

静岡医療センター研究業績集 (26)

(2018 年度)

静岡医療センター臨床研究部

発刊の辞

2018 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すし、受託研究も多く、静岡医療センターの実力を改めて実感しております。また、国立病院機構共同臨床研究も開始され、今後、NH0 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。

2018 年の静岡医療センターの研究業績は、従来の循環器・心臓血管外科の業績に加え、内科系、神経難病部門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上げます。

2019 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

目次

臨床研究部の活動状況	7
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発表論文

消化器内科	16
循環器内科	16
外科	16
心臓血管外科	16
整形外科	20
放射線科	21
歯科口腔外科	21
薬剤部	21
中央放射線室	21
リハビリテーション科	22
栄養管理室	23

著書

内科	24
循環器内科	24

学会発表

内科	25
脳神経内科	25
消化器内科	26
循環器内科	27
外科	27
整形外科	29
心臓血管外科	31
皮膚科	32
泌尿器科	32

眼科	32
放射線科	32
麻酔科	33
研修医	33
薬剤部	33
中央放射線室	35
臨床検査科	35
リハビリテーション科	36
栄養管理室	38
緩和科	38
看護部	38
管理課	39
看護学校	39
療育指導科	39

講演

内科	40
脳神経内科	40
消化器内科	40
循環器内科	40

発表論文集

・ 胆嚢早期癌 - Ip 型、Is 型、II b+ II a 型	42
・ Mid-term feasibility and safety of downgrade procedure from defibrillator to pacemaker with cardiac resynchronization therapy.	43
・ 重症大動脈弁狭窄を有する開腹手術症例に対する術前 IABP 挿入の経験	44
・ 腹腔鏡下鼠経ヘルニア修復術が有用であった再発鼠経ヘルニア嵌頓の 1 例	45
・ Long-term survival after transcatheter versus surgical aortic valve replacement for aortic stenosis: A meta-analysis of observational comparative studies with a propensity-score analysis.	46
・ Meta-Analysis of the Prognostic Value of Psoas-Muscle Area on Mortality in Patients Undergoing Transcatheter Aortic Valve Implantation.	47

• A meta-analysis of ≥ 5 -year mortality in randomized controlled trials of off-pump versus on-pump coronary artery bypass grafting.	48
• A meta-analysis of valve-in-valve and valve-in-ring transcatheter mitral valve implantation.	49
• Transcatheter mitral valve replacement for mitral regurgitation-A meta-analysis. ---	50
• A Contemporary Meta-Analysis of Antegrade versus Retrograde Cerebral Perfusion for Thoracic Aortic Surgery.	51
• Meta-analysis of Valve-in-Valve Transcatheter versus Redo Surgical Aortic Valve Replacement.	52
• Impact of concurrent tricuspid regurgitation on mortality after transcatheter aortic-valve implantation.	53
• Meta-Analysis of Impact of Anemia and Hemoglobin Level on Survival After Transcatheter Aortic Valve Implantation.	54
• Meta-Analysis of Impact of Baseline N-Terminal Pro-Brain Natriuretic Peptide Levels on Survival After Transcatheter Aortic Valve Implantation for Aortic Stenosis.	55
• Meta-analysis of impact of liver disease on mortality after transcatheter aortic valve implantation.	56
• Meta-analysis of transcatheter aortic valve implantation for bicuspid versus tricuspid aortic valves.	57
• Meta-Analysis and Meta-Regression of Transcatheter Aortic Valve Implantation for pure Native Aortic Regurgitation.	58
• Impact of low-flow/low-gradient aortic stenosis on survival after transcatheter aortic valve implantation.	59
• Comparison of early and midterm outcomes after transsubclavian/axillary versus transfemoral, transapical, or transaortic transcatheter aortic valve implantation.	60
• Meta-analysis of prognostic impact of blood transfusion on survival after transcatheter aortic valve implantation.	61
• Suppression of aortic expansion and contractile recovery in a rat abdominal aortic aneurysm model by biodegradable gelatin hydrogel sheet incorporating basic fibroblast growth factor.	62
• Is Transcatheter Aortic Valve Replacement Better Than Surgical Aortic Valve Replacement in Patients With Chronic Obstructive Pulmonary Disease? A Nationwide Inpatient Sample Analysis.	63

