVI, transcatheter aortic valve implantation; TF, transfemoral; TSc/TAx, transsubclavian (synonym for transaxillary) * Corresponding author at: Department of Cardiovascular Surgery, Shizuoka Medical Center, 762-1 Nagasawa, Shimizu-cho, Sunto-gun, Shizuoka 411-8611, Japan. E-mail address: kfgth973@ybb.ne.jp (H. Takagi).

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transapical (TAp), transaortic (TAo), transcarotid, and transcaval. The TAp access is the unique antegrade approach and may offer simple wiring and marvelous controllability.³ The TAo approach may be more controllable and advantageous to accurate implantation depth.⁴ The transcarotid (especially, left transcarotid) approach may be coaxially aligned to the ascending aorta and optimally position the transcatheter valve.⁵ Transcaval access is a new approach to attain fully percutaneous TAVI in patients with the inadequate TF access.⁶ The subclavian/axillary artery, the minimum luminal diameter of which is commonly >5.0 mm even in case of the <5.0-mm iliofemoral artery, is less atherosclerotic and sinuous than the iliofemoral artery, and the TSc/TAx approach is a fully percutaneous access as well as the transcaval approach.⁷ Because limited data for the comparison of TSc/TAx-TAVI and other approaches have been available to date, outcomes

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ORIGINAL ARTICLE



Network meta-analysis of new-generation valves for transcatheter aortic valve implantation

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Abstract

To comprehensively compare and rank new-generation valves (NGVs) for transcatheter aortic valve implantation, we performed a network meta-analysis (NMA) of all eligible comparative studies. MEDLINE and EMBASE were searched through September 2018. We included all studies comparing 4 NGVs (ACURATE, Evolut R, Lotus, and SAPIEN 3) and an early generation valve (CoreValve) as the reference transcatheter heart valve (THV) each other and reporting at least one of post-procedural incidence of all-cause death, ≥ moderate aortic regurgitation (AR), and new permanent pacemaker implantation (PMI). To compare different THVs, a random-effects restricted-maximum-likelihood NMA based on a frequentist framework for indirect and mixed comparisons was used. Using surface under the cumulative ranking curve (SUCRA), the relative ranking probability of each THV was estimated and the hierarchy of competing THVs was obtained. We identified 29 eligible studies enrolling a total of 17,817 patients. In accordance with the estimated SUCRA probability, SAPIEN 3 was the best effective for a reduction in death (80.6%) and the second best for decreased ≥ moderate AR (74.4%) and PMI (74.1%) compared with the other THVs. Lotus was ranked the best for a reduction in ≥ moderate AR (94.5%;), whereas the worst for decreased PMI (1.2%) and the second worst for a reduction in mortality (38.6%). ACURATE was the best for decreased PMI (99.2%) and the second best for a reduction in mortality (77.9%). As a whole, SAPIEN 3 may be the best effective NGV among the 4 examined NGVs (ACURATE, Evolut R, Lotus, and SAPIEN 3).

Keywords Network meta-analysis · New-generation transcatheter heart valve · Transcatheter aortic valve implantation

Electronic supplementary material The online version of this article (https://doi.org/10.1007/s00380-019-01442-w) contains supplementary material, which is available to authorized users.

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Introduction

Transcatheter aortic valve implantation (TAVI) using newgeneration valves (NGVs) (NGV-TAVI) is suggested to be associated with lower postprocedural incidence of acute kidney injury, bleeding complications, and aortic regurgitation (AR) than TAVI using early-generation valves (EGVs) (EGV-TAVI), whereas incidence of new permanent pacemaker implantation (PMI), stroke, and all-cause death after NGV-TAVI may be similar to that after EGV-TAVI [1]. Several NGVs are currently used in clinical practice, and a number of studies have compared NGVs each other to date. Evidence drawn from direct comparisons, however, is limited to a few small-size studies. Because different comparators are used in existing studies, a conventional meta-analysis may not adequately assess comparative effectiveness of ≥ 3 different NGVs. Thus, to comprehensively compare and rank NGVs for TAVI focusing early postprocedural outcomes of interest (all-cause death,≥ moderate AR, and PMI), we

Meta-analysis of the Relation of Television-Viewing Time and Cardiovascular Disease



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To determine whether television (TV) viewing is associated with cardiovascular disease (CVD) risk, we performed a meta-analysis of currently available prospective cohort studies. We systematically searched PubMed and Web of Science through April 2019. Eligible for inclusion in the present meta-analysis was a prospective cohort study investigating the association of TV viewing time with CVD risk (CVD prevalence, CVD incidence, cardiovascular events, and cardiovascular mortality). From each study, adjusted hazard ratios (HRs) of CVD risk were extracted. We separately combined study-specific estimates for dichotomous, tertile, quartile, and continuous values of TV viewing time in the randomeffects model. The pooled analysis for dichotomous time demonstrated that CVD risk was significantly higher in the longer than shorter viewing (HR 1.28; p = 0.02). In the metaanalysis for tertile time, CVD risk was significantly higher in the longest than shortest tertile (T1) (HR 1.26; p = 0.0006), but there was no significant difference between the middle tertile and T1 (p = 0.51). The meta-analysis for quartile time indicated that CVD risk was significantly higher in the longest than shortest quartile (Q1) (HR 1.32; p = 0.0007), but there were no significant differences between the second longest quartile and Q1 (p = 0.12) and between the second shortest quartile and Q1 (p = 0.60). In the meta-analysis for continuous time, longer viewing was significantly associated with higher CVD risk (HR per 1h/day increment; 1.06; p = 0.005). In conclusion, longer TV viewing time is significantly associated with higher CVD risk. © 2019 Elsevier Inc. All rights reserved. (Am J Cardiol 2019;124:1674-1683)

There is the association of sedentary time with cardiometabolic health markers (such as fasting glucose, fasting insulin, triglycerides, high-density lipoprotein cholesterol, and waist circumference), diabetes mellitus (DM), cardiovascular disease (CVD), cardiovascular disease (CVD), and the control of th

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Author contribution: HT contributed to conception, design, acquisition, analysis, and interpretation, drafted manuscript, and agrees to be accountable for all aspects of work ensuring integrity and accuracy. YH and KN contributed to acquisition and analysis. TK contributed to design, analysis, and interpretation. TA contributed to conception, acquisition, analysis, and interpretation, and critically revised manuscript. All authors gave final approval.

See page 1683 for disclosure information.

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0002-9149/© 2019 Elsevier Inc. All rights reserved. https://doi.org/10.1016/j.amjcard.2019.08.032 association of TV viewing with CVD risk remains unclear. In the present article, to determine whether TV viewing is associated with CVD risk, we performed a meta-analysis of currently available prospective cohort studies.

Methods

We conducted the present meta-analysis according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) (http://www.prisma-statement.org) and showed the PRISMA-P [PRISMA Protocols] 2015 checklist (http://www.prisma-statement.org/Extensions/Protocols. aspx) in Supplementary Table S1. We systematically searched PubMed (https://www.ncbi.nlm.nih.gov/pubmed/) and Web of Science (http://www.webofknowledge.com/wos) through April 2019 using keyword including "television"; and "cardiovascular disease(s)," "cardiovascular event(s)," "cardiovascular death(s)," or "cardiovascular mortality." Eligible for inclusion in the present meta-analysis was a prospective cohort study investigating the association of TV viewing time with CVD risk (CVD prevalence, CVD incidence, CV events, and CV mortality). We evaluated the quality of the studies using the RoBANS [Risk of Bias Assessment Tool for Nonrandomized Studies]. From each study, adjusted hazard ratios (HRs) of CVD incidence, CV events, and CV mortality (and adjusted odds ratios of CVD prevalence) with their confidence intervals (CIs) were extracted. Data were extracted in duplicate by 2 investigators (HT, TK) and independently verified by a third researcher

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CARDIAC SECTION

Meta-analysis of prognostic impact of peripheral arterial disease on mortality after transcatheter aortic valve implantation

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ABSTRACT

INTRODUCTION: The aim of this study was to determine whether peripheral arterial disease (PAD) is an independent predictor of mortality in patients who undergo transcatheter aortic valve implantation (TAVI) and we performed meta-analysis of currently available studies

EVIDENCE ACQUISITION: MEDLINE and EMBASE were searched through June 2018 using Web-based search engines (PubMed and OVID). We included comparative studies of patients with PAD *versus* those without PAD and cohort studies which investigated PAD as one of prognostic factors of mortality, which used the multivariable analysis and reported an adjusted odds and hazard ratio (OR/HR) for early (30-day or in-hospital) and late (including early) mortality after TAVI. Study-specific estimates were combined using inverse variance-weighted averages of logarithmic ORs/HRs in the random-effects model.

EVIDENCE SYNTHESIS: The primary meta-analysis which pooled all the ORs/HRs demonstrated that PAD was associated with a statistically significant increase in both early (OR, 1.21; P=0.02) and midterm (1-year to 7-year) mortality (HR, 1.31; P<0.00001). The secondary meta-analysis which exclusively pooled approach-adjusted/stratified ORs/HRs demonstrated that PAD was associated with a strong trend toward (though statistically non-significant) an increase in early mortality (OR, 1.18; P=0.07) and a still statistically significant increase in midterm mortality (OR, 1.24; P=0.0001). Meta-regression coefficients for the proportion of patients who underwent transfemoral TAVI were not statistically significant (P for early/midterm mortality =0.24/0.52).

CONCLUSIONS: The present meta-analysis clearly highlighted that PAD was an independent predictor of both early and midterm mortality in patients who underwent TAVI.

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KEY WORDS: Mortality; Peripheral arterial disease; Transcatheter aortic valve replacement.

Introduction

Patients with peripheral arterial disease (PAD) are at increased risk of atrial 61-211-22 increased risk of atrial fibrillation, chronic kidney disease, valvular heart disease, vascular dementia, pulmonary embolism, heart failure, ischemic stroke, deep vein thrombosis, ischemic heart disease, unspecified stroke, and aortic aneurysm.1 Clinical PAD is commonly recognized in survivors of myocardial infarction (MI), and it is associated with high incidence of fatal and non-fatal cardiovascular events in both the short and longer term.² Furthermore, PAD is associated with worse prognosis in patients with heart failure.3 Among patients who undergo percutaneous coronary intervention, coexisting PAD is associated with higher postprocedural mortality and MI, and it is an independent predictor of short- and long-term

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Echocardiographic outcomes from seven randomized trials of transcatheter versus surgical aortic valve replacement

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Aims We performed meta-analyses of echocardiographic outcomes, including postprocedural aortic valve area (AVA), aortic valve mean pressure gradient (MPG), and paravalvular aortic regurgitation (PAR), exclusively from all currently available randomized controlled trials (RCTs) of transcatheter aortic valve implantation (TAVI) versus surgical aortic valve replacement (SAVR).

Methods To identify all RCTs providing echocardiographic outcomes (AVA, MPG, and PAR) up to 2 years after TAVI versus SAVR, PubMed and ClinicalTrials.gov were searched through June 2019. Mean differences in AVA (and MPG) between the TAVI and SAVR groups and odds (or hazard) ratios of at least moderate PAR for TAVI versus SAVR were pooled using the random-effects meta-analysis.

Results We identified seven eligible RCTs. At 30 days (P=0.004), 1 year (P=0.006), and 2 years (P=0.03), AVA was significantly larger after TAVI than after SAVR. After TAVI than after SAVR, MPG was significantly lower at 30 days (P=0.03) and 2 years (P=0.01), and nonsignificantly lower at 1 year (P=0.06). At 30 days (P<0.00001), 1 year (P<0.00001), and 2 years

Introduction

Aortic valve mean pressure gradient (MPG) is considerably improved after both transcatheter aortic valve implantation (TAVI) and surgical aortic valve replacement (SAVR) for severe aortic stenosis. A number of comparative studies have demonstrated larger aortic valve area (AVA) and lower MPG after TAVI than after SAVR. Although a metaanalysis² of these studies has supported lower postprocedural MPG favoring TAVI, findings from randomized controlled trials (RCTs) remain limited. Recently two RCTs, the Evolut Low Risk trial³ and the Placement of Aortic Transcatheter Valves (PARTNER) 3 trial,⁴ reported better clinical outcomes after TAVI than after SAVR. In the present article, we performed meta-analyses of echocardiographic outcomes, including postprocedural AVA, MPG, and paravalvular aortic regurgitation (PAR), exclusively from all currently available RCTs of TAVI versus SAVR. Furthermore, the fragility of the statistical significance for the result of the binary outcome (PAR) was assessed using the fragility index of meta-analyses⁵ and the ratio of the fragility index to the total number of participants included in the trials.

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(P<0.00001), incidence of at least moderate PAR was significantly greater after TAVI than after SAVR.

Conclusion On the basis of the present meta-analyses of all the seven currently available RCTs, AVA is larger, MPG is lower, and incidence of at least moderate PAR is greater 30 days, 1 and 2 years after TAVI than after SAVR.

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Keywords: echocardiographic outcome, meta-analysis, randomized controlled trial, surgical aortic valve replacement, transcatheter aortic valve implantation

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Methods

To identify all RCTs providing echocardiographic outcomes after TAVI versus SAVR, PubMed (https:// www.ncbi.nlm.nih.gov/pubmed/) and ClinicalTrials.gov (https://clinicaltrials.gov/ct2/home) were through June 2019 using the following search terms: transcatheter; aortic valve; implantation(s) or replacement(s); and randomized. The following studies were included: the design was an RCT; the study population comprised patients with severe aortic stenosis; patients were randomized to TAVI versus SAVR; outcomes included postprocedural AVA, MPG, and PAR up to 2 years. Risk of bias of RCTs is assessed using the Cochrane Collaboration's tool (https://training.cochrane.org/handbook). Blinding of participants and personnel (performance bias) was not used for assessment because the treatments were interventional (TAVI) and surgical (SAVR). At baseline, 30 days, 1 year, and 2 years in each RCT, we extracted means [with standard deviations (SDs)] of AVA (and MPG) and incidence of at least moderate PAR in both the TAVI and SAVR groups. The following random-effects meta-analyses were

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Original article

Meta-analysis of propensity matched studies of robotic versus conventional mitral valve surgery



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ABSTRACT

Background: To compare early outcomes after robotic versus conventional mitral valve surgery (R-MVS versus C-MVS), we performed a meta-analysis of currently available propensity score matched (PSM)

Methods: To identify all PSM studies of R-MVS versus C-MVS, PubMed and Web of Science were searched thorough November 2018 using the terms of robotic or robot, mitral, and propensity. Inclusion criteria were PSM studies of isolated R-MVS versus C-MVS. Odds ratios of dichotomous data and mean differences for continuous data were generated for each study and combined in a meta-analysis using the random-effects model.

Results: We identified 7 PSM studies of R-MVS versus C-MVS enrolling a total of 3764 patients. Pooled analyses demonstrated significantly longer cardiopulmonary bypass (CPB) (p < 0.00001) and crossclamp time (p = 0.004) in R-MVS than C-MVS. However, intensive care unit (ICU) (p = 0.0005) and hospital stay (p < 0.0001) was significantly shorter; and incidence of red blood cell (RBC) transfusion (p = 0.03), prolonged ventilation (p = 0.048), and atrial fibrillation (AF) (p = 0.01) was significantly less frequent after R-MVS than C-MVS. There was no significant difference in incidence of reoperation for bleeding and valve dysfunction, ≥moderate mitral regurgitation, renal failure, dialysis, pneumonia, stroke, cardiac arrest, and all-cause death (p = 0.27) between R-MVS and C-MVS.

Conclusions: ICU/hospital stay was shorter and RBC transfusion/prolonged ventilation/AF was less frequent after R-MVS than C-MVS despite longer CPB and cross-clamp time in R-MVS than C-MVS. The other early outcomes including all-cause mortality were similarly frequent after R-MVS and C-MVS.

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Introduction

A previous large meta-analysis [1] of 35 studies suggested that intensive care unit (ICU) and hospital stay may be shorter and atrial fibrillation (AF) may be less frequent after minimally invasive (mainly via thoracotomy) than conventional (via sternotomy) mitral valve (MV) surgery (including repair and replacement) (MVS) although cardiopulmonary bypass (CPB) and cross-clamp

Although several comparative observational studies of robotic versus conventional MVS have been published, no randomized controlled trial (RCT) has been conducted to the best of our knowledge. The gold standard to estimate causal effects of treatments is in general considered as an RCT, notwithstanding, which is often unactable for various reasons, e.g. ethical concerns, extreme costs, or timeliness [2]. Propensity score methods can achieve the generation of similar experimental and control units balanced in terms of covariates [2]. In the present article, to compare early outcomes after robotic versus conventional MVS, we performed a meta-analysis of currently available propensity score matched (PSM) studies.

time may be longer in minimally invasive than conventional MVS.

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CARDIAC SECTION

Meta-analysis of impact of troponins on mortality after transcatheter aortic valve implantation

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ABSTRACT

INTRODUCTION: To determine whether troponin (Tn) can predict mortality after transcatheter aortic valve implantation (TAVI), we performed a meta-analysis of currently available studies investigating impact of baseline and postprocedural Tn.
EVIDENCE ACQUISITION: MEDLINE and EMBASE were searched through April 2019 using PubMed and OVID. Studies considered for

inclusion met the following criteria: the study investigating impact of baseline and postprocedural Tn on mortality; the study population was patients undergoing TAVI for aortic stenosis (AS); outcomes included early (30-day or in-hospital)/late (including early) mortality. For each study, data regarding early/late mortality in both high and low (defined in each study) level of baseline/postprocedural Tn groups were used to generate odds ratios (ORs) and 95% confidence intervals (CIs), or reported ORs and hazard ratios (HRs) with 95% CIs were directly extracted. Study-specific estimates were combined using inverse variance-weighted averages of logarithmic ORs/HRs in the random-effects model. EVIDENCE SYNTHESIS: We identified 19 eligible studies including a total of 7555 patients undergoing TAVI. Pooled analyses demonstrated

associations of high levels of baseline Tn with statistically significant increases in both 30-day (P=0.002) and midterm mortality (P<0.00001), no correlation of high postprocedural Tn with 30-day mortality (P=0.13), and an association of high postprocedural Tn with a statistically significant increase in midterm mortality (P=0.002). High levels of baseline/postprocedural TnT predicted statistically significant increases in both 30-day (P=0.002/<0.0001) and midterm mortality (P<0.00001/0.0003).

CONCLUSIONS: Both baseline and postprocedural Tn, especially TnT, may predict mortality after TAVI for AS.

(Cite this article as: Takagi H, Hari Y, Nakashima K, Kuno T, Ando T; All-Literature Investigation of Cardiovascular Evidence (ALICE) Group. Meta-analysis of impact of troponins on mortality after transcatheter aortic valve implantation. J Cardiovasc Surg 2020;61:98-106. DOI: 10.23736/ S0021-9509.19.11023-3)

KEY WORDS: Meta-analysis; Mortality; Transcatheter aortic valve replacement; Troponins.

Introduction

Proponins (Tn), such as troponin T (TnT) and troponin I (TnI), have been known to predict prognosis in patients with aortic stenosis (AS).1-5 Furthermore, baseline Tn is suggested to be a predictor of major adverse cardiac events after surgical aortic valve replacement for AS.6 Although a number of studies⁷⁻⁹ have recently investigated impact of baseline and postprocedural Tn on mortality after transcatheter aortic valve implantation (TAVI) for AS, the results remains still controversial. In the present article, to determine whether Tn can predict mortality after TAVI, we performed a meta-analysis of currently available studies investigating impact of baseline and postprocedural Tn.

Evidence acquisition

All studies investigating impact of baseline and postprocedural Tn on mortality after TAVI for AS were identified using a 2-level search strategy. First, databases including MEDLINE and EMBASE were searched through April 2019 using Web-based search engines (PubMed and OVID).

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CARDIAC SECTION

A meta-analysis of ≥5-year mortality after transcatheter versus surgical aortic valve replacement

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ABSTRACT

INTRODUCTION: It remains unclear whether long-term survival is superior following transcatheter aortic valve implantation (TAVI) than following surgical aortic valve replacement (SAVR). We performed a meta-analysis of mortality with ≥5-year follow-up in randomized controlled trials (RCTs) and propensity-score matched (PSM) studies of TAVI versus SAVR.

EVIDÈNCE ACQUISITION: MEDLINE, ÈMBASE, and the Cochrane Central Register of Controlled Trials were searched through March 2019. Eligible studies were RCTs or PSM studies of TAVI versus SAVR enrolling patients with severe aortic stenosis and reporting all-cause mortality with ≥5-year follow-up as an outcome. A hazard ratio of mortality for TAVI versus SAVR was extracted from each individual study. EVIDENCE SYNTHESIS: Our search identified 3 RCTs and 7 PSM studies enrolling 5498 patients. A pooled analysis of all 10 studies demonstrated a statistically significant 38% increase in mortality with TAVI relative to SAVR. A subgroup meta-analysis showed no statistically significant difference between TAVI and AVR in RCTs and a statistically significant 68% increase with TAVI relative to SAVR in PSM studies. CONCLUSIONS: On the basis of a meta-analysis of 7 PSM studies, TAVI is associated with greater all-cause mortality with ≥5-year follow-up than SAVR. However, another meta-analysis of 3 RCTs suggests no difference in mortality between TAVI and SAVR.

(Cite this article as: Takagi H, Hari Y, Nakashima K, Kuno T, Ando T; All-Literature Investigation of Cardiovascular Evidence (ALICE) Group. A meta-analysis of ≥5-year mortality after transcatheter versus surgical aortic valve replacement. J Cardiovasc Surg 2020;61:107-16. DOI: 10.23736/ S0021-9509.19.11030-0)

KEY WORDS: Meta-analysis; Randomized controlled trial; Transcatheter aortic valve replacement; Surgery.