• Clinical End Points of Transcatheter Aortic Valve Implantation Compared With Surgical Aortic Valve Replacement in Patients .	
<65 Years of Age (From the National Inpatient Sample Database)	-----64
• Failure to Rescue, Hospital Volume, and In-Hospital Mortality After Transcatheter Aortic Valve Implantation.	-----65
• Comparison of Health Related Quality of Life in Transcatheter Versus Surgical Aortic Valve Replacement: A Meta-Analysis.	-----66
• In-hospital outcomes of transcatheter versus surgical aortic valve replacement in non-teaching hospitals.	-----67
• Transradial versus transfemoral percutaneous coronary intervention of left main disease: A systematic review and meta-analysis of observational studies.	-----68
• Incidence, Trends, and Predictors of Palliative Care Consultation After Aortic Valve Replacement in the United States.	-----69
• Incidence, Predictors, and In-Hospital Outcomes of Transcatheter Aortic Valve Implantation After Nonelective Admission in Comparison With Elective Admission: From the Nationwide Inpatient Sample Database.	-----70
• Acute Myocardial Infarction Outcomes in Systemic Lupus Erythematosus (from the Nationwide Inpatient Sample).	-----71
• Meta-Analysis Comparing the Incidence of Infective Endocarditis Following Transcatheter Aortic Valve Implantation Versus Surgical Aortic Valve Replacement.	-----72
• Predictors of Hospital Cost After Transcatheter Aortic Valve Implantation in the United States: From the Nationwide Inpatient Sample Database.	-----73
• Should patients become obese before transcatheter aortic valve implantation?	-----74
• Can we assess which is better?-transcatheter or surgical aortic valve replacement in intermediate or lower risk patients with chronic obstructive pulmonary disease.	---75
• Incidence and predictors of readmissions to non-index hospitals after transcatheter aortic valve replacement and the impact on in-hospital outcomes:From the nationwide reanmission database.	-----76
• Perforation of a Peptic Ulcer in a Hiatal Hernia Into the Left Ventricle With Systemic Air and Food Embolism.	-----77
• Repeat Contrast Medium Administration for Patients with mild Immediate Hypersensitivity Reaction to Iodinated Contrast Media.	-----78

• Trousseau syndrome in a patient with advanced oral squamous cell carcinoma:a case report. -----	79
• 伝家の宝刀となるか（小児抗菌薬適正使用支援加算） -----	80
• Learn More about Vaccines(Vaccines & Immunizations)J-IDEO. -----	81
• 血管撮影装置における透視画像の評価方法について -----	82
• Safety and efficacy of exercise training in patients with abdominal aortic aneurysm: a meta-analysis of randomized-controlled trials. -----	83
• Characteristics of respiratory muscle fatigue upon inhalation resistance with a maximal inspiratory mouth pressure of 50%. -----	84
• Relationship between advanced glycation end-product accumulation and pulmonary function. -----	85
• ストレッチング体操が植込み型除細動器あるいは両心室ペーシング機能付き植込み型除細動器を装着した運動習慣の無い慢性心不全患者の血管内皮機能と運動耐容能に与える影響 -----	86
• プレフレイルと静的立位バランスとの関係 -----	87
• Postoperative atrial fibrillation is associated with delayed early rehabilitation after heart valve surgery: a multicenter study. -----	88
• 慢性腎臓病患者の食事療法に対する意思決定バランス -----	89
• 高齢糖尿病患者に対するフレイル予防介入プログラムの評価についての検討 - 糖尿病教室を用いた多職種連携による介入 -----	90

著書

• ANCA 関連血管炎 -----	91
• 両心室ペーシング急性効果 -----	92
• 遺伝性不整脈に対する最新のデバイス治療 -----	93
• 不整脈非薬物治療ガイドライン -----	94

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おり、2018年4月1日より臨床研究法に基づく厚生労働大臣の認定を受けた臨床研究審査委員会も本部、他4病院に設置されました。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。

平成30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

	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	志田幹雄	併任	内科部長 H30年4月～H30年6月
治療開発研究室長	黒田勝宏	併任	脳神経外科部長
人工臓器研究室長	高木寿人	併任	心臓血管外科部長
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とする慢性期医療を担う施設として診療に当たっています。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、静岡県地域がん診療連携推進病院の指定を受けています。神経・筋疾患では神経難病の診療を中心に在宅支援等も積極的におこなっていきます。

2018年4月以降、リウマチ膠原病内科、呼吸器内科、代謝内分泌、糖尿病内科、乳腺外科、脊椎外科などの医療が加わりました。

また、平成23年9月に地域医療支援病院として承認を受け、広域で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継続していくこととします。

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・総合診療をはじめ看護部門等での臨床研究にも幅広く支援をおこなっています。

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。平成27年度～平成29年度の国立機構本部による臨床研究の研究力調査でも循環器と外科・救急でのポイントが高いことが明らかになりました。

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。

4. 平成30年度活動の概要

本年度は昨年度と比べて学会発表、論文発表ともに減少しております。英文での論文発表数が昨年に比べると減少しているため、さらなる努力が必要であると考えられます。

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。

5. 平成30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
20件	25532 千円	55.5%	有

7. 平成30年度の研究発表

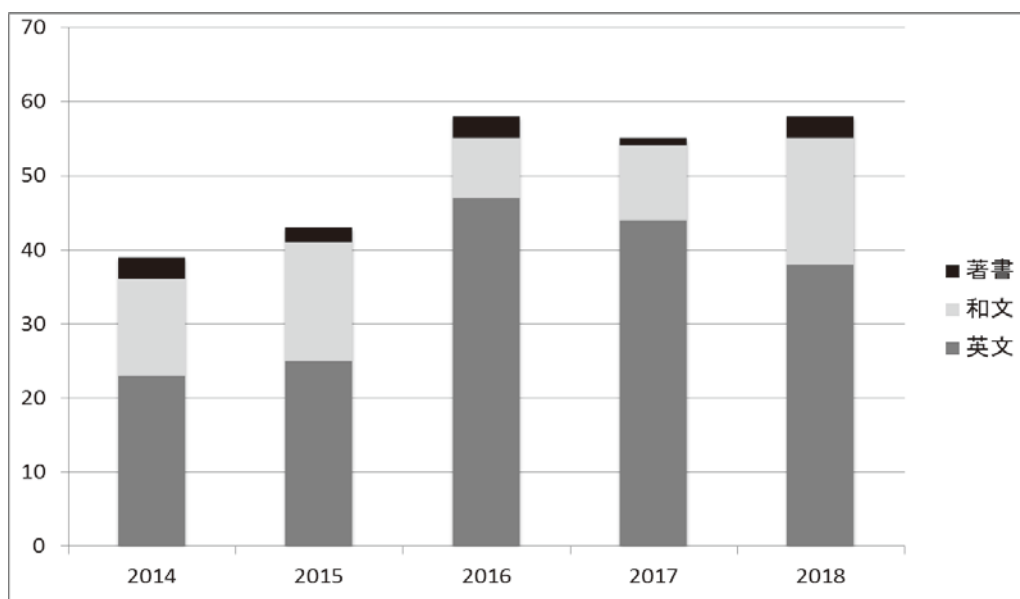
(1) 学会発表：国内 99件、国際 11件、 合計 110件

(2) 論文発表：和文 17編、英文 38編、 合計 55編

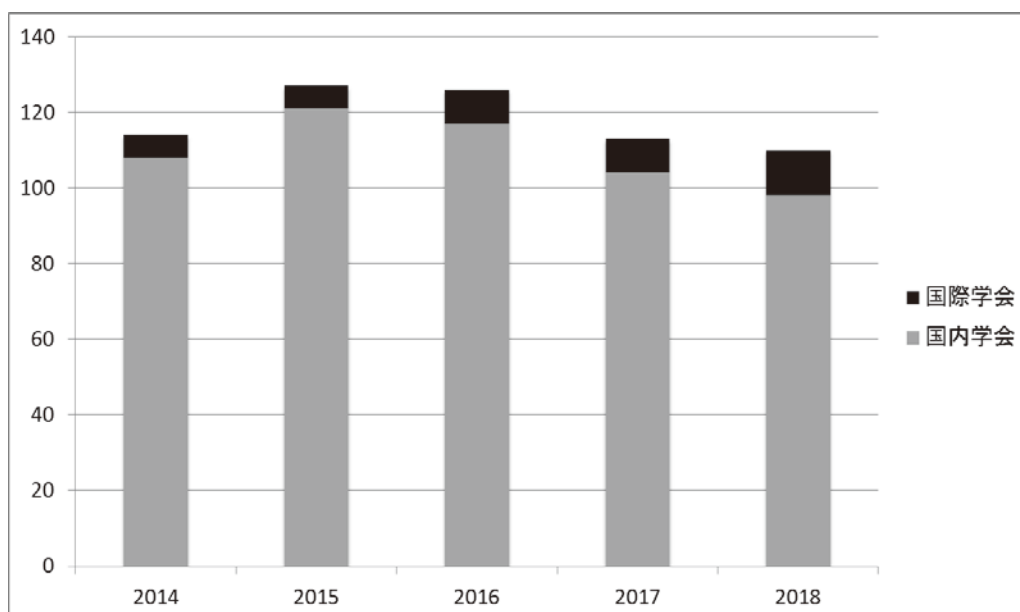
※ ただし、学会抄録、研究班報告書は含まない。

※ 英文は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)
	青木 千賀子	(日本大学国際関係学部教授)
	高田 宗享	(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	阿部 彰子	(医局長)
委員	本間 豊	(副医局長)
委員	古山 雅博	(事務部長)
委員	高木 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)