Introduction

recent systematic review of 31 studies with a total of A13,857 patients showed that long-term survival after transcatheter aortic valve implantation (TAVI) was acceptable (aggregated survival at 1-, 2-, 3-, 5-, and 7-year, 83%, 75%, 65%, 48%, and 28%, respectively) in elderly patients (mean age of 81.5±7.0 years).1 Five well-known randomized controlled trials (RCTs) - Placement of Aortic Transcatheter Valves (PARTNER) 1,2 PARTNER 2,3 CoreValve US,4 Nordic Aortic Valve Intervention (NO-TION),⁵ Surgical Replacement and Transcatheter Aortic

Valve Implantation (SURTAVI)6 — have reported mortality with follow-up of ≥2-year following TAVI versus surgical aortic valve replacement (SAVR) for severe aortic stenosis (AS), in all of which there is no statistically significant difference in follow-up mortality between TAVI and SAVR. Three (PARTNER 1,² CoreValve US,⁴ NOTION⁷) of the 5 RCTs have provided 5-year mortality. Our previous meta-analyses of observational comparative studies applying a propensity-score analysis suggest that TAVI may be associated with an increase in \geq 6-month⁸ and \geq 3year mortality⁹ relative to SAVR. Longer-term mortality following TAVI versus SAVR, however, remains unclear.

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The association of volume of intramural thrombus with rupture of abdominal aortic aneurysm



We read with great interest a systematic review and metaanalysis by Singh et al¹ of the relation of volume of intramural thrombus (IMT) to rupture of abdominal aortic aneurysm (AAA). The authors¹ identified greater volume of IMT in ruptured AAA (RAAA) than in intact AAA (IAAA) (finding A) and no difference in IMT volume between RAAA and IAAA in patients matched for AAA diameter or other covariates (finding B). The latter finding, however, was derived from only three studies^{2,3} enrolling 77 patients.

Because absolute volume of IMT may be associated with (may be potentially proportional to) size of AAA, IMT volume should be adjusted for AAA size in comparing RAAA with IAAA. There may be two potential adjustment methods: adjusting for AAA diameter and volume. In the first adjustment, IMT volume is divided by whole (luminal and IMT) diameter of AAA, resulting in a two-dimensional index; in the second adjustment, IMT volume is divided by whole (luminal and IMT) volume of AAA, leading to a no-dimensional index. We herein reassessed the analysis by Singh et al¹ using the ratio of IMT volume to AAA diameter and that percent of IMT volume to AAA volume. All analyses were performed using OpenMetaAnalyst

(www.cebm.brown.edu/openmeta/index.html) and Pro-Meta version 3.0 (https://idostatistics.com/prometa3/).

The IMT-volume/AAA-diameter ratio was unavailable and calculated in all eight studies included in the metaanalysis¹; whereas the IMT/AAA-volume ratio was directly extracted in four²⁻⁵ of the eight studies and calculated in two studies (Supplementary Table, online only). Pooled analysis using the random effects model demonstrated significantly greater IMT-volume/AAA-diameter ratio in RAAA than in IAAA (mean difference, 3.21; 95% confidence interval, 0.27-6.15; P = .03; $I^2 = 35.4\%$) (Fig. top) (finding C) and no significant difference in IMT/AAA-volume ratio between RAAA and IAAA (mean difference, 2.53; 95% confidence interval, -1.97 to 7.03; P = .27; $I^2 = 11.3\%$) (Figure, bottom) (finding D). No funnel plot asymmetry was identified in both the analyses of IMT-volume/AAA-diameter ratio and IMT/AAA-volume ratio (P=.43 and P=.52 by the linear regression test, respectively) (Supplementary Fig. online only, top and bottom, respectively).

The results of the original study¹ (findings A and B) and our present analysis (findings C and D) should be interpreted with caution because of their limitations. Finding A was based on the simple comparison without consideration of AAA size, finding B was derived from only three studies, and finding C was based on not reported but calculated

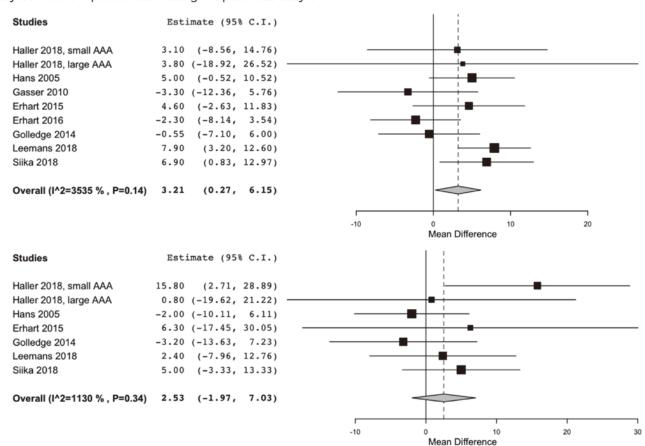


Fig. Forest plots of mean differences in intramural thrombus (IMT)-volume/abdominal aortic aneurysm (AAA)-diameter ratio (*top*) and IMT/AAA-volume ratio (*bottom*) between ruptured vs intact AAA. *Cl*, Confidence interval.

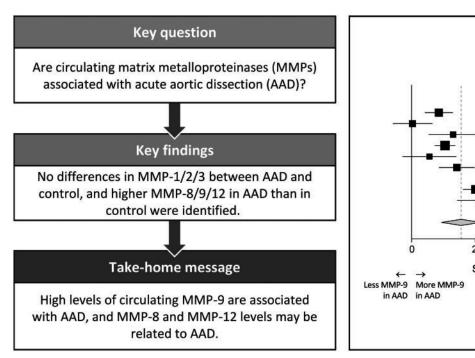
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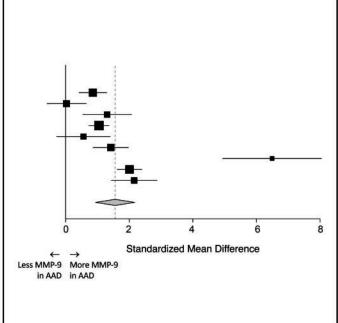
Matrix metalloproteinases and acute aortic dissection: Et Tu, Brute?

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Abstract

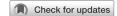
OBJECTIVES: To summarize the present evidence for the association of matrix metalloproteinases (MMPs) with acute aortic dissection (AAD), we performed the first meta-analysis of all currently available case-control studies comparing circulating MMP levels between AAD patients and control subjects.

METHODS: To identify all studies investigating the levels of circulating MMPs in AAD patients, PubMed and Web of Science were searched up to July 2019. The levels of MMPs in AAD patients and control subjects were extracted from each study, and the standardized mean differences (SMDs) in MMP levels were generated. The study-specific estimates were combined in the random-effects model.

RESULTS: Twelve studies enrolling a total of 458 AAD patients and 711 control subjects were identified and included. Pooled analyses demonstrated no significant differences in MMP-1 (4 studies; P = 0.21), MMP-2 (5 studies; P = 0.62) and MMP-3 levels (2 studies; P = 0.94) between AAD patients and control subjects; and significantly higher MMP-8 (2 studies; SMD 2.11; P = 0.020), MMP-9 (9 studies; SMD 1.54; P < 0.001) and MMP-12 levels (2 studies; SMD 1.33; P < 0.001) in AAD patients than in control subjects.

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Heart in Aorta



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Figure 1.

A woman in her late 70s presented with sudden-onset severe chest pain. Computed tomography with contrast medium revealed a heart-shaped intimal flap in the ascending aorta (Figure 1), which was diagnosed as type A acute aortic dissection. The patient underwent emergency ascending aortic replacement with brachiocephalic artery reconstruction (because of the entry located between the origins of the brachiocephalic and left common carotid artery) and is now doing well and waiting discharge. Heart-shaped construction abruptly appears in ultrasonographic, computed tomography, magnetic resonance imaging, and angiographic findings and astonishes us, such as "heart in heart," "heart in pulmonary trunk," and "intracranial heart." As a unique echocardiographic finding of type A acute aortic

dissection, intimal intussusception into the left ventricle, which leads to significant (often severe) aortic regurgitation, has been known. "Heart in aorta" identified in the present case, however, has never been reported.

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ORIGINAL ARTICLE



Baseline left ventricular diastolic dysfunction affects midterm mortality after transcatheter aortic valve implantation

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Abstract

Objectives: To determine whether preprocedural left ventricular (LV) diastolic dysfunction impairs midterm mortality after transcatheter aortic valve implantation (TAVI) for patients with severe aortic stenosis (AS), we performed a meta-analysis of currently available evidence.

Methods: We identified all studies investigating impact of preprocedural severity of LV diastolic dysfunction on midterm (≥1-year) all-cause mortality after TAVI for patients with AS through a search of databases (MEDLINE and EMBASE) until September 2019. From each study, we extracted an adjusted (if unavailable, unadjusted) hazard ratio (HR) of midterm mortality. We pooled study-specific estimates in the random-effects model.

Results: Ten eligible studies with a total of 2380 patients with AS undergoing TAVI were identified. In accordance with pooled analyses, higher-grade preprocedural LV diastolic dysfunction was associated with significantly worse midterm all-cause mortality after TAVI compared to lower-grade dysfunction (HR for grade II vs I, 1.15; P = .002; HR for grade III vs I, 1.35; P = .001; HR for grade III vs II; 1.16, P = .002; HR for grade II-III vs I, II-III vs O-I, or III vs I-II, 1.34; P < .00001 [primary meta-analysis]; HR per grade, 1.16; P = .003). No funnel plot asymmetry for the primary meta-analysis (for grade II-III vs I, II-III vs O-I, or III vs I-II) was identified, which probably indicated no publication bias (P = .381 by the linear-regression test).

Conclusion: Higher-grade preprocedural LV diastolic dysfunction was associated with worse midterm all-cause mortality after TAVI for patients with AS compared to lower-grade dysfunction.

KEYWORDS

left ventricular diastolic dysfunction, meta-analysis, mortality, transcatheter aortic valve implantation

1 | INTRODUCTION

It has been known that preprocedural left ventricular (LV) systolic dysfunction, ie, low ejection fraction (EF)¹⁻³ and low stroke volume (SV), ¹ affects prognosis after transcatheter aortic valve implantation

(TAVI) for patients with severe aortic stenosis (AS). Meanwhile, LV diastolic dysfunction (lower e' velocity [e'],^{4,5} higher E velocity to e' velocity ratio,⁴ and higher E velocity to A-wave velocity ratio [E/A]⁶) is associated with increased short-term,⁴ short-to-midterm,⁵ and midto-long-term mortality⁶ in septic patients^{4,5} and patients with chronic

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ORIGINAL ARTICLE

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Meta-Analysis and Meta-Regression of Transcatheter Aortic Valve Implantation for Pure Native Aortic Regurgitation

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Aim	To assess outcomes of transcatheter aortic valve implantation (TAVI) for pure native aortic regurgitation (AR) and to evaluate whether 30-day all-cause mortality is modulated by patient characteristics, we performed a meta-analysis and meta-regression of currently available studies.
Method	Studies enrolling ≥20 patients undergoing TAVI for AR were considered for inclusion. Study-specific estimates (incidence rates of outcomes) were combined using one-group meta-analysis in a random-effects model. Subgroup meta-analysis of studies exclusively using early-generation devices (EGD) and new-generation devices (NGD) and stepwise random-effects multivariate meta-regression were also performed.
Results	The search identified 11 eligible studies including a total of 911 patients undergoing TAVI for AR. Pooled analysis demonstrated an incidence of device success of 80.4% (NGD 90.2% , EGD 67.2% ; p < 0.001), moderate or higher paravalvular aortic regurgitation (PAR) of 7.4% (NGD 3.4% , EGD 17.3% ; p < 0.001), 30 -day all-cause mortality of 9.5% (NGD 6.1% , EGD 14.7% ; p < 0.001), mid-term (4 mo - 1 yr) all-cause mortality of 18.8% (NGD 11.8% , EGD 32.2% ; p < 0.001), life-threatening/major bleeding complications (BC) 5.7% (NGD 3.5% , EGD 12.4% ; p $= 0.015$), and major vascular complications (MVC) of 3.9% (NGD 3.0% , EGD 6.2% ; p $= 0.041$). All coefficients in the multivariate meta-regression adjusting simultaneously for the proportion of diabetes mellitus, chronic obstructive pulmonary disease, peripheral arterial disease, concomitant moderate or higher mitral regurgitation, and mean left ventricular ejection fraction (with significant coefficients in the univariate meta-regression) were not statistically significant.
Conclusions	Thirty (30)-day all-cause mortality after TAVI for AR was high (9.5%) with a high incidence of moderate or higher PAR (7.4%). Compared with EGD, NGD was associated with significantly higher device success rates and significantly lower rates of second-valve deployment, moderate or higher PAR, 30-day/mid-term all-cause mortality, serious BC, and MVC.
Keywords	Aortic regurgitation • Meta-analysis • Transcatheter aortic valve implantation

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ACS in lunar wonderland: Lunar phases and acute coronary syndrome

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The association of lunar phases with catastrophic cardiovascular events, such as intracranial and abdominal aortic aneurysm rupture and acute coronary syndrome (ACS), has been investigated. It was reported that the new moon was associated with an increased risk of aneurysmal subarachnoid hemorrhage¹ and the new/full moon correlated with intracranial aneurysm rupture.² I and my colleague also previously showed that the waxing moon was associated with an increased risk of abdominal aortic aneurysm rupture.3 Furthermore, the new moon was reported to correlate with a decreased risk of cardiopulmonary resuscitations.⁴ A number of studies have researched the association of lunar phases with ACS occurrence, but it remains unclear whether lunar phases correlate with ACS occurrence. In the present article, to determine whether the association of lunar phases with ACS occurrence is myth or reality, I performed a meta-analysis of all the currently available studies.

All studies investigating the association of lunar phases with ACS occurrence were identified by means of PubMed (https://www.ncbi.nlm.nih.gov/ pubmed/), Web of Science (http://www.webofknowledge.com/wos) and Google (https://s cholar.google.com) through May 2019. Search terms included moon or lunar; and acute coronary syndrome, myocardial infarction, or unstable angina. From each study, data regarding the total number of ACS occurrence and days during the specific lunar phase were extracted. For each study, rate (ACS occurrence per day) ratios (RRs) and their 95% confidence intervals (CIs) were generated by the use of data regarding ACS occurrence in both the full- and new-moon phases and in both the waxing- and waning-moon phases. Study-specific estimates were combined by using inverse variance-weighted averages of logarithmic RRs in the random-effects model. Funnel plot asymmetry (suggesting publication bias) was mathematically assessed through the use of the linear regression test. All analyses were performed with the use of ProMeta version 3.0 (https://idostatistics.com/prometa3/).

Seven eligible studies^{5–11} were identified and included in the present meta-analysis (Supplementary Material Table S1 online). The pooled analysis demonstrated no statistically significant difference in the rate of ACS occurrence between the full- and new-moon phases (RR, 0.94; 95% CI, 0.85 to 1.04; p=0.224; Figure 1) and between the waxing- and waning-moon phases (RR, 0.91; 95% CI, 0.70 to 1.17; p=0.450). No funnel plot asymmetry was identified (full- versus new-moon phase, p=0.451; Supplementary Material Figure S1; waxing- versus waning-moon phase, p=0.303), which suggested probably no publication bias.

The present meta-analysis suggests that the association of lunar phases with ACS occurrence is myth, not reality. Intensified anti-thrombotic therapy is efficacious against ischemic events and cardiovascular deaths despite incurrence of an overabundant risk for hemorrhagic events.¹² Antiplatelet drugs are requisite to prevent recrudescence in the acute phase and longterm follow-up of myocardial infarction because platelets play an essential role in ACS pathogenesis. 13 It is speculated that increasing the dose of aspirin before the new-moon days may potentially decrease the platelet aggregability and decrease the incidence of cardiac events.8 Because blood viscosity is increased during the beginning and last one-third of the lunar-calendar month, acute myocardial infarction may predominantly occur during this high-viscosity period. 10 These hypotheses, however, are negated by the results of the present meta-analysis.

The gravitation of the moon, not the lunar phase, may be associated with acute myocardial infarction

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Blood group and abdominal aortic aneurysm

Hisato Takagi^{1,2}; for the ALICE (All-Literature Investigation of Cardiovascular Evidence) Group

Blood group may be associated with a number of cardiovascular diseases. Previous meta-analyses suggested the relation of blood group A to coronary artery disease¹ and the association of blood group non-O with coronary artery disease, 1-3 myocardial infarction, 2,4,5 ischemic stroke⁴ (cerebral ischemia of arterial origin⁵), peripheral vascular disease⁵ and venous thromboembolism. 5,6 Although several studies investigated the relation of blood group to abdominal aortic aneurysm (AAA), no meta-analysis of them has been conducted to date. In the present article, to determine whether blood group is associated with AAA, the first meta-analysis of currently available studies was performed.

To identify all studies researching the relation of blood group to AAA, PubMed (https://www.ncbi. nlm.nih.gov/pubmed/), Web of Science (http://www. webofknowledge.com/wos) and Google (https://scholar.google.com) were searched up to June 2019. Search terms consisted of blood group or blood type; aorta or aortic; and aneurysm. From each study, the number of individuals with the specific blood group in AAA patients and control subjects (individuals without AAA or general population) was extracted. For each study, odds ratios (ORs) (with their 95% confidence intervals (CIs)) of prevalence of the specific blood group for AAA patients versus control subjects were generated. First, to exclude outlier studies, the L'Abbé, ⁷ radial (Galbraith), ⁸ normal quantile-quantile (Q-Q)⁹ and funnel plots were synthesized for ORs of blood group O for AAA patients versus control subjects in the fixed-effect model. When an outlier study was visually suspected, the chi-squared statistic (for between-study heterogeneity) and Egger linearregression test¹⁰ (for funnel-plot asymmetry) were performed in all studies and in those without the suspected outlier study. When statistically significant (p < 0.05)heterogeneity/asymmetry was detected in all studies but not in those without the suspected outlier study, the suspected study was judged outlier and accordingly excluded in a meta-analysis. Then, the remaining ORs of blood group O (or non-O) for AAA patients versus

control subjects were combined in the fixed-effect model.

Six studies^{11–16} were identified (Table 1). In all of the L'Abbé (Supplementary Material Figure S1 online), radial (Galbraith) (Supplementary Material Figure S2), normal Q-Q (Supplementary Material Figure S3) and funnel plots (Supplementary Material Figure S4), the study by Fatic et al. 11 was suspected as outlier, and accordingly the chi-squared statistic and Egger linearregression test¹⁰ were performed. Statistically significant between-study heterogeneity and funnel-plot asymmetry were detected in all studies (p for heterogeneity = 0.003; p for asymmetry = 0.019) but not in those without the study¹¹ (p for heterogeneity = 0.29; p for asymmetry = 0.594). Hence, the study by Fatic et al. ¹¹ was judged outlier, and accordingly excluded in the meta-analysis. Among the six identified studies, 11-16 the study¹¹ with the smallest number (273) of control subjects reported the highest prevalence of blood group O in AAA patients (53.1%) and the lowest group-O prevalence in control subjects (38.5%). Pooling the remaining five studies^{12–16} excepting the study by Fatic et al.¹¹ demonstrated that blood group O was associated with a statistically significant reduction in AAA prevalence (pooled OR, 0.90; 95% CI, 0.81 to 0.99; p = 0.04; $I^2 = 20\%$; Figure 1, 1.1.1) and blood group non-O was related to a statistically significant increase in AAA prevalence (pooled OR, 1.11; 95% CI, 1.01 to 1.24; p = 0.04; $I^2 = 21\%$; Figure 1, 1.1.2).

The present meta-analysis suggests the association of blood group O with reduced AAA prevalence, sc. the relation of blood group non-O to increased AAA

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Which should we eat, fruit or vegetables? The association with abdominal aortic aneurysm

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Long-term consumption of a Mediterranean diet (including high consumption of fruit and vegetables) increases circulating levels of endothelial progenitor cells more than a low-fat diet in patients with type-2 diabetes. Furthermore, adherence to the Mediterranean diet and adoption of an active lifestyle are inversely associated with incidence of cardiovascular disease.² Consumption of fruit and/or vegetables has been known to be inversely associated with risk of hypertension,^{3,4} type 2 diabetes mellitus,⁵⁻⁷ and metabolic syndrome.8 Fruit/vegetable consumption may be also inversely associated with risk of cardiovascular disease (not only incidence^{9,10} but also mortality¹¹), especially coronary heart disease¹² and stroke.¹³ The association of fruit/vegetable consumption with risk of abdominal aortic aneurysm (AAA), however, has been less investigated. In the present article, to assess whether consumption of either fruit or vegetables, both fruit and vegetables, or neither fruit nor vegetables is associated with incidence of AAA, we performed the first meta-analysis of currently available all prospective cohort studies.

To identify all prospective cohort studies researching the association of fruit/vegetable consumption with AAA incidence, we searched PubMed, Web of Science and Google Scholar up to July 2019. Search terms included fruit(s) or vegetable(s); aorta or aortic; and aneurysm(s). From each study, we extracted multivariable-adjusted hazard ratios (with their 95% confidence intervals (CIs)) of AAA incidence for higher versus the lowest fruit or vegetable consumption, then combined the specific estimates by means of inverse variance-weighted averages of logarithmic hazard ratios in the random-effects model. All analyses were conducted using Review Manager version 5.3.