9. 2018年度新規受託研究一覧

(1) 治験

研究課題	依頼者	責任医師
M16-006 試験又は M15-991 試験の導入療法で改善したクローン病患者を対象として risankizumab の有効性及び安全性を評価する多施設共同無作為化二重盲検プラセボ対照 52 週間維持療法試験及び非盲検継続投与試験	アッヴィ合同会社	消化器内科 部長 大西佳文
中等症から重症の活動性潰瘍性大腸炎患者を対象とした (ABT-494) の導入療法及び維持療法における安全性を評価する多施設共同無作為化二重盲検プラセボ対照試験	アッヴィ合同会社	消化器内科 部長 大西佳文
M16-066 試験の導入療法で改善した潰瘍性大腸炎患者を対象として risankizumab の有効性及び安全性を評価する多施設共同無作為化二重盲検プラセボ対照 52 週間維持療法試験及び非盲検継続投与試験	アッヴィ合同会社	消化器内科 部長 大西佳文
うっ血性心不全患者を対象とした OPC-61815 の第Ⅲ相試験	大塚製薬株式会社	循環器内科 臨床研究部長 田邊 潤
生物学的製剤が奏効しなかった中等症から重症の活動性潰瘍性大腸炎患者を対象とした risankizumab の有効性及び安全性を評価する多施設共同無作為化二重盲検プラセボ対照導入療法試験	アッヴィ合同会社	消化器内科 部長 大西佳文
中等症から重症の活動性クローン病患者を対象として risankizumab の有効性及び安全性を評価する多施設共同無作為化二重盲検プラセボ対照導入療法試験	アッヴィ合同会社	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
デュオドーパ配合経腸用液特定 使用成績調査（長期使用）	アッヴィ合同会社	脳神経内科 診療部長 本間 豊
ソリリス点滴静注 300mg 全身型重症筋無力 症に関する特定使用成績調査	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
ビンダケルカプセル 特定使用成績調査 ー長期使用に関する調査ー	ファイザー株式会社	循環器内科 臨床研究部長 田邊 潤
プラルエント皮下注 特定使用成績調査（J-POSSIBLE）	サノフィ株式会社	循環器内科 臨床研究部長 田邊 潤
ウプトラビ錠 0.2mg・0.4mg 特定使用成績調査（長期使用に関する調査）	日本新薬株式会社	循環器内科 臨床研究部長 田邊 潤

(3) 副作用・感染症報告

研究課題	依頼者	責任医師
アバスチン副作用詳細報告	中外製薬株式会社	外科 院長 中野 浩
バイステージ 370 注 100mL 副作用詳細報告	武田テバファーマ 株式会社	放射線科 部長 阿部彰子
サインバルタカプセルの副作用調査	塩野義製薬株式会社	脳神経外科 高橋照男

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教授）
外部委員	高田 宗享	（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	阿部 彰子	（医局長）
委員	本間 豊	（副医局長）
委員	古山 雅博	（事務部長）
委員	高木 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
右室ペーシング時の心室内興奮伝播の解析	循環器内科 部長 小鹿野道雄
静岡県東部地域における急性心不全患者の実態	循環器内科 部長 小鹿野道雄
胆道ビデオスコープ CHF-Y0012 の操作性の評価	消化器内科 部長 大西佳文
医療用麻薬に関する看護学生の認識度調査と薬剤師による教育効果の検証	薬剤部 主任 彦坂麻美
心臓デバイス装着患者における MR 検査の施行体制の検討	放射線科 診断部長 阿部彰子

(2) 多施設共同研究

研究課題	研究代表機関	研究責任者
我が国における心臓植え込み型デバイス治療の登録調査	山口大学医学部附属病院	循環器内科 部長 小鹿野道雄
カテーテルアブレーション症例全例登録プロジェクト (J-AB レジストリ)	東京慈恵医科大学病院	循環器内科 部長 小鹿野道雄
日本化学療法学会・日本感染症学会・日本臨床微生物学会 三学会合同サーベイランスー歯科・口腔外科領域感染症ー	三学会合同	歯科口腔外科 医長 新井俊弘
心房細動カテーテルアブレーション術後の血液バイオマーカーの変動と心房細動再発、血栓塞栓症イベントとの関連性の検討	日本医科大学附属病院	循環器内科 臨床研究部長 田邊 潤
難病患者の総合的支援体制に関する研究	難病患者の支援体制に関する研究班	脳神経内科 副院長 溝口功一
スモンに関する調査研究	国立病院機構鈴鹿病院	脳神経内科 副院長 溝口功一
2 型糖尿病合併急性心筋梗塞を有する患者の心突然死に対するエンパグリフロジンとプラセボのランダム化比較研究	日本医科大学附属病院	循環器内科 部長 小鹿野道雄

筋萎縮性側索硬化症の発症・進行・予後に関する因子の探索	難病患者の地域支援体制に関する研究班	脳神経内科 副院長 溝口功一
中下部胆道閉塞を伴う切除不能膵がんに対する 10mm 径および 14mm 径金属ステントの無作為化比較第Ⅲ相試験	静岡がんセンター	消化器内科 部長 大西佳文
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	静岡医療センター	リハビリテーション科 鬼頭和也
カテーテルアブレーションを施行した非弁膜症性心房細動症例の抗凝固療法の実態とその予後に関する観察研究 RYOUMA	日本医科大学付属病院	循環器内科 部長 小鹿野道雄
深部静脈血栓症及び肺血栓塞栓症の治療及び再発抑制に対するリバーロサバンの有効性及び安全性に関する登録観察研究	日本医科大学付属病院	循環器内科 臨床研究部長 田邊 潤

(3) 受託研究

研究課題	研究代表機関	研究責任者
Orsiro 薬剤溶出ステント及び冠動脈拡張用バルーンの使用実態調査	日本ライフライン株式会社	循環器内科 臨床研究部長 田邊 潤
人工股関節大腿骨コンポーネント「INHERITOR システム」の市販後使用成績調査	京セラ株式会社 メディカル事業部	整形外科 部長 太田周介
Lima セメントレス・フェモラル・システム 観察研究	日本リマ株式会社	整形外科 部長 太田周介
スマートステント市販後調査	Cardinal Health Japan 合同会社	循環器内科 臨床研究部長 田邊 潤
TMP IAB カテーテル Lightning 使用成績調査	ディービーエックス 株式会社	循環器内科 臨床研究部長 田邊 潤
PTCA 及び PTA 関連製品に関する市販後調査	オーバスネイチメディカル 株式会社	循環器内科 臨床研究部長 田邊 潤

4) 特定臨床研究

研究課題	研究代表機関	責任医師
2 型糖尿病合併急性心筋梗塞を有する患者の心突然死に対するエンバグリフロジンとプラセボのランダム化比較試験 EMBODY trial	日本医科大学付属病院	循環器内科 部長 小鹿野道雄
骨折リスクの高い原発性骨粗鬆症患者に対する骨粗鬆症治療薬の骨折抑制効果検証試験週 1 回テリパラチド製剤とアレンドネート製剤の群間比較試験 JOINT05	日本骨粗鬆症学会	整形外科 部長 太田周介

5) 他院で実施の研究

研究課題	研究責任者
高齢者糖尿病ガイドライン設定前後の治療実態についての検討	麻生克己
2 型糖尿病通院患者における癌発症についての検討	麻生克己

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不安定プラークを有する頸動脈狭窄症に対していかに安全に CAS を行うか；遠位バルーン閉塞下吸引返血法の有用性

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3) 臼杵乃理子、野越慎司、辰野健太郎、濱田祐樹、深野崇之、徳山承明、高石 智、吉田泰之、小野 元、高田達郎、植田敏浩

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発症から 6 時間以上経過してから施行した前方循環脳主幹動脈閉塞に対する血栓回収療法の当院での治療成績

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鑑別に難渋した HCA の 1 切除例

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3) 大西佳文、榎澤哲司、宮原利行、中野 浩

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7) 大西佳文、吉田有徳

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第 70 回日本消化器画像診断研究会 2019.2.23 (東京)

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第 73 回静岡県癌治療研究会 2018.9.15 (静岡)

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5) 石上雄太、高橋 啓、宮原利行、松下恒久、角 泰廣、中野 浩、吉田有徳、谷 佐世、大西佳文

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第 80 回日本臨床外科学会総会 2018.11.23 (東京)

7) 加藤喜彦、角 泰廣、松下恒久、宮原利行、高橋 啓、石上雄太、中野 浩

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9) 松下恒久、角 泰廣、宮原利行、高橋 啓、石上雄太、中野 浩