We identified three large population-based prospective cohort studies^{14–16} (Table 1) enrolling 120,055 participants. Incidence rates of AAA during follow-up of 13¹⁴ to 23 years¹³ was 0.52%¹⁶ to 3.83%.¹⁵ All studies provided multivariable-adjusted hazard ratios for

fruit and vegetables separately. We excluded a study¹⁷ reporting hazard ratios for fruit and vegetables together. In all studies, smoking and socioeconomic status (education and physical activity) were entered into the multivariable Cox proportional hazards regression as potential covariates in addition to fruit/vegetables consumption (Table 1), which means that the inverse association of fruit, not vegetable, consumption with AAA incidence (demonstrated in the present metaanalysis) is 'independent' of smoking and socioeconomic status. A sex-stratified analysis was performed in only one study, 16 which suggests that men (hazard ratio for the fourth versus lowest quartile consumption, 0.79: 95% CI, 0.64 to 0.99), not women (corresponding hazard ratio, 0.71; 95% CI, 0.45 to 1.11), benefit from fruit consumption. Unfortunately, no study reported patient ethnicity. Fruit and vegetable consumption was assessed by a 168-item food frequency questionnaire (FFQ) and a 1-h interview, 14 a 66-item FFQ, 15 and a 96-item FFQ.¹⁶ In a study by Bergwall et al.,¹⁴ fruits were divided into citrus and non-citrus fruits; vegetables were, in addition to total vegetables, divided into root vegetables (including carrots), leaf vegetables (including kale), carrots, and cabbage; and juices (including all types of vegetable and citrus juices) were excluded. In other studies, 15,16 however, fruit/ vegetable consumption was not especially defined. Bergwall et al.¹⁴ provided hazard ratios for citrus fruit, non-citrus fruit, leaf vegetables, and root vegetables separately, and Stackelberg et al.16 reported

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Colder is worse? Meteorology of acute aortic dissection

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In late afternoon on 31 December 2005, Dr Michael Ellis DeBakey at the age of 97 years, who had advocated the famous classification of aortic dissection (Supplementary reference 1), suffered from acute aortic dissection (AAD) at home in Houston (https:// www.nytimes.com/2006/12/25/health/the-man-on-thetable-devised-the-surgery.html). We wonder if it was especially cold on that particular day. A peak of the onset of aortic aneurysm rupture or aortic dissection has been known to be early morning (Supplementary reference 2). The meteorology of ruptured abdominal aortic aneurysm (RAAA) has often been investigated, and lower atmospheric pressure may be associated with RAAA (Supplementary reference 3). Furthermore, chronobiological studies have shown a greater incidence of RAAA in winter (Supplementary reference 4), December (Supplementary references 5 and 6) and January (Supplementary references 5 and 6), which suggests that lower atmospheric temperature may also be associated with RAAA. Lower outdoor temperature is related to adverse effects on risk factors of cardiovascular disease (Supplementary reference 7). The meteorology of AAD, however, has been less investigated, and no meta-analysis of it has been conducted to date. In the present article, to determine whether some meteorological factors, such as atmospheric temperature, pressure and humidity, are associated with AAD, we performed the first meta-analysis of all meteorological studies for AAD currently available.

The present meta-analysis was conducted according to PRISMA. All studies investigating the association of meteorological factors (i.e. atmospheric temperature, pressure and/or relative humidity) with AAD were identified by searching PubMed, Web of Science and Google Scholar up to August 2019. Search terms were 'atmospheric/barometric/barometrical/air pressure', 'temperature', 'humidity', 'meteorology', 'meteorologic', 'meteorological', 'climate', 'climatic', 'climatology', or 'weather' and 'aortic dissection', or 'dissecting aortic aneurysm'. The mean (and standard deviation) of meteorological factors (primary outcome) on both the days with AAD and those without

AAD (controls) were extracted from each study, and then standardised mean differences (SMDs) and their 95% confidence intervals were generated for each study. Adjusted (unadjusted if unavailable) odds ratios (ORs) for AAD per unit increment of meteorological factors were also extracted from each study. Study-specific estimates were combined using a random effects model. Between-study heterogeneity was assessed by the I^2 statistic, and values of the order of 25%, 50% and 75% were considered as low, moderate and high heterogeneity, respectively. All analyses were performed using Review Manager version 5.3 (http://tech.cochrane.org/revman).

Of 232 potentially relevant publications initially screened, 10 eligible studies^{1–10} were identified (Table 1). The mean of atmospheric temperature/pressure 1-4,6-8,10 and relative humidity 1-4,6,10 on the days with AAA and controls was available in eight studies, and the OR for AAD per unit increment of atmospheric temperature/pressure^{5,7,9,10} and relative humidity¹⁰ was reported in four studies. The OR per 1 mmHg and 1 hPa increment of pressure was converted into that per 1 kPa increment using the standard formula. In the first meta-analysis of SMDs, minimal (P = 0.003; Figure 1(a)), mean (P=0.003; Figure 1(b)), maximaltemperature (P = 0.003; Figure 1(c)) was significantly lower on the days with AAD than controls; there was no significant difference in mean pressure (P = 0.72; Figure 1(d)) and minimal humidity (P=0.20;Figure 1(e)) between the days with AAD and controls;

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Wind and coronary artery disease

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Meteorological parameters, such as atmospheric temperature, pressure, relative humidity, wind velocity, and so on, may play an important role in cardiovascular diseases. Cold exposure is associated with cardiovascular hospitalization, and lower temperature is related to cardiovascular mortality2 and intracerebral hemorrhage.3 Lower temperature is also associated with myocardial infarction (MI).4 Furthermore, lower maximal humidity and higher minimal humidity are suggested to be related to hospitalization for angina.⁵ The association of wind velocity with coronary artery disease (CAD), however, has been less investigated, and no meta-analysis of this has been conducted to date. In the present article, to determine whether wind velocity is related to CAD, we performed the first meta-analysis of contemporary meteorological studies.

The present meta-analysis was conducted according to PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) (http://www.prisma-statement.org). All studies investigating the meteorology of CAD were identified using the following two-level search strategy. First, PubMed, Web of Science, and Google Scholar were searched up to August 2019. Studies investigating the association of wind velocity with CAD were included. The outcome of interest was CAD, especially acute coronary syndrome (ACS), including acute MI and unstable angina. The quality of the studies was evaluated using the Risk of Bias Assessment Tool for Nonrandomized Studies (RoBANS),6 and risk of bias was evaluated as low, high, and unclear in accordance with six components. Adjusted (unadjusted if unavailable) relative risks (RRs) with their confidence intervals (CIs) for CAD per unit increment of wind velocity were extracted from each study. Data were extracted by two investigators (HT and TK) in duplicate and independently ascertained by a third researcher (TA), and disagreements were solved by consensus. Study-specific estimates were combined using a random-effects model. Between-study heterogeneity was assessed by the I^2 statistic, and values on the order of 25%, 50%, and 75% were considered as low, moderate, and high heterogeneity, respectively. Funnel plot symmetry (suggesting publication bias) was mathematically estimated by Egger's linear regression test.⁷ To visually evaluate inconsistency, heterogeneity, distribution, and publication bias for RRs, the radial (Galbraith)⁸ and normal quantile-quantile (Q-Q)⁹ plots were generated in the random-effects model. Sensitivity analyses were conducted to examine the contribution of each study to the pooled estimate by eliminating individual studies one at a time and recombining RRs for the remaining studies. All analyses were performed using Review Manager version 5.3 (http://tech.cochrane.org/revman) and JASP version 0.10.2 (https://jasp-stats.org).

As illustrated in Supplementary Figure S1, nine eligible studies^{10–18} were identified (Table 1). The quality (risk of bias) of the studies is shown in Supplementary Figures S2 and S3. The outcome was CAD death in one study,¹⁰ acute MI in four studies,^{11–14} and ACS (including acute MI and unstable angina) in four studies.^{15–18} Daily mean wind velocity was used for the analysis in all but one (analyzing wind velocity measured at 18 p.m.)¹⁷ study (Table 2). Some RRs per non-1-m/s increment in wind velocity were converted into those per 1-m/s increment using the standard formula.

The primary meta-analysis demonstrated a relation of higher wind velocity to a statistically significant increase in CAD risk (RR per 1-m/s increment, 1.0217; 95% CI, 1.0060 to 1.0375; p=0.006; $I^2=80\%$; Figure 1). Funnel plot asymmetry was not identified (p=0.204; Supplementary Figure S4, upper

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Marriage and mortality after acute coronary syndrome

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Married individuals are associated with lower mortality compared with unmarried (consisting of widowed, divorced/separated, and never married) individuals (see Supplementary Reference 1). The association of marital dissolution (i.e. divorce and separation) with higher mortality is also known (see Supplementary Reference 2). Furthermore, married individuals are associated with a lower incidence of cardiovascular disease and coronary heart disease and lower coronary heart disease and stroke mortality compared with unmarried (including never married, divorced, and windowed) individuals (see Supplementary Reference 3). Although more than a dozen studies have investigated the association of marital status with prognosis after acute coronary syndrome (ACS), no meta-analysis of them has been conducted to date. In the present article, to determine whether marital status is associated with survival after ACS, a meta-analysis of contemporary studies was performed.

The present meta-analysis was conducted in accordance with the preferred reporting items for systematic reviews and meta-analyses (PRISMAS) statement (http://www.prisma-statement.org) (see Supplementary Appendix). PubMed, EMBASE, Scopus and Web of Science were searched from January 2000 to July 2019. Search terms included 'marriage', 'marital', 'married', 'matrimony', or 'matrimonial'; 'myocardial infarction', 'unstable angina', or 'acute coronary syndrome'; and 'death or mortality'. The PubMed search algorithm was the following: (death OR mortality) AND (marriage OR marital OR married OR matrimony OR matrimonial) AND ('myocardial infarction' OR 'unstable angina' OR 'acute coronary syndrome'). The following studies were included in the present meta-analysis: those enrolling patients with ACS and investigating an association of marital status with early and overall mortality after ACS. We excluded studies from which only unadjusted, not adjusted (using the multivariable analysis), odds ratios (ORs)/ hazard ratios (HRs) could be extracted. The primary outcome was all-cause mortality. From each study,

ORs of early mortality and HRs of overall mortality with their confidence intervals (CIs) for married versus unmarried (consisting of never married, windowed and divorced) patients were extracted. Study-specific estimates were combined using inverse varianceweighted averages of logarithmic ORs (for early mortality) and HRs (for overall mortality) separately in the random effects model. Between-study heterogeneity was assessed using the I^2 statistic, and values in the order of 25%, 50% and 75% were considered as low, moderate and high heterogeneity, respectively. The primary meta-analysis pooled ORs/HRs for married versus unmarried patients. Funnel plot asymmetry (suggesting the existence of publication bias) was mathematically assessed using the linear regression test. All analyses were conducted using Review Manager version 5.3 (http://tech.cochrane.org/revman) and ProMeta version 3.0 (https://idostatistics.com/prometa3/).

As illustrated in Supplementary Figure 1, 14 potentially eligible studies with a total of 89,176 patients were identified (Table 1) (see Supplementary References 4–7). The risk of bias of each study is summarised in Supplementary Table 1. Extracted and calculated ORs/HRs are listed in Table 1. Adjusted ORs for early (one-day, inhospital of and 30-day (see Supplementary Reference 5)) mortality were available in five studies (see Supplementary Reference 5), 4,6–8 and adjusted HRs for overall (one-year to 77-month (see Supplementary Reference 6)) mortality were

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Association of aortic and intracranial aneurysm: Tweedledum and Tweedledee?

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Abdominal aortic aneurysm (AAA), thoracic aortic aneurysm (TAA), and intracranial aneurysm (ICA) are the most common arterial aneurysms, and their rupture is absolutely catastrophic and mostly fatal. In the general population, prevalence rates have been reported to be 5.5% for AAA, S1 4.2% for TAA, S2 and 3.2% for ICA. S3 Common genes, biological processes, and pathways are suggested between AAA and ICA. S4 Furthermore, the association of TAA with bicuspid aortic valve^{S5} and the relation of ICA to bicuspid aortic valve^{S6} suggests that TAA and ICA may share the etiology of bicuspid aortic valve. Although several studies investigated the relation of aortic aneurysm (AoA; i.e. either AAA or TAA) to ICA, the prevalence of AoA in patients with ICA and prevalence of ICA in patients with AoA have never been systematically estimated to date. Are AoA and ICA similar to each other like "Tweedledum and Tweedledee" (characters in Lewis Carroll's novel "Through the Looking Glass")? In the present study, we performed a meta-analysis of the above-mentioned prevalence. The pooled estimate could become a reference value in clinical practice and a basis for whether or not screening of AAA in patients with ICA should be undertaken.

We identified all studies investigating AoA prevalence in ICA patients and/or ICA prevalence in AoA patients using PubMed and Web of Science up to July 2019. Using the Bayes theorem, we calculated unknown AoA prevalence rate in ICA patients from reported ICA prevalence rate in AoA patients and unknown ICA prevalence rate in AoA patients from reported AoA prevalence rate in ICA patients (Supplementary Material Appendix). Then, we combined study-specific estimates (prevalence rates) using the random-effects empirical Bayes model. Funnel plot asymmetry was assessed using the adjusted rank-correlation test. We conducted all analyses using JASP (https://jasp-stats.org) and OpenMetaAnalyst (http://www.cebm.brown.edu/openmeta/index.html).

As illustrated in Supplementary Material Figure 1, we identified eight eligible studies¹⁻⁸ including 3529

patients (Table 1). The AoA prevalence in ICA patients was distributed from 0.6% to 54.4%, and the ICA prevalence in AoA patients from 2.2%⁴ to 33.3%.⁸ The pooled AoA prevalence in ICA patients was 13.3% ($I^2 = 99.8\%$, p for funnel plot asymmetry = 0.059) (20.5% for AAA and 11.2% for TAA) (Figure 1), and the pooled ICA prevalence in AoA patients was 10.2% $(I^2 = 93.0\%, p \text{ for funnel plot asymmetry} = 0.046)$ (12.0% for AAA and 8.4% for TAA) (Supplementary Material Figure 2). Sex-specific results are summarized in Supplementary Material Table 1 and Supplementary Material Figure 3. In ICA patients, the AoA prevalence was significantly lower in women than in men (odds ratio, 0.18; p < 0.001). Whereas, in AoA patients, the ICA prevalence was significantly higher in women than in in men (odds ratio, 2.16; p < 0.001). Age and concomitant major cardiovascular diseases are summarized in Supplementary Material Table 2, and random-effects meta-regression analyses were performed. All examined diseases (i.e. hypertension, dyslipidemia, diabetes mellitus, coronary artery disease, and stroke) were associated with the ICA prevalence in AoA patients (as the proportion of patients with a given concurrent disease increases, the prevalence increases) but not with the AoA prevalence in ICA patients (Supplementary Material Table 3).

The AoA prevalence (20.5% for AAA and 12.2% for TAA) in ICA patients and the ICA prevalence (10.2%) in AoA patients (demonstrated in the present meta-analysis) are likely much greater than the AAA

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Egg Consumption and Coronary Artery Disease: A Nice Knockdown Argument

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Abstract

To identify prospective cohort studies enrolling adults and investigating an association of egg consumption with incidence and mortality of coronary artery disease (CAD), PubMed and Web of Science were searched through June 2019. Adjusted hazard ratios (HRs) of CAD incidence/mortality for more versus the least frequent egg consumption were extracted from each study. Study-specific estimates were pooled in the random-effects model. Sixteen eligible studies with a total of I 285 505 participants were identified and included in the present meta-analysis. The primary meta-analysis pooling all HRs for the most versus least frequent egg consumption demonstrated that egg consumption was associated with significantly low CAD incidence/mortality (pooled HR: 0.93; 95% confidence interval: 0.89-0.98; $I^2 = 9\%$). In the secondary meta-analyses (separately combining HRs for the third vs first tertile, the fourth vs first quartile, the third vs first quartile, the fourth vs first quintile, and the third vs first quintile egg consumption), the fifth (vs first) quintile egg consumption was only associated with significantly low CAD incidence/mortality. In conclusion, egg consumption is independently associated with low incidence/mortality of CAD, which may be derived from the comparisons of the fifth versus first quintile egg consumption.

Keywords

coronary artery disease, egg consumption, meta-analysis

Introduction

The relation of egg consumption to incidence and mortality of coronary artery disease (CAD, synonym of coronary heart disease and ischemic heart disease including myocardial infarction) has been insufficiently understood.¹ Previous meta-analyses suggest that egg consumption may not be associated with low cardiovascular disease (CVD) mortality, 1 all-cause mortality, 1-3 CAD incidence, 3-6 and CAD mortality.¹⁻³ The potential association of dietary cholesterol with cardiac outcomes has been investigated for several decades.⁵ Although eggs are rich in nutrition, their cholesterol content is a concern.2 However, a recent large (>400 000 participants) prospective cohort study⁷ reported a strong trend toward an association of fifth (vs first) quintile egg consumption with low CAD incidence, and another recent large (>460 000 participants) prospective cohort study⁸ showed significant associations of fifth/fourth/ third/second (vs first) quintile egg consumption with low CAD incidence.

We hypothesized that egg consumption may be associated with low incidence and mortality of CAD. To verify our hypothesis, we performed an updated meta-analysis of currently available prospective cohort studies.

Methods

The present meta-analysis was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement (http://www.prisma-statement.org).

Search Strategy

PubMed (https://www.ncbi.nlm.nih.gov/pubmed/) and Web of Science (http://www.webofknowledge.com/wos) were searched through June 2019. Search terms consisted of *egg* and

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Original article

Gait and fate: Baseline gait speed and mortality after transcatheter aortic valve implantation

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ABSTRACT

Background: To determine whether baseline gait speed predicts mortality after transcatheter aortic valve implantation (TAVI), a meta-analysis of currently available studies was performed.

Methods: To identify all studies researching the impact of preprocedural gait speed on mortality after TAVI, PubMed and Web of Science were searched through May 2019. Adjusted (if unavailable, unadjusted) hazard/odds ratios (ORs/HRs) with their confidence interval of mortality for slow (if available, the slowest) versus fast (if available, the fastest) gait speed (with cut-off values defined in each study) and those for unable to walk versus walker (if available, with the fastest gait speed) were extracted from each study, and then separately pooled by means of inverse variance-weighted averages of logarithmic ORs/HRs in the random-effects model.

Results: Twelve eligible studies (7 and 5 based on the distance-limited and time-limited walk test, respectively) were identified and integrated in the present meta-analysis. The pooled analysis of all ORs/HRs demonstrated that slow walkers (primary meta-analysis; OR/HR, 2.38; p < 0.00001) and unable to walk (OR/HR, 1.75; p = 0.01) were significantly associated with increased mortality. The subgroup analysis for the primary meta-analysis indicated no significant subgroup difference between studies utilizing the 4-m/5-m/15-foot walk test and those applying the 6-min walk test (p = 0.45). Combining studies with 1-year follow-up did not alter the primary result (p < 0.0001). Pooling studies with adjusted ORs/HRs did not change the principal result (p = 0.0002). No funnel plot asymmetry for the primary meta-analysis was identified. Conclusions: Slow baseline gait speed (and unable to walk) is associated with increased mortality after TAVI.

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Introduction

Worse frailty status defined by the frailty index score, the Canadian Study of Health and Aging Clinical Frailty Scale, the Geriatric Status Scale, the Katz index, etc., is associated with greater incidence of early death [1,2], acute kidney injury [1], lifethreatening or major bleeding [1], and late death [1,2] after transcatheter aortic valve implantation (TAVI). Gait speed is one of

the important indices of frailty status and a predictor of midterm mortality and rehospitalization after cardiac surgery [3]. Although a number of studies have investigated the impact of gait speed alone on mortality after TAVI, it remains unclear whether slow gait speed is related to poor prognosis after TAVI. In the present article, to determine whether baseline gait speed predicts mortality after TAVI, a meta-analysis of currently available studies was performed.

Methods

To identify all studies researching the impact of preprocedural gait speed on mortality after TAVI, PubMed (https://www.ncbi.nlm.nih.gov/pubmed/) and Web of Science (http://www.

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ORIGINAL ARTICLE



Prognostic impact of baseline C-reactive protein levels on mortality after transcatheter aortic valve implantation

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Abstract

Objectives: To determine whether baseline C-reactive protein (CRP) levels can predict mortality after transcatheter aortic valve implantation (TAVI), we performed a meta-analysis of currently available studies.

Methods: All studies investigating the prognostic impact of baseline (preprocedural) CRP levels on all-cause mortality after TAVI were identified by means of searching PubMed and Google Scholar through May 2019. For each study, (preferentially, adjusted rather than unadjusted) odds/hazard ratios (ORs/HRs) with corresponding 95% confidence intervals of mortality per standard-deviation (SD) (or unit) increase in CRP levels or those for high vs low CRP levels.

Results: Our search identified 14 eligible studies including a total of 3449 patients undergoing TAVI and reporting early (in-hospital to 3-month) and midterm (1-year to 3-year) all-cause mortality after TAVI. Pooled analyses demonstrated associations of high-baseline CRP levels with a marginal, but statistically nonsignificant increase in early mortality (pooled OR/HR per SD increase in CRP levels, 2.72; P = .09 and pooled OR/HR for high vs low CRP levels, 3.32; P = .07) and a statistically significant increase in midterm mortality after TAVI (pooled OR/HR per SD increase in CRP levels, 1.45; P < .0001 and pooled OR/HR for high vs low CRP levels, 1.78; P < .00001). Excluding HRs for high-sensitivity CRP, combining ORs/HRs of 1-year mortality, pooling HRs of ≥ 2 -year mortality, and combining adjusted HRs did not alter the primary results.

Conclusion: High-baseline CRP levels may predict increased midterm, but not early, mortality after TAVI.