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10) 高橋 啓、角 泰廣、松下恒久、宮原利行、石上雄太、中野 浩
TAPP(transabdominal preperitoneal repair)法で修復した膀胱ヘルニアの1例
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11) 石上雄太、角 泰廣、松下恒久、宮原利行、高橋 啓、中野 浩
若年男性に発症し肝FNHが疑われた1例
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2) 太田周介、岡本康義、上用祐士、土井孝信
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3) 米津大貴
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4) 太田周介
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第55回日本リハビリテーション医学会学術集会 2018.6.28 (福岡)

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- 8) 内山田修一、星野啓介、室 秀紀、戸野祐二、福田 誠、多和田兼章、五十棲秀幸、井上淳平、大野木宏洋、加藤治朗
 当院における非転位型大腿骨頸部骨折に対する Hansson pin と Hansson pinloc の
 前向き比較試験の検討
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- 1 0) 加藤治朗、太田周介、土井孝信、米津大貴
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- 1 2) 米津大貴、土井孝信、加藤治朗、福島悠太郎、町田ゆり子、森 雄司、竹下直紀、松永 香、高瀬三貴子、太田周介
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- 1 3) 加藤治朗、太田周介、土井孝信、米津大貴
 デノスマブ中断後に胸椎圧迫骨折を生じた関節リウマチ患者の 1 例
 第 44 回静岡県リウマチ懇話会 2019.1.26 (静岡)
- 1 4) 米津大貴、太田周介、土井孝信、加藤治朗
 足関節開放骨折術後の感染性偽関節に対し腓骨遠位端切除を行った 1 例
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- 1 5) 米津大貴、太田周介、土井孝信、加藤治朗
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当院における低侵襲手術の試み

第 99 回沼津医師会臨床医学集談会 2019.1.26 (沼津)

9) 波里陽介

計画的 LABP 下に行ったハイリスク大動脈弁置換

第 12 回静岡県東部心臓外科循環器科連携の会 2019.2.1 (沼津)

【皮膚科】

1) 前波真梨子、杉山由華、戸倉新樹

Gottron 丘疹を契機に食道癌と診断された 1 例

第 122 回日本皮膚科学会静岡地方会 2018.10.13 (三島)

【泌尿器科】

1) 間庭章光

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第 56 回日本癌治療学会学術集会 2018.10.18-20 (横浜)

【眼科】

1) 片山雄治

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【放射線科】

1) 阿部彰子、一瀬あずさ、五十嵐郁己、杉山 彰、小鹿野道雄

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2) 五十嵐郁己、阿部彰子、一瀬あずさ、杉山 彰

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【麻酔科】

1) 小澤章子

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非挿管患者の鎮静教育を始めよう

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2) 小澤章子

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3) 小澤章子

「酸素がなければ生きられない」

～院内医療ガス安全・管理委員会の役割～

第 99 回沼津医師会臨床医学集談会 2019.1.26 (沼津)

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夢を語ろう「20@@年@月@日鎮静研修」

～初期研修医 2 年目 A 先生の日記より～

第 31 回日本老年麻酔学会 2019.2.2 (東京)

【研修医】

1) 石井宏和、阿部彰子、宮原利行、石上雄太、中野 浩、米津大貴

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2) 黒坂洋平、阿部彰子、田尻正治、河合憲一

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【薬剤部】

1) 今田美里、内野達宏、柴田晋弥、稲葉真実、片岡市義、滝 久司、

高木 亮

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2) 薄 雅人、黒田勝宏、塩川幸子、市川竜太郎、上田真也、滝 久司、

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第 4 回日本医薬品安全性学会 2018.8.18 (倉敷)

3) 上田真也、薄 雅人、田代 匠、稲葉真美、彦坂麻美、深見和宏、
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アセトアミノフェンをアンカードラッグとして使用した

大腿骨転子部骨折の周術期疼痛管理の検討

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大規模コホートをを用いた抗てんかん薬による脂質異常症の発症リスクの検討

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認知症ケアチームが介入したせん妄患者における薬物療法の実態調査

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1 1) 片岡市義

プレアボイド事例報告

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1 2) 内野達宏

NST 認定

THP 教育研修地区勉強会 in 静岡 2018.12.8 (静岡)

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緩和認定

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1 4) 無藤大地

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当院における高齢者に対する転倒予防訓練介入の検討～TUGに着目して～
第22回静岡県理学療法士学会 2018.6.24 (静岡)

4) 鬼頭和也、加藤倫卓、光地海人、森本大輔、森 雄司、角谷星那、福富弥生、高木寿人

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1) 丹羽正人

CONUT 法に変わる CONUT 変法は、栄養スクリーニング指標として有用か？
(第 1 報)
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4) 土原菜美

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急性期病院における認知症ケアチームの活動報告
ー多職種協働による介入事例報告ー
第 72 回国立病院総合医学会 2018.11.9 (神戸)

【管理課】

1) 岸本英祐

勤務環境への取り組み あなたの上司は年休取っていますか？
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1) 土屋早紀、桑原啓吏、溝口功一

病院機能移転後の静岡医療センターの短期入所の現状
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1) 岡崎貴裕

現在の大型血管炎の考え方と治療

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【脳神経内科】

1) 溝口功一

～病気を理解し安心して暮らすために～

症状に合わせた生活の仕方、取り入れたいこと

脊髄小脳変性症・多系統萎縮症講演会 2018.11.18 (沼津)

2) 溝口功一

災害に備えた難病患者への支援

難病講演会 2019.1.24 (柳井)

3) 溝口功一

神経難病における地域連携～これまでの経験から～

平成 30 年度東部保健所難病患者在宅療養支援者研修会 2019.1.31 (三島)

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要配慮者として難病患者の災害対策

平成 30 年度難病患者等災害時要配慮者の避難支援関係者研修会

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5) 溝口功一

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平成 30 年度難病患者災害連絡協議会 2019.2.15 (静岡)

【消化器内科】

1) 大西佳文

胆道鏡による内視鏡診断と治療 (胆道癌を含む)

沼津外科医会 第 393 回外科懇話会 2018.4.16 (沼津)

【循環器内科】

1) 小鹿野道雄

CRT の最適化

第 11 回植込みデバイス関連冬季大会 2019.2.14-16 (東京)

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。

Ⅲ. 胆嚢 1. ポリープ—2 cm くらいまで

胆嚢早期癌

—Ip型, Is型, Ib+IIa型—

Early gallbladder carcinoma: Type of Ip, Is, Ib+IIa

大西佳文・吉田有徳・谷 佐世・榎澤哲司

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key words: 早期胆嚢癌, 腺腫内癌, ICPN, CEUS, RAS

■ 疾患の概要

胆道癌取り扱い規約（以下、規約）第5版での早期胆嚢癌の定義は、リンパ節転移の有無は問わず、組織学的深達度が粘膜内または固有筋層内にとどまるものとされている。規約第6版に記載はないが、TisおよびT1(a), T1(b)が早期胆嚢癌に相当する。その肉眼型は隆起型(I型), 表面型(II型), 陥凹型(III型)に分類され、I型は有茎性(Ip)と無茎性(Is)に、II型は表面隆起型(IIa), 表面平坦型(IIb), 表面陥凹型(IIc)に亜分類されるが、陥凹型IIcやIII型は存在しない。頻度はI型37%, II型63%で、I型のうちIpが7%, Isが30%で、その他は混在型である¹⁾。Is病変のほとんどは周囲にIIaやIIb病変を伴い、IIa病変の半数は周囲にIIb病変を伴う。また、Ip型は周囲にII型病変を伴うことは稀で、ほとんどが腺腫内癌で進行癌は存在しない。したがってIp型であれば早期癌とも考えられる。

■ 症例の概要と画像所見の読み方

【症例1】52歳女性。概要は図1の冒頭に記載した。CTでは体部に後期相まで遷延する弱い造影効果の隆起性病変を認めた(図1a)。超音波内視鏡(EUS)では、表面分葉状、内部は無エコー領域を有する実質様高エコーであった(図1b)。造影超音波(CEUS)では、1分後から有茎部が明瞭に染影され、Ip型胆嚢腫瘍を疑った(図1c)。術中エコーでは有茎も否定できず胆嚢床切除術を施行した。剖面像(図1d)では細い茎を有し、ルーペ像(図1e)では腺腫を疑った。ミクロ像では核異型や構造異型を有する領域もあり、腺腫内癌と診断した(図1f)。

【症例2】67歳女性。概要は図2の冒頭に記載した。CTではRokitansky-Ashoff洞(RAS)上部に造影効果を有するIs病変を認めた(図2a)。内視鏡的逆行性胆道造影(ERC)では透亮像を認めた(図2b)。EUSでは乳頭状Is病変はRAS内進展し、内側低エコー層の軽度肥

厚を認めた(図2c)。SS浸潤も否定できず胆嚢床切除術を施行した。剖面像(図2d)では無茎性の乳頭状腫瘍でRAS内部に白色調粘液貯留を認めた。ルーペ像(図2e)ではRAS上部に乳頭状腫瘍が内部に表層進展していた。ミクロ像(図2f)ではfibro-vascular coreを有する乳頭状腫瘍で、ICPN (intracholecystic papillary-tubular neoplasms of the gallbladder) high grade, 規約ではpTis-RAS(SS)と診断した。