KEYWORDS

C-reactive protein, meta-analysis, mortality, transcatheter aortic valve implantation

1 | INTRODUCTION

C-reactive protein (CRP) levels play an important role in predicting prognoses of cardiovascular diseases (CVD) (stable coronary artery disease, ¹ acute coronary syndrome, ^{2,3} and peripheral artery disease ⁴) and outcomes after cardiovascular (CV) interventions (percutaneous

coronary intervention [PCI],⁵⁻⁷ coronary artery bypass grafting [CABG],⁸ and vascular surgery⁹). Several biomarkers (brain natriuretic peptides, troponins, galectin-3, growth differentiation factor-15, and microRNAs) have been known to predict outcomes after transcatheter aortic valve implantation (TAVI).¹⁰ A number of relatively small-size studies have investigated the prognostic impact of

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Mortality after transcatheter versus surgical aortic valve replacement: an updated meta-analysis of randomised trials

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Abstract

Background To determine whether transcatheter aortic valve implantation (TAVI) improves early (30-day) and midterm (1-year) mortality compared with surgical aortic valve replacement (SAVR), we performed an updated meta-analysis of all the currently available randomised controlled trials (RCTs).

Methods To identify all RCTs providing both 30-day and 1-year mortality after TAVI versus SAVR, PubMed and ClinicalTrials.gov were searched up to and including July 2019. A risk difference (RD) and its 95% confidence interval were generated using data of prespecified outcomes in both the TAVI and SAVR groups. Study-specific estimates were pooled using inverse variance-weighted averages of RDs in the random-effects model.

Results We identified seven eligible high-quality RCTs including a total of 7631 as-treated patients. Pooled analyses demonstrated significantly lower 30-day (RD -0.60%; p=0.046) and 1-year all-cause mortality (RD

Electronic supplementary material The online version of this article (https://doi.org/10.1007/s12471-020-01378-1) contains supplementary material, which is available to authorized users.

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Division of Interventional Cardiology, Department of Cardiology, New York Presbyterian Hospital/Columbia University Medical Center, New York, NY, USA -1.12%; p=0.03) after TAVI than after SAVR. No funnel plot asymmetry was detected for 30-day and 1-year mortality. Meta-regression analyses indicated that RDs of 30-day and 1-year mortality between TAVI and SAVR were not modulated by mean Society of Thoracic Surgeons Predicted Risk of Mortality score. Bleeding complications at 30 days and 1 year and stage 2/3 acute kidney injury at 30 days were significantly less frequent after TAVI than after SAVR, whereas major vascular complications and new permanent pacemaker implantation at 30 days and 1 year were significantly more frequent after TAVI than after SAVR.

Conclusion The best evidence from the present metaanalysis of all the currently available RCTs suggests that TAVI may reduce 30-day and 1-year all-cause mortality compared with SAVR.

What's new?

- To determine whether transcatheter aortic valve implantation (TAVI) improves early (30-day) and midterm (1-year) mortality compared with surgical aortic valve replacement (SAVR), we performed an updated meta-analysis of all the currently available randomised controlled trials (RCTs).
- We identified seven eligible high-quality RCTs including a total of 7631 as-treated patients.
- None of the included RCTs showed significantly lower all-cause mortality after TAVI than after SAVR.
- Pooled analyses demonstrated significantly lower 30-day [risk difference (RD) -0.60%; p=0.046] and 1-year all-cause mortality (RD -1.12%; p=0.03) after TAVI than after SAVR.



Mortality after transcatheter versus surgical aortic valve replacement: an updated meta-analysis of...

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Impact of postprocedural thrombocytopenia on mortality after transcatheter aortic valve implantation

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Aims We performed a meta-analysis of currently available studies investigating the impact of postprocedural thrombocytopenia on mortality after transcatheter aortic valve implantation (TAVI).

Methods All studies researching the impact of postprocedural thrombocytopenia on mortality after TAVI were identified after searching PubMed and Web of Science through July 2019. The outcome of interest was early (in-hospital or 30-day) and overall (1- to 2-year) all-cause mortality after TAVI. From each study, the number of deaths in both patients with major (moderate/severe or higher postprocedural drop platelet counts defined in each study) and nonmajor (no/minor or lower drop platelet counts defined in each study) postprocedural thrombocytopenia was extracted. Then, odds ratios (ORs) of mortality for major vs. no/minor thrombocytopenia and their confidence intervals were generated. Alternatively, ORs and hazard ratios of mortality for major vs. no/minor thrombocytopenia (if available, adjusted) were directly extracted. Studyspecific estimates were pooled in both the fixed-effect and random-effects models.

Results The principal pooled analysis demonstrated that postprocedural thrombocytopenia was associated with statistically significant increases in early (OR, 3.79; P for effect <0.00001; P for heterogeneity = 0.89) and overall

mortality (OR/hazard ratio, 1.22; P for effect = 0.009; P for heterogeneity = 0.17) in the fixed-effect model. All sensitivity analyses did not substantively alter the results of the principal analysis. No funnel plot asymmetry of the principal analysis was detected (P for early mortality = 0.88; P for overall mortality = 0.14), which suggested probably no publication bias.

Conclusion Postprocedural thrombocytopenia is associated with increased early and overall mortality after TAVI.

Keywords: meta-analysis, mortality, thrombocytopenia, transcatheter aortic valve implantation

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Introduction

New-onset in-hospital thrombocytopenia in patients with acute coronary syndrome may be associated with short-term major bleeding, stent thrombosis, reinfarction or ischemia, unplanned revascularization, stroke, heart failure, and mortality; and long-term reinfarction or ischemia and mortality. Development of thrombocytopenia after isolated surgical aortic valve replacement also may independently predict postoperative bleeding and operative mortality.² Furthermore, the impact of postprocedural thrombocytopenia on mortality after transcatheter aortic valve implantation (TAVI) has been recently researched. It remains unclear, however, whether new-onset thrombocytopenia after TAVI impairs postprocedural survival. In the present article, we performed a meta-analysis of currently available studies investigating the impact of postprocedural thrombocytopenia on mortality after TAVI.

Methods

The present meta-analysis was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (Supplementary Appendix). All studies researching the impact of postprocedural thrombocytopenia on mortality after TAVI were identified searching PubMed (https://www.ncbi.nlm.nih.gov/pubmed/) and Web of Science (http://www.webofknowledge.com/wos) through July 2019. Search terms consisted of thrombocytop(a)enia; transcatheter; aortic valve; and implantation or replacement. The outcome of interest was early (in-hospital or 30-day) and overall (1- to 2-year) all-cause mortality after TAVI.

From each study, the number of deaths in both patients with major ['moderate/severe' or 'higher postprocedural drop platelet counts (DPC)' defined in each study] and nonmajor ('no/minor' or 'lower DPC' defined in each

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Jigsaw puzzle-like multiple-barreled aorta in acute aortic dissection

A man in his late 70's, who had undergone replacement of the ascending aorta for acute type A aortic dissection 10 years before and whose descending thoracic aorta had been dilated (4.5 cm) on postoperative follow-up computed tomography (CT) 2 years before, presented with sudden-onset and severe back pain. Non-electrocardiogram-gated contrast-medium CT revealed the dilated (5.7 cm in diameter) jigsaw puzzle-like descending thoracic aorta with quadruple false lumens (Figure 1) (4 cm in continuous length of the aorta). The patient was diagnosed as acute type B aortic dissection. Aggressive anti-hypertensive treatment was immediately initiated and then continued. Despite appropriate blood-pressure control, the patient suddenly died of rupture of the dissected aorta 3 days later.

Several cases of multiple-barreled aortic dissection have been reported.¹⁻⁴ Sueyoshi *et al.*⁵ reported that the manifestation was presented in 9.0% of patients (20 of 221 patients) suffering from

Figure 1.—Jigsaw puzzle-like descending thoracic aorta with quadruple false lumens.

acute type B aortic dissection. Between patients with and without multiple false lumens, no significant differences in age, sex, current smoking, concomitant diseases (hypertension, hyperlipidemia, diabetes mellitus, atherosclerotic diseases, and Marfan Syndrome), hemodialysis, and initial CT findings (arch involvement, pleural effusion, and maximum diameter of the dissected aorta) were identified. Furthermore, multiple-barreled dissection was an independent and strong predictor (multivariate-adjusted hazard ratio, 5.61; P<0.0001) of long-term (10-year) dissection-related mortality but not events (aneurysmal dilatation, organ ischemia, type A re-dissection, and spontaneous rupture) (P=0.19).5 The diameter of the patient's descending thoracic aorta had been 4.5 cm 2 years before and then was 5.7 cm in the acute phase of dissection. Aortic aneurysms with dissection may be at higher risk of rupture. In the present case, although the expansion timing (already before dissection or immediately after dissection) is impossible to be ascertained and, a rapid expansion, not multiple false lumens per se, may primarily contribute to rupture. Medical treatment could be continued until its effects are evaluated when an ongoing rapid expansion (if it exists) is confirmed. Cautious acute-phase management including very-early reimaging of the aorta and long-term follow-up should be recommended for aortic dissection with multiple false lumens. Because randomized trials demonstrated that endovascular repair of uncomplicated acute6 and subacute/chromic7 type B aortic dissection induced remodeling with false-lumen thrombosis and reduction at 1 year6 and improved aorta-related mortality and dissection progression at 5 years,7 endovascular repair may be a feasible treatment option for multiple-barreled dissection.

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Predictors of Hospital Cost After Transcatheter Aortic Valve Implantation in the United States: From the Nationwide Inpatient Sample Database



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We aimed to identify risk factors of high hospitalization cost after transcatheter aortic valve implantation (TAVI). TAVI expenditure is generally higher compared with surgical aortic valve replacement. We queried the Nationwide Inpatient Sample database from January 2011 to September 2015 to identify those who underwent endovascular TAVI. Estimated cost of hospitalization was calculated by merging the Nationwide Inpatient Sample database with cost-to-charge ratios available from the Healthcare Cost and Utilization Project. Patients were divided into quartiles (lowest, medium, high, and highest) according to the hospitalization cost, and multivariable regression analysis was performed to identify patient characteristics and periprocedural complications associated with the highest cost group. A total of 9,601 TAVI hospitalizations were identified. Median in-hospital costs of the highest and lowest groups were \$82,068 and \$33,966, respectively. Patients in the highest cost group were older and more likely women compared with the lowest cost group. Complication rates (68.4% vs 22.5%) and length of stay (median 10 days vs 3 days) were both approximately 3 times higher and longer, respectively, in the highest cost group. Co-morbidities such as heart failure, peripheral vascular disease, atrial fibrillation, anemia, and chronic dialysis as well as almost all complications were associated with the highest cost group. The complications with the highest incremental cost were acute respiratory failure requiring intubation (\$28,209), cardiogenic shock (\$22,401), and acute kidney injury (\$16,974). Higher co-morbidity burden and major complications post-TAVI were associated with higher hospitalization costs. Prevention of these © 2019 Elsevier Inc. All rights reserved. complications may reduce TAVI-related costs. (Am J Cardiol 2019;123:1142-1148)

Transcatheter aortic valve implantation (TAVI) is an attractive treatment method from a clinical standpoint, however, healthcare-related cost should be examined as value-based therapies, and cost containment measures are gaining increasing relevance. In 2012, the total expenditure for TAVI from Medicare was 215,770,200 US dollars for 4,083 TAVI procedures and the hospital costs were higher for TAVI compared with surgical aortic valve replacement (SAVR) (median \$50,200 vs \$45,500). In addition, TAVI had higher hospitalization costs compared with SAVR when factoring readmission costs. When

procedure-related complications occur, this additional cost will further increase the hospital cost of TAVI and may make it a less attractive option compared with SAVR. Arnold et al have reported procedural costs associated with TAVI from the PARTNER trial.³ However, the data were limited for initial TAVI experience in the United States. This study identifies baseline characteristics and periprocedural complications associated with high cost and also to calculate the incremental cost of major in-hospital complications after TAVI using the Nationwide Inpatient Sample (NIS) database.

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See page 1147 for disclosure information. *Corresponding author: Tel: 313-745-6035.

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Methods

This study was conducted using the NIS database, which is part of the Healthcare Cost and Utilization Project (HCUP).⁴ NIS is the largest all-payer inpatient admission database in the United States. It represents a 20% stratified sample of all discharges from community hospitals in the United States. Rehabilitation and long-term acute care hospitals are not included. The NIS includes data on primary and secondary discharge diagnoses, procedures, patient demographics, hospital characteristics, expected payment source, total hospitalization cost, discharge status, length of

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Incidence, Trends, and Predictors of Palliative Care Consultation After Aortic Valve Replacement in the United States

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Abstract

Aim: Transcatheter aortic valve replacement (TAVR) and surgical aortic valve replacement (SAVR) have become a reasonably safe procedure with acceptable morbidity and mortality rate. However, little is known regarding the incidence, trends, and predictors of palliative care (PC) consult in aortic valve replacement (AVR) patients. The main purpose of this analysis was to assess the incidence, trends, and predictors of PC consultation in AVR recipients using the Nationwide Inpatient Sample (NIS) database. Materials and Methods: We queried the NIS database from 2005 to September 2015 to identify those who underwent TAVR or SAVR and had PC referral during the index hospitalization. Adjusted odds ratio (aOR) was calculated to identify patient demographic, social and hospital characteristics, and procedural characteristics associated with PC consult using multivariable regression analysis. We also reported the trends of PC referral in AVR recipients. Results: A total of 522 765 admissions (mean age: 75.3 ± 7.8 years, 40.3% female) who had TAVR (1.7% transapical and 9.2% endovascular approach) and SAVR (89.2%) were identified. Inpatient mortality was 3.96%, and 0.5% patients of the total admissions had PC consultation. The PC referral for SAVR increased from 0.90 to 7.2 per 1000 SAVR from 2005 to 2015 (P = .011), while it remained stable ranging from 9.30 to 13.3 PC consults per 1000 TAVR (P = .86). Age 80 to 89 (aOR: 1.93), age \geq 90 years (aOR: 2.57), female sex (aOR: 1.36), electrolyte derangement (aOR: 1.90), weight loss (aOR: 1.88), and do not resuscitate status (aOR: 44.4) were associated with PC consult. West region (aOR: 1.46) and Medicaid (aOR: 3.05) were independently associated with PC consult. Endovascular (aOR: 1.88) and transapical TAVR (aOR: 2.80) had higher PC referral rates compared with SAVR. Conclusions: There was an increase in trends for utilization of PC service in SAVR admissions while it remained unchanged in TAVR cohort, but the overall PC referral rate was low in AVR recipients during the index hospitalization.

Keywords

surgical aortic valve replacement, transcatheter aortic valve replacement, palliative care

Introduction

Candidates of either transcatheter aortic valve replacement (TAVR) or surgical aortic valve replacement (SAVR) for severe, symptomatic aortic stenosis are often old, have multiple comorbidities related to atherosclerotic disease (ie, coronary artery disease), and frail. Improvements in patient selection, perioperative managements, and advancements in technologies have led to improved outcomes in these patients. Indeed, the contemporary short-term (in-hospital or 30-day) mortality of TAVR and SAVR is relatively low, ranging from 2.8% to 3.9% and 1.7% to 6.5% in intermediate to high surgical risk patients, respectively. 1-4 Although some perioperative clinical events may not necessarily lead to mortality, it could culminate in significant disabilities and impair quality of life.

Palliative care (PC) has been a valuable resource in patients with terminally ill cancer as well as in noncancer medical conditions (ie, advanced heart failure),⁵⁻⁸ but PC has been underutilized in cardiovascular disease.⁹ The Valve Academic

Research Consortium-2 document delineates several clinically important complications post-TAVR.¹⁰ However, there is scarce discussion regarding the care required for patients who experienced significant complications affecting their quality of

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ORIGINAL STUDIES

WILEY

In-hospital outcomes of transcatheter versus surgical aortic valve replacement in non-teaching hospitals

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Abstract

Objectives: To assess the in-hospital outcomes of transcatheter aortic valve replacement (TAVR) vs. surgical aortic valve replacement (SAVR) in non-teaching hospitals.

Background: TAVR has become widely available in the United States. However, the comparative outcomes of TAVR vs. SAVR in non-teaching hospitals are largely under explored.

Methods: We queried the Nationwide Inpatient Sample database from 2011 to September 2015 to identify those who were 50 years or above and underwent either trans-arterial TAVR or SAVR at non-teaching hospital. In-hospital clinical outcomes were compared with odds ratio (OR) in propensity-matched cohorts.

Results: We identified un-weighted 957 and 7,465 SAVR admissions. In propensity-matched model, 596 admissions in each arm were included for final analysis. In-patient mortality (3.9 vs. 2.5%, OR 1.54, P = 0.34), acute kidney injury requiring dialysis (2.2 vs. 2.7%, OR 0.80, P = 0.57), stroke (2.0 vs. 3.2%, OR 0.61, P = 0.20), and pacemaker placement (8.9 vs. 6.4%, OR 1.47, P = 0.09) was similar between TAVR and SAVR. Sub-group analysis showed that female and those with prior coronary artery bypass surgery had higher risk of in-patient morality in TAVR admission. Cost was higher (59,103 vs. 53,411 dollars, P = 0.006) but length of stay was shorter in TAVR (6.9 vs. 10.2 days, P < 0.001).

Conclusions: TAVR conferred similar in-hospital mortality and major peri-procedural complications compared with SAVR in non-teaching hospitals. For those with limited access to teaching hospitals, non-teaching hospitals appear to be a reasonable option for candidates of aortic valve replacement for severe aortic stenosis.

KEYWORDS

aortic stenosis, non-teaching hospital, surgical aortic valve replacement, transcatheter aortic valve replacement

1 | INTRODUCTION

The procedural number of transcatheter aortic valve replacement (TAVR) has dramatically increased as large randomized control studies have demonstrated its similar efficacy and safety compared with surgical aortic valve replacement (SAVR). According to the 2016 Annual report of the Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy Registry, number of TAVR

performed was 4,627 in 2012 but almost increased by 6-folds up to 24,808 in 2015 with decline in in-hospital mortality from 5.9% in 2012 to 2.9% in 2015. With its expansion in utilization as a major treatment modality for severe, symptomatic aortic stenosis, the number of TAVR performed at non-teaching hospitals also increased from only 3.6% in 2011 to 8 to 10% in 2012 to 2014. 4

Outcomes of invasive cardiac procedures between teaching and non-teaching hospitals have been reported in the past with unique

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Comparison of Health Related Quality of Life in Transcatheter Versus Surgical Aortic Valve Replacement: A Meta-Analysis



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Background	Data on the effects of transcatheter aortic valve replacement (TAVR) compared to surgical aortic valve replacement (SAVR) on health-related quality of life (HRQOL) outcomes are limited. To assess the comparative HRQOL outcomes between TAVR and SAVR, we performed a systematic review and meta-analysis.
Methods	PubMed and EMBASE databases were searched for articles that compared the HRQOL scores, Kansas City Cardiomyopathy Questionnaire (KCCQ), Medical Outcomes Study Short-Form Health Survey 12 or 36 (SF-12/36), or the EuroQoL 5 Dimension score (EQ-5D) at 30 days and 1 year between TAVR and SAVR. Mean difference (MD) and 95% confidence interval (CI) was calculated with inverse variance statistical method and random-effects model.
Results	A total of four studies with 4,125 patients (1268 transfemoral [TF]-TAVR, 1261 Non-TF TAVR [transsubclavian, transapical or transaortic], and 1,596 SAVR) were included in the studies. KCCQ overall summary scores and its subscales, SF-12/36, and EQ-5D were significantly higher in TF-TAVR compared to SAVR but were similar in non-TF TAVR vs. SAVR at 30 days. At 1-year follow-up, TF-TAVR and non-TF TAVR conferred similar HRQOL scores in KCCQ overall summary and subscales scores, SF-12/36, and EQ-5D compared to SAVR.
Conclusions	Transfermoral-TAVR achieved better HRQOL at 30 days but similar HRQOL at 1 year compared to SAVR. Non-TF TAVR resulted in similar improvements in HRQOL at both 30 days and 1 year compared with SAVR.
Keywords	Meta-analysis • Surgical aortic valve replacement • Transcatheter aortic valve replacement • Quality of life

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WILEY

ORIGINAL STUDIES

Transradial versus transfemoral percutaneous coronary intervention of left main disease: A systematic review and meta-analysis of observational studies

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Abstract

Objectives: To assess the efficacy and safety of transradial (TR) versus transfemoral (TF) percutaneous coronary intervention (PCI) in left main (LM) lesion.

Background: TR-PCI is the preferred approach compared with TF approach because of less bleeding risk. LM-PCI is often challenging because of the anatomical complexity and uniqueness of supplying a large myocardium territory. We performed a systematic review and meta-analysis to assess the safety and efficacy of TR-PCI compared with TF-PCI of the LM lesions.

Methods: A comprehensive literature search of PUBMED, EMBASE, and Cochrane database was conducted to identify studies that reported the comparable outcomes between both approaches. Odds ratio (OR) and 95% confidence interval (CI) was calculated using the Mantel-Haenszel method.

Results: A total of eight studies were included in the quantitative meta-analysis. TR-PCI resulted in lower bleeding risk (OR 0.31, 95%CI 0.18–0.52, P < 0.01, $I^2 = 0\%$) while maintaining similar procedural success rate, target lesion revascularization, myocardial infarction, stent thrombosis, and all-cause mortality during the study follow-up period.

Conclusions: TR-PCI may achieve similar efficacy with decreased bleeding risk compared to TF-PCI in LM lesions. When operator experience and anatomical complexity are favorable, TR approach is an attractive alternative access over TF approach in LM-PCI.

KEYWORDS

left main, percutaneous coronary intervention, transfemoral, transradial

1 | INTRODUCTION

Transradial (TR) percutaneous coronary intervention (PCI) has been increasingly adopted as the preferred approach across the spectrum of coronary artery disease compared with transfemoral (TF)-PCI owing mainly to low bleeding risk and in some studies even lower mortality rate. ¹⁻⁷ In the latest European revascularization guideline, radial access was recommended as the standard approach for PCI, unless other considerations override (Class I, level of evidence A).⁸ However,

there is less consensus on whether this would hold true for left main (LM) lesions. A PCI of the LM lesion poses unique and challenging task as it jeopardizes significant myocardial territory and frequently includes PCI of the bifurcation, another form of a formidable lesion for PCI.

The data regarding the safety and efficacy of TR-PCI compared with TF-PCI in LM disease are limited. TF-PCI seem attractive as it would assure more secure catheter back up support during PCI and allows the use of larger size catheter to perform complex-PCI.

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In-Hospital Outcomes of ST-Segment Elevation Myocardial Infarction Complicated With Cardiogenic Shock at Safety-Net Hospitals in the United States (from the Nationwide Inpatient Sample)



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Safety-net hospitals (SNHs) are hospitals that serve a higher proportion of patients insured by Medicaid or uninsured and have been reported to have poor outcomes compared with non-SNHs. Procedural and clinical outcomes of ST-segment elevation myocardial infarction complicated by cardiogenic shock (STEMI-CS) at SNHs have not been well described. Nationwide Inpatient Sample from 2005 to 2011 was queried to identify STEMI-CS and age ≥18. SNHs were defined as hospitals with the highest number of inpatient stays that were paid by Medicaid or were uninsured (the top quartile). A total of 23,229 STEMI-CS of which 3,639 (15.7%) were treated at SNHs. Admissions to SNHs were younger (mean age 66.0 vs 67.2, p < 0.001), more likely men (64.0% vs 62.2%, p = 0.04), more frequently ethnic minorities (Black; 11.0% vs 6.0%, Hispanic 20.4% vs 5.8%, p < 0.001), and had higher Elixhauser ≥ 4 (25.8% vs 21.9%, respectively, p < 0.001). Percutaneous coronary interventions were less performed (60.4% vs 65.8%, p < 0.001) whereas administrations of thrombolysis (2.9% vs 2.1%, p = 0.001) were more frequent at SNHs. Coronary artery bypass and the use of mechanical circulatory support was similar. In-hospital mortality was significantly elevated at SNHs (36.6% vs 32.7%, adjusted odds ratio 1.24, 95% confidence interval 1.10 to 1.39) whereas new dialysis, stroke, and fatal arrhythmias were similar. The median length of stay was similar (6 vs 7 days, p = 0.58) but the median cost was higher (40,175 vs 38,012 US dollars, p = 0.01) at SNHs. SNHs had lower utilization of percutaneous coronary intervention and higher in-hospital mortality compared with non-SNHs in STEMI-CS. Further cause analysis is warranted to improve outcomes of STEMI-CS admitted at SNHs. © 2019 Elsevier Inc. All rights reserved. (Am J Cardiol 2019;124:485-490)

Safety-net hospitals (SNHs) are defined as hospitals that serve high proportions of patients insured by Medicaid or uninsured. SNHs accounted for approximately one-third of all hospital stays in the United States in 2014 and play vital roles in providing healthcare to vulnerable populations. However, some studies have reported worse outcomes in SNHs. When higher intensity of care is necessary, SNHs may have disadvantages due to limitations in resources and available services. The outcomes of ST-segment elevation myocardial infarction (STEMI) has improved dramatically due to primary percutaneous coronary intervention (PCI) and advancements of adjunctive pharmacological therapies.

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See page 489 for disclosure information.

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0002-9149/© 2019 Elsevier Inc. All rights reserved. https://doi.org/10.1016/j.amjcard.2019.05.037 to 50%. ^{13–17} The care of patients with STEMI-CS is complex as it requires intensive care unit stay, use of mechanical circulatory support (MCS), and prompt access to subspecialties. We sought to assess the patient demographics, procedural characteristics, and in-hospital outcomes of STEMI-CS between SNHs and non-SNHs.

Methods

However, the mortality of STEMI complicated with cardio-

genic shock (STEMI-CS) remains high, ranging from 30%

The Nationwide Inpatient Sample (NIS) database, an administrative database that contains 20% sample of all the discharges in the United States produced by the Healthcare Cost and Utilization Project. We used the data from January 2005 to December 2011 and *International Classification of Diseases, Ninth Edition Clinical Modification* (ICD-9-CM) codes to identify the primary discharge diagnosis of STEMI (ICD-9-CM; 410.0x, 410.1x, 410.2x, 410.3x, 410.4x, 410.5x, 410.6x, and 410.8x) and diagnosis of CS (ICD-9-CM; 785.51) other than the primary diagnosis with age more than 18. We excluded those with a previous heart transplant (ICD-9-CM; V42.1) and left ventricular assist device or artificial heart (ICD-9-CM; V43.21). Additionally, elective

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Meta-Analysis of Effectiveness and Safety of Transcatheter Aortic Valve Implantation Versus Surgical Aortic Valve Replacement in Low-to-Intermediate Surgical Risk Cohort



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Transcatheter aortic valve implantation (TAVI) has been used to treat high surgical risk cohorts but has been expanded to treat low-to-intermediate risk cohort as well. We performed a systematic review and meta-analysis to compare the outcomes between TAVI and surgical aortic valve replacement (SAVR) in low-to-intermediate risk cohort. We queried PUBMED, EMBASE, and ClinicalTrial.gov for relevant articles. Randomized controlled trials that compared at least one of the outcomes of interest between TAVI and SAVR were included. Risk ratio (RR) and 95% confidence interval (CI) were pooled with a randomeffects model to compare the risk of the primary outcome between the 2 procedures. The primary outcome was a composite of all-cause mortality or disabling/major stroke at 1 year. Seven studies with a total of 7,143 patients (3,665 TAVI) were included. All-cause mortality or disabling/major stroke at 30 days (6 studies, RR 0.71, 95% CI 0.49 to 1.03) was similar between TAVI and SAVR but was significantly lower in TAVI at 1 year (5 studies, RR 0.81, 95% CI 0.67 to 0.98). All-cause mortality was similar at both 30 days (7 studies, RR 0.90, 95% CI 0.67 to 1.21) and 1 year (6 studies, RR 0.89, 95% CI 0.76 to 1.04). Disabling/major stroke was similar between the 2 procedures (6 studies, RR 0.69, 95% CI 0.42 to 1.12) at 30 days but was significantly lower in TAVI at 1 year (5 studies RR 0.71, 95% CI 0.51 to 0.98). Age, gender, diabetes, and surgical risk score did not modulate the primary outcome. TAVI had a significantly lower composite of all-cause mortality or disabling/major stroke at 1 year compared with SAVR in low-to-intermediate surgical risk cohort. © 2019 Elsevier Inc. All rights reserved. (Am J Cardiol 2019;124:580-585)

Transcatheter aortic valve implantation (TAVI) is a class IIa recommendation for intermediate surgical risk and there is no recommendation for low surgical risk patients. Surgical aortic valve replacement (SAVR) is a class I for low, intermediate, and high surgical risk patients. Low-to-intermediate surgical risk patients comprised >90% of candidates for aortic valve replacement. Therefore, it is important to compare the outcomes of TAVI and SAVR in this cohort. Recently, 2 trials have been published that compared outcomes between TAVI and SAVR in low-risk patients. AVI our aim was to compare TAVI versus SAVR outcomes in low-to-intermediate surgical risk candidates that vast majority belong to with severe aortic stenosis requiring intervention. We

hypothesized that TAVI confers similar clinical outcomes compared with SAVR.

Methods

A comprehensive online database search (PUBMED, EMBASE, and ClinicalTrial.gov) was performed from January 1, 2002 to March 20, 2019. The search term was (TAVI OR TAVR OR transcatheter aortic valve replacement OR TAVI OR percutaneous aortic valve replacement OR percutaneous aortic valve intervention OR aortic valve replacement OR aortic valve intervention) and (random OR randomized OR randomization OR randomized OR randomization). Two authors (TA and SA) independently searched the online database. Any disagreement was resolved through discussion. The third author (HT) was consulted when an agreement was not met between these 2 authors. We did not apply language restriction. First, the title of the manuscript was screened for potential eligibility to our study purpose and if considered relevant, an abstract was carefully read to assess for further consideration to evaluate the full manuscript. Full manuscripts were obtained after the final list of included studies was made. Reference list of finally included manuscripts was manually searched for further screening of relevant articles. No contact was made to the corresponding author when the study did not report outcomes of interest. This systematic

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Incidence and predictors of readmissions to non-index hospitals after transcatheter aortic valve replacement and the impact on in-hospital outcomes: From the nationwide readmission database



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ABSTRACT

Introduction: Whether readmission to non-index hospitals (where the initial procedure was not performed) could result in adverse outcomes and increased utilization of healthcare resources compared with readmission to index hospitals after transcatheter aortic valve replacement (TAVR) remains unclear.

Methods: From January 2012 to September 2015, a nationwide readmission database was queried to identify those who were older than 50 years and had endovascular TAVR, using the International Classification of Disease, 9th Revision, Clinical Modification code 35.05. Elective readmissions were excluded. In-hospital outcomes were compared between the index and non-index hospital readmissions. A multivariable logistic regression analysis was performed to identify predictors of non-index hospital readmissions.

Results: A total of 6808 readmissions were identified of which 2564 (37.7%) were readmitted to non-index hospitals. Residents at smaller counties, metropolitan non-teaching hospitals, or hospitals at large metropolitan areas were predictors of non-index readmissions. In-hospital mortality (adjusted odds ratio [aOR] 1.27, p=0.20), acute myocardial infarction (aOR 0.83, p=0.53), pacemaker placement (aOR 0.97, p=0.90), acute kidney injury (aOR 0.98, p=0.84), and stroke (aOR 1.03, p=0.90) were similar between index and non-index readmissions but bleeding events requiring transfusions were more frequently observed in readmissions at non-index hospitals (aOR 1.32, p=0.025). Hospital cost (15,410 dollars vs. 16,390 dollars, p=0.25) and length of stay (5.70 days vs. 5.65 days, p=0.85) were comparable between groups.

Conclusions: Non-index readmissions post-TAVR was relatively common but did not result in increased hospital mortality or healthcare utilization. Our results are reassuring for TAVR recipients with limited access to index hospitals.

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1. Introduction

Candidates for transcatheter aortic valve replacement (TAVR) are usually older, frail, and have multiple comorbid conditions resulting in relatively high readmission rate, ranging from 15 to 18% within 30-days [1,2]. Early readmission has a negative impact on clinical and financial outcomes and could potentially be considered as a performance metric of TAVR [3,4].

E-mail address: tomo.ando@wayne.edu (T. Ando).

https://doi.org/10.1016/j.ijcard.2019.04.056 0167-5273/© 2019 Elsevier B.V. All rights reserved. Readmission to non-index hospitals could result in fragmentation of care. Worse outcomes have been reported with the fragmentation of care or when readmissions occurred at non-index hospitals [5–7]. However, the rate and impact of readmission to non-index hospitals are scarce post-TAVR. To avoid readmission to non-index hospitals and fragmentation of care, patients should ideally be readmitted to index hospitals but geographical access and socioeconomic factors may limit readmission to index hospitals given that TAVR is often performed at large centers. The incidence and predictors of non-index hospitalization, as well as its impact on clinical and financial outcomes, are limited in TAVR population.

The aim of this study was to clarify these clinically important issues from the Nationwide Readmission Database (NRD).

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ORIGINAL ARTICLE



The impact of safety-net burden on in-hospital outcomes after surgical aortic valve replacement

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Abstract

Background and Aim: Surgical aortic valve replacement (SAVR) is the most common valvular surgery and thus needs to be widely available including minorities and socially disadvantaged patients. SAVR outcomes at safety-net hospitals, which serve a high percentage of these patients, are limited. We aimed to compare the outcomes of SAVR at different safety-net burden hospitals.

Methods: Nationwide Inpatient Sample from 2005 to 2011 was queried to identify SAVR performed for over the age of 50. The safety-net burden of hospitals was calculated as the number of admission to a hospital in a year who were uninsured or insured by Medicaid divided by the total number of admissions for the respective year. Hospitals were categorized into quintiles of safety-net rate and then into three categories based on the safety-net burden (low burden hospitals [LBHs], lowest quintile, medium burden hospitals [MBHs], 2nd-4th quintiles; and high burden hospitals [HBHs], highest quintile).

Results: A total of 85 441 SAVR were included. In unadjusted models, in-hospital mortality was higher in HBHs compared with LBHs but became nonsignificant after adjustments for patient and hospital-level characteristics. Major perioperative complications and hospital costs were similar, but hospital stay was longer at HBHs compared with LBHs. At MBHs, acute kidney injury requiring dialysis and bleeding requiring transfusion was lower compared with LBHs. Length of stay and cost were shorter and lower at MBHs compared with LBHs. Nonroutine discharge was similar for HBHs and MBHs compared with LBHs.

Conclusion: SAVR outcomes are reassuring at MBHs and HBHs.

KEYWORDS

safety-net hospital, surgical aortic valve replacement

1 | INTRODUCTION

Surgical aortic valve replacement (SAVR) is the most common cardiac surgery performed for valvular heart disease in the United States and more than 40 000 cases have been performed in 2015. Severe aortic stenosis is the most common indication for SAVR. Those who are medically treated do poorly, with a mean survival of only 1.8 years,

and pose a substantial financial burden on the healthcare system.² It is estimated that approximately 1.9 million patients are eligible for SAVR in 37 advanced economies.³ SAVR continues to be an important surgical procedure among other surgeries, and thus needs to be widely available, including to minorities and vulnerable patients. Safety-net hospitals serve those who are socially disadvantaged, insured by Medicaid or uninsured. Safety-net hospitals,

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Paliative Care

Palliative care referral in ST-segment elevation myocardial infarction complicated with cardiogenic shock in the United States



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ABSTRACT

Background: ST-segment elevation myocardial infarction complicated with cardiogenic shock (STEMI-CS) is associated with high mortality but the trends of utilization and predictors of palliative care (PC) referral in this population have not been well described.

Objectives: To investigate the utilization trends and predictors of PC referral in STEMI-CS.

Methods: Nationwide inpatient sample from 2005-2014 was queried to identify patients with STEMI-CS of age ≥ 18 . PC referral was identified International Classification of Diseases, Ninth Edition Clinical Modification, V66.7.

Results: A total of 33,294 admissions were identified and 1,878 (5.6%) had PC encounter. PC referral group were older and had higher comorbidities. PC consultation increased approximately 10 times over the study period in those who died (from 2.3% to 27.4%) and in those who survived (from 0.21% to 2.83%). In multivariable analysis, age, higher Exlixhauser score, no revascularization, teaching hospital, large bed hospital, mechanical circulatory support use, and lower income status were associated with increased PC referral whereas coronary artery bypass graft was associated with lower PC referral rates. Patients under PC group were more often discharged to an extended care facility and less likely discharged home.

Conclusion: PC utilization increased substantially during the 10-years study period in the United States in STEMI-CS. Several baseline, procedural, hospital, and socioeconomic factors were associated with PC referral in the setting STEMI-CS.

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Introduction

Cardiogenic shock continues to have unacceptably high in-hospital mortality of over 50% and ST-segment elevation myocardial infarction (STEMI) is the leading cause of cardiogenic shock among other causes such as myocarditis, non-ST-elevation myocardial infarction, acute exacerbation of chronic heart failure, and pulmonary embolism.¹ STEMI resulting in left ventricular failure accounts for 70–80% of STEMI complicated with cardiogenic shock (STEMI-CS) and the prevalence of STEMI-CS was 6.5 to 10.1% in the United States between 2003–2010.^{1–4} Despite a declining trend in mortality of STEMI-CS because of early revascularization^{5,6} and increased use of

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https://doi.org/10.1016/j.hrtlng.2019.10.005 0147-9563/© 2019 Elsevier Inc. All rights reserved. mechanical circulatory support (MCS) devices, STEMI-CS remains a significant cause of morbidity and mortality. 1,2,6,8

Management of STEMI-CS is complex, and disease course varies from rapid demise of the patient to prolonged hospital course in the intensive care unit. In addition, various treatment options including revascularization and MCS are time sensitive and decisions need to be made in a timely manner among physicians, patients and caregivers. This can be challenging given the acuity of the disease and the burden of stress on caregivers and patients.

Palliative care (PC) has been shown to enhance patient satisfaction, improve care providers' communication, and reduce total health care cost. ^{9,10} PC consultation can be a potentially useful intervention in STEMI-CS given its high mortality but the use of PC has not been well studied in this population. Indeed, STEMI-CS is not discussed in the policy statement from the American Heart Association on PC in



Early Invasive Versus Ischemia-Guided Strategy in Non-ST-Segment Elevation Acute Coronary Syndrome With Chronic Obstructive Pulmonary Disease: A National Inpatient Sample Analysis

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Abstract

Chronic obstructive pulmonary disease (COPD) is a risk factor for non-ST-segment elevation—acute coronary syndromes (NSTE-ACS). Whether early invasive strategy (EIS) or ischemia-guided strategy (IGS) confers better outcomes in NSTE-ACS with COPD is largely unknown. Nationwide Inpatient Sample database of the United States was queried from 2010 to 2015 to identify NSTE-ACS with and without COPD. Early invasive strategy was defined as coronary angiogram with or without revascularization on admission day 0 or 1, whereas IGS included patients who did not receive EIS. Standardized morbidity ratio weight was used to calculate the adjusted odds ratio. A total of 228 175 NSTE-ACS admissions with COPD were identified of which 34.0% received EIS. In-hospital mortality was lower with EIS in patients with COPD (3.1% vs 5.5%, adjusted odds ratio 0.57, 95% confidence interval 0.50-0.63) compared to IGS, but the magnitude of mortality reduction observed in EIS in patients with COPD was less compared to non-COPD patients ($P_{\text{interaction}} = .02$). Length of stay was shorter (4.2 vs 4.7 days, P < .0001) but the cost was higher (US\$23 804 vs US\$18 533, P < .0001) in EIS in COPD. Early invasive strategy resulted in lower in-hospital mortality and marginally shorter length of stay but higher hospitalization cost in NSTE-ACS with COPD.

Keywords

chronic obstructive pulmonary disease, early invasive, non-ST-segment elevation acute coronary syndromes, ischemia-guided strategy

Introduction

Chronic obstructive pulmonary disease (COPD) is a major health issue affecting an estimated 7.6% of the population worldwide. Chronic obstructive pulmonary disease and non-ST-elevation–acute coronary syndromes (NSTE-ACS) share several common risk factors, the most important being smoking, and therefore, the 2 conditions commonly coexist. Ischemic heart disease affects 10% to 16% of patients with COPD, 2,3 and COPD increases the risk of developing cardiovascular disease by 5-fold.

Chronic obstructive pulmonary disease is a predictor of worse in-hospital survival in those presenting with ACS. ⁵⁻⁸ The COPD cohorts were found to have more severe coronary artery disease on coronary angiography ⁹⁻¹¹ and lower utilization of β -blockers, statins, and coronary interventions. ⁶⁻⁸ The guidelines for NSTE-ACS recommend early invasive strategy (EIS), invasive strategy, or ischemia-guided strategy (IGS) based on clinical presentation and high-risk comorbidities (ie, prior

coronary artery bypass). 12,13 Despite the reported negative impact of COPD on NSTE-ACS and association with more severe coronary artery disease, it remains unknown whether EIS should be the preferred approach in these patients. We hypothesized that EIS and IGS may have different effects on the early outcomes of patients with NSTE-ACS and COPD. For

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ORIGINAL ARTICLE

Meta-Analysis of Hospital-Volume Relationship in Transcatheter Aortic Valve Implantation

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Whather a values outcome relationship that is higher values

Background	Whether a volume-outcome relationship, that is, higher volume centres have better outcomes compared with lower volume hospitals, exists in transcatheter aortic valve implantation (TAVI) has not yet been systematically explored.
Methods	We performed a systematic review and meta-analysis to evaluate whether highest or intermediate annual TAVI volume hospitals has better short-term (in-hospital or 30-days) mortality compared with the lowest volume hospitals. Odds ratio (OR) and 95% confidence interval (CI) was calculated with the Mantel-Haenszel method.
Results	We identified 10 publications from nine different countries including TAVI performed between 2005–2017. Included patients were mainly high-risk cohorts. We included five and six studies to assess volume-outcome relationship in the highest and intermediate volume hospitals compared with the lowest volume hospitals, respectively. Our results showed that in both the highest (OR 0.66, 95%CI 0.53–0.83, p=0.0003, I^2 =78%) and intermediate (OR 0.85, 95%CI 0.79–0.92, p<0.0001, I^2 =0%) volume hospitals, there was a statistically significant volume-outcome relationship for short-term mortality compared with the lowest volume hospitals.
Conclusions	Our review suggests a significant volume-outcome relationship post-TAVI in both the highest and intermediate volume hospitals compared with the lowest volume hospitals mainly in high surgical risk patients. The high heterogeneity in this relationship between the highest and the lowest volume hospitals warrant cautious interpretation. Whether this relationship remains significant in low-risk cohort requires further study.
Keywords	Aortic stenosis ● Transcatheter aortic valve implantation ● Volume ● Mortality

Introduction

The numbers of transcatheter aortic valve implantations (TAVI) are exponentially increasing worldwide supported by large randomised clinical trials showing non-inferior

TAVI results compared with surgical aortic valve replacement (SAVR) and evolving transcatheter heart valves technologies [1,2]. In this regard, a multi-society consensus document has recently been updated for recommendations on institutional annual TAVI volume to initiate or maintain

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Unplanned Thirty-Day Readmission After Alcohol Septal Ablation for Hypertrophic Cardiomyopathy (From the Nationwide Readmission Database)

Tomo Ando MD $^1 \stackrel{\triangle}{\sim} \boxtimes$, Oluwole Adegbala MD, MPH 2 , Ankita Aggarwal MD 2 , Luis Afonso MD 2 , Cindy L. Grines MD 3 , Hisato Takagi MD, Ph.D. 4 , Alexandros Briasoulis MD, Ph.D. 5

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Abstract

Alcohol septal ablation (ASA) is indicated for symptomatic hypertrophic cardiomyopathy (HC) patients. We sought to analyze the incidence of the 30-day readmission rate, predictors, causes of readmission, and incremental healthcare resource (cost and length of stay) utilization after ASA. Nationwide readmission database from 2010 January to 2015 September was queried to identify 30-day unplanned readmission after ASA for HC by using the International Classification of Disease, 9th Revision, Clinical Modification. Those readmitted were similar in terms of age and sex but had higher burden of comorbidities compared with those not readmitted within 30-days. The 30-day unplanned readmission rate was 10.4% (511/4,932) after ASA. Readmissions lead to an additional hospitalization cost of 8,433 U.S. dollars for hospitalization cost and 4.9 days of length of stay in the readmitted cohorts. Predictors of 30-day unplanned readmission were liver disease (adjusted odds ratio [aOR] 2.62, 95% confidence interval [CI] 1.22-5.59), renal failure (aOR 2.30, 95%CI 1.52-3.50), prior myocardial infarction (aOR 1.97, 95%CI 1.16-3.33), prior pacemaker (aOR 1.50, 95%CI 1.09-2.08), atrial fibrillation (aOR 1.43, 95%CI 1.08-1.89), Medicaid (aOR 1.74, 95%CI 1.12-2.68), and weekend admission (aOR 1.75, 95%CI 1.12-2.75). Common reasons for readmissions were atrial fibrillation (12.6%), acute on chronic systolic heart failure (12.6%), paroxysmal ventricular tachycardia (6.4%), atrioventricular block (4.9%), and HC (3.0%). Unplanned readmissions after ASA occur in patients with higher burden of comorbidities and are mainly caused by cardiac etiologies.

Keywords

Hypertrophic cardiomyopathy; alcohol septal ablation; readmission

Angiology

Palliative Care in Ruptured Aortic Aneurysm in the United States: A Retrospective Analysis of Nationwide Inpatient Sample Database

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Research Article

https://doi.org/10.1177/0003319720917239



Abstract

We assessed the trend of palliative care (PC) referrals and its effect on hospitalization cost and length of stay (LOS) in ruptured aortic aneurysm (rAA). The Nationwide Inpatient Sample from 2005 to 2014 was used to identify admissions with age ≥50 and rAA. A total of 54 134 rAA admissions were identified and 5019 (9.3%) had PC referrals. During the study period, PC referral rate increased from 0.97% to 15.3% (*P* trend < .0001). Length of stay (1.7 vs 2.8 days, adjusted mean ratio [aMR] = 0.62, 95% confidence interval [CI]: 0.58-0.66), and cost (US\$7778 vs US\$13 575, aMR = 0.57, 95% CI: 0.52-0.63) were significantly lower in rAA admissions that did not undergo interventions. In the percutaneous repair group, LOS was similar but the cost was higher (US\$61 759 vs US\$52 260, aMR = 1.18, 95% CI: 1.05-1.30), whereas in surgical repair group, LOS was shorter (4.6 vs 5.9 days, aMR = 0.77, 95% CI: 0.73-0.82) but the cost was higher (US\$59 755 vs US\$52 523, aMR = 1.14, 95% CI: 1.02-1.28). Palliative care could shorten LOS and save hospitalization cost in rAA admissions not a candidate for repair. Further studies are required to investigate the variable effects of PC on rAA.

Oral Anticoagulation for Patients With Atrial Fibrillation on Long-Term Dialysis



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ABSTRACT

BACKGROUND Patients on long-term dialysis are at increased risk of bleeding. Although oral anticoagulants (OACs) are recommended for atrial fibrillation (AF) to reduce the risk of stroke, randomized trials have excluded these populations. As such, the net clinical benefit of OACs among patients on dialysis is unknown.

OBJECTIVES This study aimed to investigate the efficacy and safety of OACs in patients with AF on long-term dialysis.

METHODS MEDLINE and EMBASE were searched through June 10, 2019, for studies that investigated the efficacy and safety of different OAC strategies in patients with AF on long-term dialysis. The efficacy outcomes were ischemic stroke and/or systemic thromboembolism, all-cause mortality, and the safety outcome was major bleeding.

RESULTS This study identified 16 eligible observational studies (N = 71,877) regarding patients on long-term dialysis who had AF. Only 2 of 16 studies investigated direct OACs. Outcomes for dabigatran and rivaroxaban were limited to major bleeding events. Compared with no anticoagulants, apixaban and warfarin were not associated with a significant decrease in stroke and/or systemic thromboembolism (apixaban 5 mg, hazard ratio [HR]: 0.59; 95% confidence interval [CI]: 0.30 to 1.17; apixaban 2.5 mg, HR: 1.00; 95% CI: 0.52 to 1.93; warfarin, HR: 0.91; 95% CI: 0.72 to 1.16). Apixaban 5 mg was associated with a significantly lower risk of mortality (vs. warfarin, HR: 0.65; 95% CI: 0.45 to 0.93; vs. apixaban 2.5 mg, HR: 0.62; 95% CI: 0.42 to 0.90; vs. no anticoagulant, HR: 0.61; 95% CI: 0.41 to 0.90). Warfarin was associated with a significantly higher risk of major bleeding than apixaban 5 min/2.5 mg and no anticoagulant (vs. apixaban 5 mg, HR: 1.41; 95% CI: 1.07 to 1.88; vs. apixaban 2.5 mg, HR: 1.40; 95% CI: 1.07 to 1.82; vs. no anticoagulant, HR: 1.31; 95% CI: 1.15 to 1.50). Dabigatran and rivaroxaban were also associated with significantly higher risk of major bleeding than apixaban and no anticoagulant.

CONCLUSIONS This meta-analysis showed that OACs were not associated with a reduced risk of thromboembolism in patients with AF on long-term dialysis. Warfarin, dabigatran, and rivaroxaban were associated with significantly higher bleeding risk compared with apixaban and no anticoagulant. The benefit-to-risk ratio of OACs in patients with AF on long-term dialysis warrants validation in randomized clinical trials. (J Am Coll Cardiol 2020;75:273-85)

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Listen to this manuscript's audio summary by Editor-in-Chief Dr. Valentin Fuster on JACC.org. From the ^aDepartment of Medicine, Icahn School of Medicine at Mount Sinai, Mount Sinai Beth Israel, New York, New York; ^bDepartment of Cardiovascular Surgery, Shizuoka Medical Center, Shizuoka, Japan; ^cDepartment of Cardiology, Detroit Medical Center, Detroit, Michigan; ^dDiabetes and Metabolism Information Center, Research Institute, Center for Global Health and Medicine, Tokyo, Japan; ^eDepartment of Health Services Research, Faculty of Medicine, University of Tsukuba, Tsukuba, Japan; ^fDepartment of Public Health/Health Policy, Graduate School of Medicine, the University of Tokyo, Tokyo, Japan; ^gDivision of Cardiology, Department of Medicine, Columbia University Medical Center, New York, New York; ^hDepartment of Cardiology, Japanese Red Cross Ashikaga Hospital, Ashikaga, Japan; ⁱDivision of Cardiovascular Medicine, Section of Heart Failure and Transplantation, University of Iowa, Iowa City, Iowa; and the ^jDivision of Cardiovascular Medicine, New York University School of Medicine, New York, New York. Dr. Shimada is supported in part by unrestricted grants from the American Heart Association National Clinical and Population Research Award and Career Development Award, Honjo International Scholarship Foundation, and Korea Institute of Oriental Medicine. Dr. Bangalore is supported by grants from Abbott Vascular and the National Heart, Lung, and Blood Institute; and is a member of the Advisory Board of Abbott Vascular, Biotronik, Amgen, Pfizer, and Reata. Dr. Burger holds stock in Potola Pharmaceutical. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose. Louise Pilote, MD, MPH, PhD, served as Guest Associate Editor for this paper.

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Meta-analysis of Antithrombotic Therapy in Patients With Atrial Fibrillation Undergoing Percutaneous Coronary Intervention



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For patients with atrial fibrillation (AF) who undergo percutaneous coronary intervention (PCI), antithrombotic therapy including oral anticoagulants and antiplatelets are indicated. The optimal combination is not known. We investigated the efficacy and safety of different antithrombotic strategies in patients with AF undergoing PCI. PUBMED and EMBASE were searched through September 2019 for randomized trials investigating the efficacy and safety of different antithrombotic strategies in patients with AF who underwent PCI and/or acute coronary syndrome. Nine antithrombotic strategies were compared including combinations of vitamin K antagonist (VKA) with dual antiplatelet therapy (DAPT) or P2Y₁₂ inhibitor, combinations of direct oral anticoagulants (DOAC) (apixaban, dabigatran, rivaroxaban, and edoxaban) with DAPT or P2Y12 inhibitor (clopidogrel, prasugrel, and ticagrelor). The primary safety outcome was trial defined primary bleeding outcome. The primary efficacy outcome was trial defined major adverse cardiovascular events. Our search identified 5 eligible trials that enrolled a total of 11,532 patients and compared 9 treatment strategies. VKA+DAPT significantly increased bleeding when compared with most combinations (for example, vs VKA + P2Y₁₂ inhibitor: odds ratio 2.11; 95% confidence interval [1.76 to 2.52], p <0.001). Of all the combinations, apixaban + P_2Y_{12} inhibitor showed the lowest bleeding risk (for example, vs VKA + $P2Y_{12}$ inhibitor: odds ratio 0.63; 95% confidence interval [0.51 to 0.78], p <0.001) and was ranked the best treatment. There were no significant differences in ischemic outcome of major adverse cardiovascular events between various antithrombotic regimens. In conclusion, in patients with AF undergoing PCI, apixaban + P2Y₁₂ inhibitors were associated with lowest bleeding compared with other regimens including other DOACs + P2Y12 inhibitors with no increase in ischemic outcomes. © 2019 Elsevier Inc. All rights reserved. (Am J Cardiol 2020;125:521-527)

Antithrombotic agents are necessary for thromboembolic risk protection in patients with atrial fibrillation (AF) undergoing percutaneous coronary interventions (PCI) and/or for

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See page 526 for disclosure information. *Corresponding author: Tel: (212) 420-2000.

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those presenting with acute coronary syndrome (ACS). Although triple antithrombotic therapy can increase bleeding risk, stroke, and stent thrombosis prevention are crucial for these patients. Pecent randomized controlled trials have demonstrated favorable outcomes of patients with AF with dual antithrombotic strategies including P2Y₁₂ inhibitors and direct oral anticoagulants (DOACs). Based on these results, the most recent guidelines recommend oral anticoagulant (OAC) + P2Y₁₂ inhibitors in patients with AF who underwent PCI with stenting for ACS. Although, regimens without aspirin are shown to have lower bleeding, it remains unknown whether any particular strategy (VKA vs DOAC with dual antiplatelet therapy [DAPT] or P2Y₁₂ inhibitors) is preferable. We investigated the safety and efficacy of various antithrombotic combination therapies in AF patients who underwent PCI.

Methods

All studies investigating the impact of antithrombotic strategy in patients with AF who underwent PCI were searched using a 2-level search strategy. First, PUBMED and EMBASE were searched through September 13, 2019 using web-based search engines. Second, relevant studies

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ORIGINAL STUDIES

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Antithrombotic strategies after transcatheter aortic valve implantation: Insights from a network meta-analysis

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Objectives: We aimed to investigate the efficacy and safety of different antithrombotic strategies in patients undergoing transcatheter aortic valve implantation (TAVI) using network meta-analyses.

Background: Meta-analyses comparing single antiplatelet therapy (SAPT) vs. dual antiplatelet therapy (DAPT), ± oral anticoagulant (OAC) was conducted to determine the appropriate post TAVI antithrombotic regimen. However, there was limited direct comparisons across the different therapeutic strategies.

Methods: MEDLINE and EMBASE were searched through December 2018 to investigate the efficacy and safety of different antithrombotic strategies (SAPT, DAPT, OAC, OAC + SAPT, and OAC + DAPT) in patients undergoing TAVI. The main outcome were all-cause mortality, major or life-threatening bleeding events, and stroke.

Results: Our search identified 3 randomized controlled trials and 10 nonrandomized studies, a total of 20,548 patients who underwent TAVI. All OACs were vitamin K antagonists. There was no significant difference on mortality except that OAC + DAPT had significantly higher rates of mortality compared with others (p < .05, $I^2 =$ 0%). SAPT had significantly lower rates of bleeding compared with DAPT, OAC +SAPT, and OAC+DAPT (hazard ratio [HR]: 0.59 [0.46-0.77], p < .001, HR: 0.58 [0.34-0.99], p = .045, HR: 0.41 [0.18-0.93], p = .033, respectively, $I^2 = 0\%$). There was no significant difference on stroke among all antithrombotic strategies.

Conclusion: Patients who underwent TAVI had similar all-cause mortality rates among different antithrombotic strategies except OAC+DAPT. Patients on SAPT had significantly lower bleeding risk than those on DAPT, OAC + SAPT, and OAC + DAPT. Our results suggest SAPT is the preferred regimen when there is no indication for DAPT or OAC. When DAPT or OAC is indicated, DAPT + OAC should be avoided.

Abbreviations: CI, confidential interval: DAPT, dual antiplatelet therapy: HR, hazard ratio: NOAC, novel oral anticoagulant; OAC, oral anticoagulant; SAPT, single antiplatelet therapy; TAVI, transcatheter aortic valve implantation; VKA, vitamin K antagonist.

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Abstract Abstract

Keywords

Background

References.

S.

Article Info

Related Articles

Transcatheter aortic valve implantation (TAVI) has become the main treatment for symptomatic severe aortic stenosis but patients on dialysis have been excluded from major randomized controlled trials. Our aim was to compare mortality and procedure-related complications after TAVI in patients with end-stage renal disease (ESRD) on dialysis versus those without.

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Methods

EMBASE and MEDLINE were searched through November 2019 to investigate the comparative outcomes between ESRD patients on dialysis and those without who underwent TAVI. The main outcomes were short-term (30-day/in-hospital) mortality and procedural complications, and long-term (> 6 months) all-cause mortality.

Results

Our search identified 10 observational studies enrolling 128,094 (5,399 on dialysis) patients who underwent TAVI. Dialysis patients had a significantly higher rate of short-term and long-term mortality than non-dialysis patients (odds ratio [95% confidential interval]: 2.18 [1.64-2.89], P < 0.001, $I^2 = 60\%$; 1.91 [1.46-2.50], P < 0.001, $I^2 = 80\%$, respectively). In addition, dialysis patients had significantly higher rates of short-term life threatening and/or major bleeding, permanent pacemaker implantation, and device failure compared to non-dialysis patients (OR [95% CI]: 1.90 [1.24-2.90], P < 0.001, $I^2 = 67\%$; 1.33 [1.15-1.53], P < 0.001, $I^2 = 0\%$; 2.08 [1.05-4.10], P = 0.03,

respectively), but did not have significantly higher rates of vascular complications and stroke.

Conclusion

Dialysis patients had significantly higher rates of short- and long-term mortality, short-term life threatening and/or major bleeding, permanent pacemaker implantation, and device failure compared to non-dialysis patients. Careful patient selection who would benefit from TAVI in patients with ESRD requiring dialysis, is necessary to prevent high-rates of post-procedural complications.

ARTICLE IN PRESS

Meta-Analysis Evaluating the Effects of Renin-Angiotensin-Aldosterone System Blockade on Outcomes of Heart Failure With Preserved Ejection Fraction

Toshiki Kuno, MD, PhD^b, Hiroki Ueyama, MD^b, Tomohiro Fujisaki, MD^c, Artemis Briasouli, MD, MPH^d, Hisato Takagi, MD, PhD^e, and Alexandros Briasoulis, MD, PhD^a,*

Clinical trials of renin-angiotensin-aldosterone system (RAAS) antagonists in heart failure with preserved ejection fraction (HFpEF) have suggested neutral results and treatment is focused on associated symptoms and comorbidities. MEDLINE and EMBASE were searched through October 2019 for randomized controlled studies investigating the effects of different RAAS antagonists in patients with HFpEF. The main outcomes were all-cause mortality, trial defined cardiovascular mortality, and heart failure (HF) hospitalizations. To compare different RAAS antagonists, a random-effects restricted-maximum-likelihood network meta-analysis based on a frequentist framework for indirect and mixed comparisons was used. We used p scores to rank best treatments per outcome. Our search identified 5 eligible clinical trials (PEP-CHF, perindopril; CHARM-preserved, candesartan; I-PRESERVE, irbesartan; TOPCAT, spironolactone; PARAGON-HF, sacubitril-valsartan and valsartan) enrolling a total 10,523 on RAAS antagonists and 6,259 controls. We did not identify any statistical difference in all-cause and cardiovascular mortality among RAAS antagonists and placebo. The combination of sacubitril-valsartan was associated with significantly decreased HF hospitalization risk compared with controls (odds ratio 0.73, 95% confidence interval 0.61 to 0.87) and angiotensin II receptor blockers (odds ratio 0.80, 95% confidence interval 0.71 to 0.91), without heterogeneity among studies ($I^2 = 0$). Angiotensin receptor neprilysin inhibitor (ARNI) ranked better than other RAAS antagonists for HF hospitalizations (p value 0.9). In conclusion, RAAS antagonists do not affect mortality but the combination of sacubitril-valsartan is associated with lower HF hospitalizations in HFpEF patients. © 2020 Elsevier Inc. All rights reserved. (Am J Cardiol 2020;00:1-7)

Heart Failure with preserved ejection fraction (HFpEF) is the most common type of heart failure (HF) in the elderly and affects more than 2 million Americans.¹ Despite its importance, there are large gaps in our understanding of treatment of HFpEF. The role of renin-angiotensin-aldosterone system (RAAS) inhibitors in HFpEF remains controversial, with multiple clinical studies showing conflicting results.²-6 The PARAGON-HF trial of angiotensin receptor-neprilysin inhibitor (ARNI) in patients with HFpEF did not show a statistically significant lower rate of hospitalization for HF and death from cardiovascular causes but suggested possible benefit among patients with an LVEF ≤ 57% (the median) and among women.² The TOPCAT trial of spironolactone in patients with HFpEF showed overall lower hospitalization for HF in the treatment arm.⁸ In this

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See page 6 for disclosure information.

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context, we performed a net-work meta-analysis of the main randomized controlled trials (RCTs) in the field^{2-4,7,8} to compare the effects of different RAAS antagonists with each other and with placebo, with regards to HFpEF outcomes.

Methods

We conducted a network meta-analysis in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines. A comprehensive literature search was conducted through September, 2019 in the MEDLINE and EMBASE database to include all relevant studies investigating the impact of immunosuppression strategy after heart transplantation. The search term included "heart failure with preserved ejection fraction," "angiotensin-converting enzyme inhibitors," "Angiotensin Receptor Antagonists,'' "mineralocorticoid receptor antagonists," "aldosterone antagonists," "angiotensin receptor neprilysin inhibitor," and the names of individual angiotensin-converting enzyme inhibitors (ACE-I), Angiotensin Receptor Antagonists (ARB), mineralocorticoid receptor antagonists (MRA), ARNI agents. There was no language restriction.

We included RCTs that met the following criteria: the study was published in peer-reviewed journals; designed to compare the effects of ACE-I, ARB, MRA, ARNI in the

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Antithrombotic Therapy in Patients with Atrial Fibrillation and Acute Coronary Syndrome Undergoing Percutaneous Coronary Intervention; Insights from a Meta-Analysis.

Toshiki Kuno^a, Hiroki Ueyama^a, Tomo Ando^b, Alexandros Briasoulis^c and Hisato Takagi^d

Background Acute coronary syndrome (ACS) patients are at increased risk for future adverse cardiac events. The optimal antithrombotic regimen for patients undergoing percutaneous coronary intervention (PCI) in ACS with concomitant atrial fibrillation (AF) is largely under investigated.

Method PUBMED and EMBASE were searched through October 2019 for randomized trials (RCTs) or subgroup analyses of RCTs investigating the efficacy and safety of different antithrombotic strategies in patients with AF and ACS undergoing PCI. We compared dual antithrombotic therapy (DAT) vs. triple antithrombotic therapy (TAT). DAT was defined as vitamin K antagonist (VKA) or direct oral anticoagulant (DOAC) plus P2Y12 inhibitor. TAT was defined as VKA or DOAC plus dual antiplatelet therapy (aspirin plus P2Y12 inhibitor). The primary safety outcome was trial defined primary bleeding outcome. The primary efficacy outcome was trial defined major adverse cardiovascular events (MACE).

Results Our search identified 5 eligible sub-group analyses of RCTs that enrolled a total of 4,733 patients and compared the two treatment strategies. DAT significantly decreased the bleeding risk when compared with TDAT (hazard ratio (HR): 0.61; 95% confidential interval (CI) [0.51-0.71], P < 0.001, $I^2=31\%$). However, there were no significant differences in MACE between DAT vs. TAT (HR: 1.081; 95%CI: 0.893-1.3123, P = 0.4493, $I^2=0\%$).

Conclusion Among In patients with AF and ACS undergoing PCI, DAT was associated with lower bleeding risk compared with TAT while conferring similar MACE risk. Our results should be interpreted cautiously since we did not analyze the risk of stent thrombosis. Therefore, DAT might be the preferred antithrombotic regimen in ACS patients undergoing PCI with concomitant AF.

Keywords: acute coronary syndrome, atrial fibrillation, antiplatelet therapy, oral anticoagulant, percutaneous coronary intervention

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Meta-analysis Comparing Direct Oral Anticoagulants Versus Vitamin K Antagonists After Transcatheter Aortic Valve Implantation



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Atrial fibrillation (AF) is a common co-morbidity in patients undergoing transcatheter aortic valve implantation (TAVI), but whether direct oral anticoagulants (DOACs) confer similar safety and efficacy compared with vitamin K antagonist (VKA) remains unclear in this population. The aim of our study was to investigate the safety and efficacy of DOACs compared with VKA in patients undergoing TAVI with concomitant indication of oral anticoagulation. PUBMED and EMBASE were searched through October 2019 for studies comparing DOACs versus VKA in patients undergoing TAVI with indication of oral anticoagulation. The main efficacy outcomes were all-cause mortality and stroke whereas the main safety outcome was major and/or life-threatening bleeding. Our search identified 5 eligible studies including 2,569 patients. Majority of patients had atrial fibrillation as indication of anticoagulation. There were no significant differences in all-cause mortality, major and/or lifethreatening bleeding, and stroke in patients treated with DOACs versus VKA (odds ratio [OR] 1.07, 95% confidence interval [CI] [0.73 to 1.57], p = 0.72, OR = 0.85, 95% CI [0.64 to 1.12], p = 0.24, OR 1.52, 95% CI [0.93 to 2.48], p = 0.09, respectively). In conclusion, in patients undergoing TAVI with concomitant indication for oral anticoagulation, all-cause mortality, major and/or life-threatening bleeding, and stroke were similar between DOACs and VKA. Further large scale randomized controlled trials are needed to search the optimal oral anticoagulation regimen in this population. © 2020 Elsevier Inc. All rights reserved. (Am J Cardiol 2020;125:1102-1107)

Indication of transcatheter aortic valve implantation (TAVI) has rapidly expanded to now include patients in all categories of surgical risk with severe aortic stenosis, supported by randomized control trials showing superiority or noninferiority of TAVI compared with surgical aortic valve replacement. Preexisting atrial fibrillation (AF) and new onset AF is a common co-morbidity in patients undergoing TAVI with rates ranging from 32.9% to 46.8% and 7.2 to 8.4%, respectively. These together put this population at a higher risk for both thromboembolic and bleeding events. Previous randomized control trials comparing direct oral anticoagulants (DOACs) versus vitamin K antagonist (VKA) in nonvalvular AF have demonstrated noninferiority or superiority of DOACs compared with VKA in both safety and efficacy outcomes.

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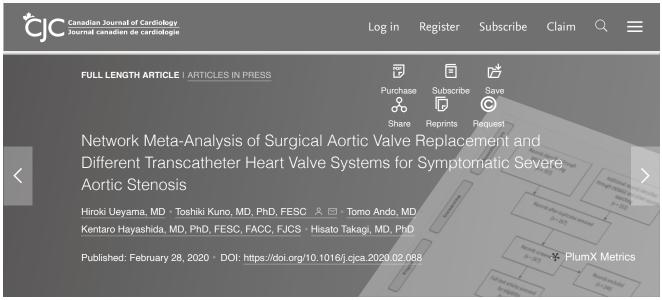
study demonstrated that the use of rivaroxaban in patients with TAVI without AF was associated with increased risk of thromboembolic events, bleeding events, and all-cause death. ^{12,13} Optimal anticoagulation strategy, whether including DOACs or VKA, remains unclear and is actively debated in this population. Therefore, we conducted a meta-analysis of studies comparing DOACs versus VKA in patients undergoing TAVI with a concomitant indication for oral anticoagulation to explore the safety and efficacy of DOACs compared with VKA in this population.

Methods

A comprehensive literature search was conducted to include all relevant articles from inception to October 13, 2019 in the PUBMED and EMBASE database. There was no restriction on publication language. The search term included transcatheter aortic valve implantation or transcatheter aortic valve replacement, or TAVI or TAVR; atrial fibrillation; venous thromboembolism or VTE; anticoagulation or anticoagulant or antithrombotic or vitamin K antagonist or VKA or Coumadin or Warfarin or novel oral anticoagulant or NOAC or direct oral anticoagulant or DOAC or Dabigatran or Apixaban or Rivaroxaban or Edoxaban.

Studies were included in our meta-analysis when the following criteria were met: (1) the study was published in peer-reviewed journals, (2) and compared the use of DOACs versus VKA in patients undergoing TAVI with a concomitant indication of anticoagulation, (3) and reported

www.ajconline.org



Abstract

Abstract

References

Background

Article Info

Related Articles

Although different transcatheter heart valve (THV) systems have been introduced to overcome transcatheter aortic valve replacement (TAVR) specific complications, head-to-head comparisons of these THV systems are scarce. The aim of this study was to compare different THV systems and surgical aortic valve replacement (SAVR) by conducting a network meta-analysis.

Methods

PUBMED and EMBASE were searched through November 2019 for studies comparing safety and efficacy of balloon-expandable valve (BEV), self-expanding valve (SEV), mechanically-expandable valve (MEV) and SAVR for symptomatic severe aortic stenosis. Endpoints of short-term at 30 days or at discharge and long-term up to 2 years were assessed.

Results

We identified 11 randomized controlled trials with a total of 10,300 patients eligible for inclusion in our study. There were no significant differences in all-cause death among different THV systems and SAVR both in short- and long-term. Disabling stroke was significantly lower with MEV compared to BEV and SAVR (HR 0.31, 95% CI 0.12-0.77; HR 0.33, 95% CI 0.14-0.76, respectively) in the long-term. MEV was associated with an increased risk of new permanent pacemaker implantation compared to BEV, SEV, and SAVR (HR 3.82, 95% CI 1.83-7.97; HR 1.85, 95% CI 1.02-3.36; HR 5.23, 95% CI 2.61-10.47, respectively) in the long-term.

Conclusions

In patients with symptomatic severe aortic stenosis undergoing intervention, there were no significant differences in all-cause death among different THV systems and SAVR. MEV had low frequency of disabling stroke compared to BEV and SAVR, but had an increased frequency of permanent pacemaker implantation compared to other interventions.

Meta-Analysis of Antithrombotic Strategies in Patients with Heart Failure with Reduced Ejection Fraction and Sinus Rhythm

Hiroki Ueyama, MD^a, Hisato Takagi, MD, PhD^b, Alexandros Briasoulis MD PhD^c, Matthew Harrington MD^a, Daniel Steinberg MD^a, and Toshiki Kuno, MD, PhD^{a,*}

Heart failure with reduced ejection fraction (HFrEF) is associated with an increased risk of thrombotic events. We compared the safety and efficacy of different antithrombotic strategies for HFrEF and sinus rhythm. PUBMED and EMBASE were searched through January 2020 for studies comparing oral anticoagulants versus antiplatelet agents or placebo in HFrEF and sinus rhythm to include in this network meta-analysis. We identified 5 randomized controlled trials with a total of 9,390 patients randomized to low dose rivaroxaban, vitamin K antagonist (VKA), antiplatelets, or placebo. Low dose rivaroxaban and VKA did not show a significant decrease in stroke compared to placebo but were associated with an increased risk of major bleeding (risk ratio [RR] 6.86, 95% confidence interval [CI] 1.16-40.7; RR 8.62, 95% CI 1.52-48.9, respectively). When compared to antiplatelets, low dose rivaroxaban and VKA were associated with a significantly decreased risk of stroke (RR 0.67, 95%CI 0.47-0.96; RR 0.50, 95% CI 0.33-0.76, respectively), but with a significantly increased risk of major bleeding (RR 1.65, 95% CI 1.16-2.33; RR 2.07, 95% CI 1.51-2.84, respectively). There was no significant difference in these outcomes between low dose rivaroxaban versus VKA and antiplatelets versus placebo. There were no significant differences in all-cause mortality, myocardial infarction or rehospitalization for heart failure among each treatment. In conclusion, in patient with HFrEF and sinus rhythm, use of oral anticoagulation with or without antiplatelet agents increases the risk of bleeding without substantial effects on the risk of ischemic stroke.

Heart failure with reduced ejection fraction (HFrEF) is associated with an increased risk of thrombogenesis, which may lead to cerebral embolism.¹⁻³ Although anticoagulation with either a vitamin K antagonist (VKA) or a direct oral anticoagulant (DOAC) is recommended in patients with heart failure with concomitant atrial fibrillation,⁴ the role of oral anticoagulation therapy in HFrEF and sinus rhythm remains unclear. Randomized controlled trials (RCTs) assessing the effect of VKA, antiplatelets or placebo in patients with HFrEF and sinus rhythm have yielded conflicting results.⁵⁻⁸ The COMMANDER HF trial of rivaroxaban versus placebo in patients with HFrEF with sinus rhythm showed no significant reduction in a composite outcome of all-cause mortality, myocardial infarction or stroke.⁹ A meta-analysis of RCTs comparing oral anticoagulation (VKA or rivaroxaban) to antiplatelets or placebo found anticoagulation to be associated with a decreased risk of stroke but an increased risk of major bleeding.¹⁰ Rivaroxaban and VKA have not yet been compared in patients with HFrEF and sinus rhythm. The aim of our study was to perform a network meta-analysis to investigate the safety and efficacy profile of each type of antithrombotic strategy in patients with HFrEF and sinus rhythm.

Meta-analysis of phase-specific survival after elective endovascular versus surgical repair of abdominal aortic aneurysm from randomized control and propensity-score matched studies

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ABSTRACT

Objective: Although endovascular repair (EVAR) for abdominal aortic aneurysm (AAA) significantly decreases perioperative mortality compared to open surgical repair (OSR), we have not concluded superiority between EVAR and OSR beyond the perioperative period. Our aim of this study was to compare phase-specific survival after EVAR versus OSR.

Methods: The review was conducted according to PRISMA guideline. EMBASE and MEDLINE were searched up to November 2019 to identify randomized control trials (RCTs) and propensity-score matched (PSM) studies that investigated ≥2-year all-cause mortality (primary outcome) after EVAR versus OSR for intact infrarenal AAA. For each study, the hazard ratio (HR) with 95% confidence interval (CI) of mortality for EVAR versus OSR was calculated using survival curves for the following specific phases: the early-term (0-2 years after repair), mid-term (2-6 years after repair), long-term (6-10 years after repair), and very long-term (≥10 years after repair) periods. The risk ratio (RR) in the perioperative (in-hospital or 30-day) period was also extracted. Phase-specific HRs or RRs were separately pooled using the random-effects model. Sensitivity analyses were performed by removing one study at a time to confirm that our findings were not derived from any single study. Funnel-plot asymmetry was also examined using the linear-regression test.

Results: Our search identified 4 RCTs and 7 PSM studies enrolling a total of 106,243 AAA patients assigned to EVAR (n = 53,123) or OSR (n = 53,120). The mortality after EVAR compared with OSR was significantly lower in the perioperative period (RR, 0.39; 95% CI, 0.29-0.51; P < .00001), and similar in the early-term period (HR, 0.93; 95% CI, 0.84-1.03; P = .16). Notably, significant higher mortality was observed in the EVAR group compared with the OSR group in the mid-term period (HR, 1.15; 95% CI, 1.03-1.29; P = .01). However, similar mortality was observed between the EVAR group and the OSR group in the long-term (HR, 1.06; 95% CI, 0.96-1.17; P = .27) and very long-term (HR, 1.17; 95% CI, 0.93-1.47; P = .19) periods. In sensitivity analyses, the significant benefit of EVAR in the perioperative period and that of OSR in the mid-term period were not changed. No funnel plot asymmetry was identified in all analyses.

Conclusions: Compared to OSR, EVAR associated with lower perioperative mortality and higher mortality in the mid-term period for intact infrarenal AAA. The superiority of EVAR was absent in the early-term period, and the inferiority of EVAR in the mid-term period disappeared in the long-term and very long-term periods.

Keywords: Abdominal aortic aneurysm, Endovascular aneurysm repair, Open surgical repair, Phase specific mortality, Meta-analysis



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Risk of amputation associated with sodiumglucose co-transporter 2 inhibitors: A metaanalysis of five randomized controlled trials

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ABSTRACT

Amputation has been known to be a rare adverse event of sodium glucose co-transporter-2 (SGLT2) inhibitors. It remains unclear whether the SGLT2 inhibitor as a class or specific categories of the SGLT2 inhibitors are linked with an increased risk of amputation. The objective of this meta-analysis was to investigate the association between the amputation risk and the use of SGLT2 inhibitors. The main outcome measure was the risk of amputation. Multiple databases were searched up to February 2020 and data extraction was performed. Inclusion criteria were randomized controlled trials (RCTs) which reported risk of amputation with SGLT2 inhibitors over non-SGLT2 inhibitors or placebo. The risk of bias was assessed by Cochrane bias tool. The initial search yielded 1,873 citations and a total of five RCTs were included in the meta-analysis. The five included studies evaluated a total of 39,067 patients with diabetes mellitus, including 21,395 patients on SGLT2 inhibitors. The incidence rate of amputation ranged from 0.36 to 3.18% in the SGLT2 inhibitor group and from 0% to 2.87% in the control group. Follow up duration ranged from 24 weeks to 4.2 years. Use of SGLT2 inhibitors was not associated with significant increase in the risk of amputation as compared with controls (OR: 1.31, 95% CI: 0.92-1.87, I² = 75%). Subgroup analysis showed that neither canagliflozin, empagliflozin, nor dapagliflozin associated with increased risk of amputation. In conclusion, our meta-analysis showed that neither cana-

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過去の常識と現在の常識

3. リスク患者での造影検査における前投薬と薬剤変更

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New Strategy for Prevention of Repeat Hypersensitivity Reactions to Contrast Media

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Summary

The high risk of repeat hypersensitivity reactions to contrast media is well known. A number of studies have reported on the effectiveness of premedications and changing of the contrast medium. Recommendations by guidelines have continued to change. A current focus is on skin testing. The mechanism of repeat hypersensitivity reactions is reviewed and a new strategy for the prevention of repeat adverse reactions is discussed.

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ヨード造影剤の副作用に関する報告は数多いが、その中でも、1990年にRadiology誌に発表されたKatayamaらによる論文は、日本医学放射線学会が最も誇れる叡智と努力の賜物であろう¹¹。当時、過渡期にあったイオン性造影剤と非イオン性造影剤の比較をし、非イオン性造影剤の安全性を世界に知らしめるものであった。その後、ヨード造影剤の主流は、イオン性造影剤から非イオン性造影剤に変わり、またガドリニウム造影剤も数多く使用されるようになったことは言うまでもない。

造影剤リスク患者についても、多くの文献の中で検討 され続け、時に変化しながら現在に至る。日々の診療の 中で安全な検査を行っていくためには、時代に即した知 識が必要である。

造影剤の副作用の機序

本項目のトピックスを理解し、より安全な検査を遂行 するためには、まずは造影剤に対する副作用の機序を知 っておく必要がある。しかし、いまだその機序は解明さ れたとは言えない。広く認識されているのは、種々の造影剤の投与により、IgEや補体を介さず、マスト細胞が活性化され、ヒスタミンやトリプターゼなどのメディエータが遊離し、アナフィラキシー(かつてはアナフィラキシー様反応と呼んでいたが、抗原抗体反応によるアナフィラキシーとの区別は困難で、臨床的にも区別する必要がないため、そのどちらもアナフィラキシーと呼ぶこととなった)あるいはアレルギー様反応が起こるという機序であろう^{2,3)}。抗原抗体反応ではないので、造影剤投与初回であろうと、2回目以降であろうと、副作用は起こり得る。しかし、後述する皮膚テストの有用性の報告の中には、IgEが関連する用量非依存性のアレルギー反応の関与について論じる報告も多く、今後の検討課題である^{4,5)}。

ガドリニウム造影剤の副作用の機序に関しては文献も 少ないが、その機序は、ヨード造影剤と大きくは変わら ないと考えられる⁶⁾。

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23 (105)

外来での抗菌薬使用の手引き(小児版) 補足

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2019 年 9 月静岡県 HP で外来での抗菌薬使用手引き(小児版)が公開されました。

https://www.pref.shizuoka.jp/kousei/ko-420a/amr.html

https://www.pref.shizuoka.jp/kousei/ko-420a/documents/2019tebikisouni.pdf

公開に至っては、静岡県感染症発生動向調査委員会薬剤耐性(AMR)対策部会での討論、修正を重ねて公開の運びとなりました。外来でよく経験する疾患で、市中感染症を考えての抗菌薬の選択と使用量を示しています。普段、小児をご専門に診療されている先生方には、受け入れられやすいと思いますが、外科、眼科、耳鼻咽喉科、泌尿器科、皮膚科など成人も小児も混在して診療をされる外来診療科では、必ずしも使い慣れた薬剤ではないかもしれません。そこで 手引きに示された抗菌薬について、使用法について少しだけ補足をさせていただきます。力価で分かりにくい場合があるので、製剤量で処方量を下表に示しました。商品名は後発を中心に代表的なものを記載していますが、これらを推奨しているわけではありません。

	製剤量 (g/kg/日)	力価 (mg/kg/日)	用法
アモキシシリン(AMPC)			
溶連菌			
ワイドシリン細粒10%	0.4	40	分3 (分1も可)
ワイドシリン細粒20%	0.2	40	分3 (分1も可)
肺炎球菌			
ワイドシリン細粒10%	0.9	90	分3
ワイドシリン細粒20%	0.45	90	分3
アモキシシリン/クラブラン酸			
(AMPC/CVA)			
クラバモックスDS	0.15	96.4	分2 食直前
セファレキシン(CEX)			
通常			
ケフレックス細粒10%	0.5	50	分3
ケフレックス細粒20%	0.25	50	分3
重症			
ケフレックス細粒10%	1	100	分3
ケフレックス細粒20%	0.5	100	分3
クラリスロマイシン(CAM)			
クラリスロマイシンDS10%	0.1~0.15	10~15	分2
アジスロマイシン(AZM)			
アジスロマイシン細粒10%	0.1	10	分1,3日間
スルファメトキサール・			
トリメトプリル(ST合剤)			
ダイフェン配合顆粒	0.12	10	分2
	ST合剤全体で	(トリメトプリムとして)	

小児用の内服用抗菌薬の飲ませ方

静岡医療センター薬剤部 滝 久司

令和元年 11 月 9 日(土)、野村コンファレンスプラザ日本橋において、第 3 回薬剤耐性(AMR)対策普及啓発活動表彰式&「薬剤耐性へらそう!」応援大使によるトークイベントに参加してきた。その中で応援大使から"抗菌薬は医師の指示通りちゃんと飲みきる~"と会場に向かってオリジナルソングが披露された。大人はそれでよいが、ところで小児は?との思いを巡らせながら、通報 50 に続き、小児用の内服用抗菌薬の飲ませ方にフォーカスをあててみた。

溶出・放出制御技術の開発と応用

小児用に開発された内服用抗菌薬の多くは服薬コンプライアンスを向上させるためストロベリー味やオレンジ味など溶出・放出制御技術が開発、応用されている。しかし、抗菌薬を溶くときに強く混ぜすぎ、飲ませ方によっては苦みを生じてしまうなど適切な方法で抗菌薬の服用を行わないとその恩恵をあずかることができなくなってしまうばかりでなく、小児に「くすり=まずい」という認識をもたせてしまい、その抗菌薬の服薬コンプライアンスの低下が感染症に対する治療の失敗やAMRにつながってしまう恐れがある。

内服用抗菌薬の飲ませ方の工夫

小児に散剤を飲ます際に、散剤を溶く飲料水は必ず水で溶いている介護者(保護者)が 64%、水やジュースで溶いている介護者(保護者)が 36%であったとのアンケート報告がある。さらに、その報告の中では「薬なので水にしか溶いてはいけないと思っていた」「ジュースに溶いたけど良かったですか?」との質問もあったという。また、小児の年齢と服薬に抵抗を示した子の調査をした報告では、全体の 73%の子が服薬を嫌がったことがあるとの回答だったとある。その服薬拒否・困難を示した比率は 1 歳から 5 歳は年齢とともに増加傾向を示し、一度服薬に失敗するとその体験を覚えており、その後の服薬に苦労するとのアンケート結果がそれを裏付けており、最初に服薬させるときにいかに薬嫌いにさせないことが最大のポイントであると述べられている。

また、一般的に散薬の飲ませ方としてインターネットなどの情報源に総論として各種ジュース類やスポーツ飲料などがあげられているが、製剤毎にそれぞれの特徴として色、味、においがあるように混ぜると飲みやすくなるもの、混ぜると相性の悪いものがある。そこで、各インタビューフォーム及び各メーカーからの聞き取り調査をもとに"小児用内服用抗菌薬に混ぜると飲みやすくなるもの・悪いもの"を一覧表にまとめてみた(表 1)。ただし、メーカーからの聞き取り調査では、もともと何かと混合すること自体を推奨しておらず、混合した製剤の有効性・安全性・品質は保証できないということが前提であり、インタビューフォーム掲載事項を除いては配合における相性についての正式見解はないとの回答があったことを補足しておきたい。

SCIENTIFIC RESEARCH ARTICLE

Postoperative atrial fibrillation is associated with delayed early rehabilitation after heart valve surgery: a multicenter study

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ABSTRACT. Objective: Postoperative atrial fibrillation (POAF) is a common complication after cardiac surgery. The aim of this multicenter study was to determine the relationship between POAF and patients' progress in early rehabilitation after heart valve surgery. Methods: We enrolled 302 patients (mean age, 69 \pm 10 years) who had undergone heart valve surgery. POAF was monitored using continuous electrocardiogram telemetry, and the Short Physical Performance Battery (SPPB) was used to assess lower-extremity function before surgery and at the time of discharge. Progress in early rehabilitation was evaluated by the duration from the surgery to independent walking. We determined factors associated delayed early rehabilitation and evaluated the interplay of POAF and delayed early rehabilitation in increasing the risk of decline in lower-extremity function from preoperatively to hospital discharge. Results: Multivariate analysis determined POAF to be independent predictors of delayed early rehabilitation after heart valve surgery (OR: 3.906, P = .01). The association between delayed early rehabilitation and decline in lower extremity function was stronger in patients with POAF (OR: 2.73, P = .041) than in those without (OR: 2.22, P = .052). Conclusions: POAF was clinical predictors of delayed early rehabilitation in patients undergoing heart valve surgery. The combination of POAF with delayed early rehabilitation conferred a high risk of decline in lower-extremity function during hospitalization.

Key words: postoperative atrial fibrillation, heart valve surgery, rehabilitation, lower-extremity function

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In patients who have undergone cardiac surgery, prolonged inactivity postoperatively is associated with increased sensation of fatigue and reduced functional capacity¹⁾. Recently, early rehabilitation has been shown to play an important role in enhancing postoperative recovery of physical function during hospitalization after cardiac surgery²⁾. Studies have reported that early rehabilitation significantly reduced both the length of hospital stay and

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Factors Related to Physical Functioning Decline After Cardiac Surgery in Older Patients: A Multicenter Retrospective Study

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Abstract

Background: As few studies have examined physical functioning changes after cardiac surgery, the factors related to the decline in physical functioning remain unclear. This study aimed to investigate the factors related to physical functioning decline after cardiac surgery in older patients.

Methods: The final study sample consisted of 523 older (≥65 years) patients (age 74.2±6.1 years, 66% male) who underwent cardiac surgery at 8 Japanese institutions. We excluded patients who were unable to walk independently or had a slow gait speed (<0.8m/s) before surgery, and those who were unable to regain independent walking after surgery. We divided the patients into two groups, a decline-in-gait-speed group and a non-decline-in-gait-speed group, according to whether their gait speed was less than 0.8m/s at discharge. We analyzed patients' clinical characteristics to identify the factors that predicted the postoperative decline in gait speed.

Results: Eighty-nine patients (17.0%) showed a postoperative decline in gait speed. Multivariate logistic regression analysis showed that the following factors predicted a postoperative decline in gait speed: age [odds ratio (OR) 1.06, 95% confidence interval (CI) 1.02-1.11]; estimated glomerular filtration rate (OR 0.98, CI 0.96-0.99); preoperative gait speed (OR 0.01, CI 0.00-0.08); and the postoperative day on which the patient could walk independently (OR 1.08, CI 1.02-1.14).

Effect of Obesity and Underweight Status on the Hospital-Acquired Functional Decline in Patients With Cardiovascular Surgery: An Analysis of Data From a Prospective Observational Multicenter Cohort Study

<u>Masakazu Saioth</u> ___, <u>Kenta Kamisaka</u> ___, <u>Michitaka Kato</u> ____, <u>Kentaro lwata</u> ____, <u>Koji Sakurada</u> ____, <u>Masayuki Tahara</u> _____, <u>Keisuke Oura</u> ____, <u>Yuji Mori</u> ____, <u>Shota Otuka</u> _____, <u>Tomoyuki Morisawa</u> _______, <u>Tetsuya Takahashi</u> ______ Affiliations Expand

Affiliations PMID: **31865600** DOI: <u>10.1007/s11748-019-01279-0</u>

Abstract

Objects: The aim of this study was to determine the association between underweight or obese status and hospital- acquired functional decline (HAFD) following cardiovascular surgery.

Methods: We performed a retrospective, observational, multicenter cohort study of cardiovascular surgery patients between April, 2010, and June, 2017. Body mass index (BMI) was categorized into four classes: underweight group (< 18.5 kg/m^2), normal weight group ($18.5 \text{ to} < 25 \text{ kg/m}^2$), overweight group ($25 \text{ to} < 30 \text{ kg/m}^2$), and obese group ($\ge 30 \text{ kg/m}^2$). HAFD was defined as a decrease of at least one point on the short physical performance battery score at discharge, compared with the preoperative score.

Results: A total of 3,850 adult patients were included in the analysis data set (median age 72 years, 35% female). A total of 811 (21.0%) patients demonstrated HAFD: 27.2% in the underweight group, 21.3% in the normal weight group, 18.8% in the overweight group, and 19.3% in the obese group. The relative risk for HAFD was 1.381 (95% CI 1.052-1.814) for the underweight group versus the normal weight group, although that is comparable to the obese group after adjustment by confounding factors.

Exercise-based Cardiac Rehabilitation for Patients With Catheter Ablation for Persistent Atrial Fibrillation: A Randomized Controlled Clinical Trial

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Affiliations Expand PMID: **31272205** DOI: <u>10.1177/2047487319859974</u>

Abstract

Aims: The efficacy and safety of cardiac rehabilitation for patients with persistent atrial fibrillation who restored sinus rhythm after catheter ablation remains unclear. The aim of the present study was to evaluate the effects of cardiac rehabilitation on exercise capacity, inflammatory status, cardiac function, and safety in patients with persistent atrial fibrillation who had catheter ablation.

Methods: In this randomized controlled study, 61 patients treated with catheter ablation for persistent atrial fibrillation (male, 80%; mean age, 66 ± 9 years) were analyzed. Thirty patients underwent cardiac rehabilitation (rehabilitation group), whereas the remaining 31 patients received usual care (usual care group). The rehabilitation group underwent endurance and resistance training with moderate intensity, at least three times per week for six months. Sixminute walk distance, muscle strength, serum high-sensitivity C-reactive protein, plasma pentraxin 3, left ventricular ejection fraction and atrial fibrillation recurrence were assessed at baseline and at six-month follow-up.

Results: In the rehabilitation group, significant increases in the six-minute walk distance, handgrip strength, leg strength and left ventricular ejection fraction and significant decreases in high-sensitivity C-reactive protein and plasma pentraxin 3 concentrations were observed at sixmonth follow-up compared with baseline (all p < 0.05). No significant changes were observed in the usual care group. During the six-month follow-up period, the number of patients with atrial fibrillation recurrence was six (21.4%) in the rehabilitation group and eight (25.8%) in the usual care group (risk ratio, 0.83; 95% confidence interval, 0.33 to 2.10).

心不全一薬物療法と慢性心不全

加藤倫卓1) 小鹿野道雄2)

Key Words 心不全 治療薬 運動療法

Point

- ●心不全のステージにより投与される治療薬の種類は異なる
- ●治療薬の変更や処方量の増減がある場合、心不全の病態が変化している可能性が考えられ、運動療法の調整も視野に入れる
- ●治療薬による重篤な副作用が疑われる場合、担当医に運動療法の継続の可否を確認することが 望ましい

はじめに

高齢者心不全に対しては多職種の心不全チームによる介入の有効性が認められ徐々に普及しているが、これには多職種で共通の知識と言語を用いて患者の治療方針を一致させていくことが重要である。言うまでもなく薬物療法は心不全治療の根幹であり、基本的な知識を踏まえ、なぜこの薬が使われているのかを十分に理解し、個々の患者の最適な治療を築く一端を理学療法士も担わなければならない。以上より、心不全チームの一員として理学療法士が知っておくべき主な治療薬について、その効能と作用機序、副作用、そして運動療法を実施する際に留意すべき点について述べる。

慢性心不全で使用される治療薬

2013 米国心臓病学会財団(ACCF)/米国心臓協会(AHA)心不全ガイドラインでは、心不全を病期の進行によって4つのステージに分類している¹⁾. 各ステージにおける治療目標はステージの進行を抑制することにある(図1). 特に、心不全症状が存在するステージ C(心不全ステージ)やステージ D(治療抵抗性心不全ステージ)では症状の軽減、(再)入院の予防、そして予後の改善を目標としている。慢性心不全で理学療法が処方される場合、ほとんどがステージ C あるいは D である。ステージ C および D では、図 1 下段に示されるような治療薬が使用される。以下にそれぞれについて触れていく。

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心臓再同期療法後の心不全患者に対する訪問リハビリテーションにより日常生活動作が改善した要介護症例

Effects of home-visit rehabilitation in heart failure patient with cardiac resynchronization therapy: a case report

石月亜由美1) 尾熊洋子1) 森 雄司2) 加藤倫卓3)

Key words: 訪問リハビリテーション CRT-D 植込み術 アセスメント 要介護者

図書うっ血性心不全を発症後、急性期病院にて両心室ペーシング機能付き植込み型除細動器(cardiac resynchronization therapy-defibrillator: CRT-D)を施行した要介膜症例に対して、理学療法士による訪問リハビリテーションを実施した。症例は79歳の女性。うっ血性心不全、心房細動と診断され入院、介助量が多いが、自宅退院を強く希望した。退院4日目より訪問リハビリテーションとして、リスク管理や「できること」の明確化、リハビリテーションマネジメントを行い、不安軽減、活動量向上をめざして6か月間施行した。

開始時に比べ、植込み機器や心不全増悪に関する不安が軽減し、筋力や認知機能、ADLが向上、生活空間がベッド 上から屋外へと拡大した。また訪問リハビリテーション実施期間中、心不全増悪や再入院は認めなかった。

心疾患術後の要介護状態の患者であっても、退院直後からの訪問リハビリテーション介入は活動性、ADL向上に影響を及ぼすと考えられ、退院調整時には訪問リハビリテーションの導入検討が有効と考えられた。

はじめに

「心血管疾患におけるリハビリテーションに関するガイドライン」¹⁾によると、両心室ペーシング機能付き植込み型除細動器(cardiac resynchronization therapy-defibrillator: CRT-D)装着後は、運動耐容能やQOLが改善する。また、CRT-D後の運動療法は運動耐容能の向上が見込めるため、推奨されている²⁾.

一方で、高齢社会に伴い複数の疾病を合併する 症例が増加しており、この傾向は心不全患者にも顕 著に表れている。先行研究によると、高齢の心不全 患者は整形外科疾患、脳血管疾患ならびに認知症 などの合併症を複数抱えており³⁾、さらにフレイル を合併していることが報告されている⁴⁾。このよう な高齢の心不全患者は移動能力の低下に加え、通 院手段の確保が困難であり、病院や施設に通い回復 期の心臓リハビリテーションを受けることが難しい 場合が多い. 平成 28(2016) 年度介護報酬改定検証・研究調査⁵⁾では、訪問リハビリテーション実施者において、訪問リハビリテーションが必要となった原因のうち、心不全が占める割合はわずか 8%であり、心不全患者に対する訪問リハビリテーションの実績や報告は少ないのが状況である。

今回,うっ血性心不全を発症後,急性期病院にて CRT-D 植込み術を施行した要介護症例に対して, 理学療法士による訪問リハビリテーションを実施した。その結果,6か月の訪問リハビリテーション期間 中の再入院は認めず,運動,認知機能,ADLが著明に向上したため,その経過と訪問リハビリテーションの実際を報告する。

症例紹介

症例は79歳の女性である。息切れ、胸痛が出現

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第二内科という場所がもたらしたもの

昭和63年卒 国立病院機構 静岡医療センター 副院長 岡崎貴裕



研修医を修了して第二内科へ入局し、まだ右 も左もわからない状態で最初に出席した学会が 日本臨床免疫学会(長崎)であった。演題を発表 するわけでもなく学会というものの雰囲気を知る ためにいったわけなので、自分の興味の赴くま まに唯々聞き流していた。

井村裕夫教授が神経・免疫・内分泌に関する 講演をされる予定だったので、私は2階席の前列 から拝聴した記憶がある。恥ずかしながら詳細 は覚えていない。しかし、それぞれの分野の連 関がヒトの生理学的なバランスと病態を形作っ ている可能性が心の中に残された。

それから約10年後、留学先のNIHの研究室の 図書室で一つの論文が目にとまった。その論文 は、アンジオテンシンTypel受容体のノックア ウトマウスにおいて、T細胞の増殖活性がおちる というものであった。大学院から留学先の研究 室においてもずっとT細胞による抗原認識と細胞 障害メカニズムの研究に携わってきた私にとっ て、その論文は極めて斬新な結果であった。

以来、免疫が、自己であれ外来抗原であれ、その破壊と排除だけではなく、生体内での生理機能に関与する可能性があっても良いのではと考え始めた。帰国後、vasculitisの診断と治療の方向性を探られていた尾崎承一教授のもとで、その考え方は、自己免疫反応による血管破壊の結果としての血管炎という病態以外に、血管の生体機能に影響を与える機能不全あるいは変性病態(vasculopathy)もありうるのではないかという着想に変化していった。頼みると、このことが、T細胞と血

管収縮の調節因子との関係性を探る上での大きな 動機づけとなったことは疑いようがない。

現在の臨床医学の大きな潮流は、Clinical study である。様々な研究から得られた既定の仮説を 大規模なMass studyによって検証し、その結果 は医療現場にガイドラインとして反映される。こ れが極めて重要であることは、いうまでもない。

では、このClinical studyを行う上での既定の仮説はどこから来るのであろうか。基礎医学から得られる結果だけが仮説を生み出すわけではない。基礎医学から提示されてくる仮説だけで論理付けることのできない臨床現場の事象も数多くあり、その矛盾を探ることにより、新しい仮説を生み出そうとする行為もClinical researchとして重要であると私は考えている。前者のClinical studyは、結果如何を問わずその結果が臨床現場に反映される。これに対し後者のClinical researchにおいては、その行為のすべてが何らかの成果を伴うものではない。新しい仮説を提示するためには既存にはない発想が必須となり、その獲得は容易ではない。

私にとっての第二内科は、専門分野の違いから生み出される考え方の違いを感じ、時にはそれを取り込み、自分の分野にある矛盾を説明できないかどうか、自身の問題のみに囚われずに考えることの重要性を、常に教えてくれる場であったように思う。その意味において、第二内科で大学院時代を送ることができたことは、私にとって無二の財産となったのではないかと考えている。

ANCA関連血管炎

岡崎 貴裕

血管炎症候群の中に、小型血管(細動脈、毛細血管、細静脈)が障害され、その血中に抗好中球細胞質 抗体(ANCA)が検出されることを特徴とした、顕微鏡的多発血管炎(MPA)、多発血管炎性肉芽腫症 (GPA)、好酸球性多発血管炎性肉芽腫症(EGPA)の3疾患がある。これらはANCAという疾患標識抗体 が陽性であることが多いことから、ANCA関連血管炎(AAV)と総称される。AAVの診断・治療につい ては、欧州リウマチ学会(EULAR)による治療推奨(2016年)のみならず、わが国でも罹患人口の増加 に伴い、厚生労働科学研究班によりANCA関連血管炎の診療ガイドライン(2011年、2017年)として 提言がまとめられている。

診断

ANCA関連血管炎(AAV)は、顕微鏡的多 発血管炎 (MPA)、多発血管炎性肉芽腫症 (GPA (旧Wegener肉芽腫症))、好酸球性多発 血管炎性肉芽腫症(EGPA〈IEChurg-Strauss 症候群、アレルギー性肉芽腫性血管炎〉) の3 つの血管炎における抗好中球細胞質抗体 (ANCA) 陽性例の総称となる。3疾患とも小 型血管炎 (small vessel vasculitis) に分類さ れ、それぞれの疾患の診断基準が厚生労働科学 研究班により示されている。外来の診察におけ るポイントは、小型血管炎の症候を見逃さない ように心がけることである。原発性血管炎症候 群の症候診断では、一見異なったようにみえる 個々の局在症候が、血管の炎症の結果起こる虚 血や出血により顕在化した症候として一元的に 説明可能かどうかを吟味することが重要とな る。

(1)全身症状

血管炎ではしばしば発熱、全身倦怠感、食欲 不振、体重減少、筋痛、関節痛などの非特異的 な全身症状が、局所的臓器症候が出現する前の 数週から数カ月にわたり前駆症状として出現す

る場合がある。AAVの中でもMPAは60~70 歳代、GPAは50~60歳代での発症が多い。わ が国ではMPAの患者が多く、高率に腎病変を 伴うことから、特に高齢者で原因不明の炎症症 候が持続している場合や、血尿や蛋白尿などの 臓器症候を1つ以上認める場合、鑑別診断の中 にAAVを含めてANCAの測定(間接蛍光抗体 法、ELISA法)を行う。

(2) 臓器障害によってもたらされる局所症状

皮疹では、いわゆる触知可能な紫斑が特徴と なり、特に下腿に好発する。また、リベドと呼 ばれる網目状の皮斑、皮膚潰瘍がみられる。

多発性単神経炎は当該神経を養う中~小動脈 の血管炎によって引き起こされる症状と考えら れ、初期には感覚障害としての知覚過敏(痺 れ)、知覚鈍麻などが出現し、進行すると運動 障害を併発し重度の場合は下垂手や下垂足とな る。

眼病変として、強膜炎を示唆する眼の痛み、 充血のほか、複視、視力低下、眼球突出などの 症状を来し得る。

耳病変の症状は、難聴や耳閉感が最も多く、 耳痛、耳漏、耳鳴を伴う場合がある。

鼻・副鼻腔病変はGPAやEGPAに特徴的であ

≫ MCIって知ってる?



~東京オリンピック・パラリンピックに向け~

MCI 多数傷病者災害:麻酔科医も勤務施設の備えに参画を! 災害発生場所は大会会場のみではない!

(地下鉄サリン事件・JR 福知山線脱線事故・相模原障害者施設事件・他)

MCI 関連知識のポイント

- 1 思考回路を『最大多数の最大幸福』に転換!
- 2 「治療対象と医療資源のバランス」が崩れる!
- 3 災害発生付近の施設に『直ぐに』『大量に』来る
- 4 緊急手術が必要な四肢・脳・腹部外傷が多数
- 5 「輸血」が必要例多数 (駆血帯解除は OR が原則!)
- 6 災害の種類は多岐(外傷・熱傷・中毒・爆傷・銃創)

各施設で確保すべき 45

- 1 物的資源(Stuff)
- 2 人的資源(Staff)
- **B** スペース (Space)
- 4 システム (System)



例)マドリード多発列車爆破

3駅4列車(通勤時間帯 10回爆発) 死者 191名、負傷者 2,062名

近隣2病院に患者集中!

【Gegorio Maranon 大学病院】

最初の患者来院:爆発から19分!

ICU28 床の空床確保

OR 予定手術中止緊急手術 37 件 /24h

全国の麻酔科医は MCI に備え

- 1 良好な院内コミュニケーションを!
- 2 優先順を含む手術対応と院内連携を!
- 3 手術室外での診療にも参画を!
- 4 事前に院内シミュレーション実施を!





JSA オリパラ MCI 委員会

内野博之・大嶽浩司・小澤章子 倉橋清泰・櫻井淳・森崎浩

本手引きの目的と使用法

我が国においても、自然災害はもとより、地下鉄サリン事件、JR福知山線脱線事故あるいは相模原障害者施設事件など、多数傷病者事故(Mass Casualty Injury: MCI)が数多く発生している。2005年に発足した災害派遣医療チーム(DMAT)体制は一定の成果を上げつつあるものの、テロや爆発事故など多数傷病者発生に対応する社会的基盤や医療機関の体制は欧米諸国に比べ十分整備されているとは言い難い。2020年夏の東京オリンピック・パラリンピック開催を控え、関連する学術団体が「救急災害医療体制に係る学術連合体(http://2020ac.com/)」を2016年5月に結成、公益社団法人日本麻酔科学会も2018年10月より23番目の学術団体として参画した。MCIは必ずしも競技会場で発生するとは限らず、対応可能な医療機関の体制や諸準備を整える重要な機会と捉え、安全かつ効率的な手術室運営に主眼を置いた院内対応について、全国の麻酔科医が適切に対応するための手引きを作成した。

なお本手引きは、大規模自然災害によりライフラインが途絶あるいは医療機関が被災する広域災害を想定したものではない。これまでに公表されている海外文献や学術団体指針等を参考に箇条書きにまとめているが、我が国における医療環境や社会基盤など異なる点も多く、文献を基にした「推奨」に加え当委員会「提案」も数多く含まれている。また勤務施設の規模や地域、診療体制等に院内MCI対応は左右されるため、「MCI発生時の対応のポイント(推奨と提案)」「MCI対応準備のためのチェックリスト」として集約した。また当該施設に該当する職位がない場合にはそれに相当する職位に置き換えて対応頂くことを想定している。

日本麻酔科学会会員が勤務する医療機関あるいは地域において、麻酔科医師の社会的責務を果たして頂く一助となれば幸いである。

公益社団法人日本麻酔科学会 オリ・パラ MCI 委員会 内野博之、大嶽浩司、小澤章子、倉橋清泰、櫻井淳、森崎浩

編集後記

2019年度の業績集が完成いたしました。日常診療が忙しいなか、臨床研究および治験に多大な努力をされている先生方、誠にありがとうございます。そして治験管理室看護師の井上さん、薬剤師の薄先生、いままで本当にありがとうございました。それぞれ新天地での活躍をお祈りしています。また治験管理室看護師の勝又さん、今年もありがとうございました。そして受託研究審査委員会のメンバーのみなさん、特に外部委員の先生方にはお忙しいところ貴重なお時間をいただき、改めて感謝申し上げます。それから事務の渡邉光子さん。今年もまた締切間際まで仕事が終わらない私のためにご迷惑をおかけしました。渡邉さんの多大なる努力なしでこの業績集は完成できませんでした。ここに改めて心より感謝の意を表したいと思います。本当にありがとうございました。

2020年9月

静岡医療センター 臨床研究部長 田邊 潤

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