【症例3】82歳男性。概要は図3の冒頭に記載した。USで胆嚢壁が全周性に肥厚し、体部には乳頭状隆起性病変を認めた。病変内部の血流速度は23.7cm/秒(図3a)であった。EUSでは内側低エコー層のびまん性肥厚と低エコーを示す隆起性病変を認めた(図3b)。CTでは造影効果を有するびまん性壁肥厚と造影効果の弱い隆起性病変を認めた(図3c)。ERC(図3d)では結石と不整透亮像を認め、IIb+IIa病変を疑い、SS浸潤も否定できなかった。全身状態を考慮して、胆嚢床切除術および領域リンパ節郭清を施行した。固定後標本(図3e)では、胆嚢全域に拡がる平坦IIb病変と多発乳頭状IIa病変を認めた。異型円柱上皮が粘膜全域に拡がり、一部で乳頭状増殖していた(図3f)。深達度MPの乳頭状腺癌、ly0, v0, pn0であり、広範IIbにIIa病変を伴った早期胆嚢癌と診断した。

■ 鑑別疾患と鑑別点

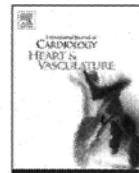
Ip型胆嚢癌の鑑別は、コレステロールポリープや過形成性ポリープ、繊維性ポリープなどである。EUSの鑑別所見として、腫瘍では表面乳頭状、結節状で、内部は実質様低エコーを示し、非腫瘍では表面平滑で、内部は点状高エコー、間質高エコーを示す。II型病変では慢性胆嚢炎による壁肥厚との鑑別が重要である。壁に胆嚢動脈の最大血流速度が35.2cm/秒で良悪性の有意差を認め、鑑別診断に有用との報告もある。

■ 治療方針

術前に胆嚢癌を強く疑う症例では、pT1であっても原則、開腹胆嚢摘出術を行うべきである。pT1早期胆嚢癌では、リンパ節転移はほとんどないため、断端陰性であれば胆嚢摘出術のみとし、追加切除は必要ないとされている²⁾。

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Mid-term feasibility and safety of downgrade procedure from defibrillator to pacemaker with cardiac resynchronization therapy

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ABSTRACT

Backgrounds: Some patients who undergo implantation of cardiac resynchronization therapy with defibrillator (CRT-D) survive long enough, thus requiring CRT-D battery replacement. Defibrillator therapy might become unnecessary in patients who have had significant clinical improvement and recovery of left ventricular ejection fraction (LVEF) after CRT-D implantation.

Methods: Forty-nine patients who needed replacement of a CRT-D battery were considered for exchange of CRT-D for cardiac resynchronization therapy with pacemaker (CRT-P) if they met the following criteria: LVEF >45%; the indication for an implantable cardioverter defibrillator was primary prevention at initial implantation and no appropriate implantable cardioverter defibrillator therapy was documented after initial implantation of the CRT-D.

Results: Seven patients (14.2%) were undergone a downgrade from CRT-D to CRT-P without any complications. No ventricular tachyarrhythmic events were observed during a mean follow-up of 39.7 ± 21.1 months and there was no significant change in LVEF between before and 1 year after device replacement ($53.5\% \pm 6.2\%$ vs. $56.4\% \pm 7.3\%$, $P = 0.197$).

Conclusions: This study confirmed mid-term feasibility and safety of downgrade from CRT-D to CRT-P alternative to conventional replacement with CRT-D.

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1. Introduction

Some patients with an implanted cardiac resynchronization therapy (CRT) device with defibrillator (CRT-D) are confirmed to have significant clinical improvement and recovery of left ventricular ejection fraction (LVEF) during follow-up and are therefore less likely to require implantable cardioverter-defibrillator (ICD) therapies [1]. In the Multicenter Automatic Defibrillator Implantation Trial with Cardiac Resynchronization Therapy (MADIT-CRT), patients who showed recovery of LVEF (>50%) after CRT were reported to have very low absolute and relative risks of ventricular tachycardia/fibrillation (VT/VF) [2]. These patients could be considered for downgrade from a CRT-D to a CRT with pacemaker (CRT-P) at the time of battery replacement. Although several observational studies [3–6] have indicated the possibility of such a downgrade procedure, there have been no relevant feasibility and safety studies.

In this study, we aimed to investigate the feasibility and safety of a downgrade from CRT-D to CRT-P in selected patients who achieved significant improvement of left ventricular function after CRT.

2. Materials and methods

2.1. Study population

This is a prospective, single-center, and non-randomized study involving 49 consecutive patients who underwent CRT-D generator replacement because of battery depletion from December 2012 to December 2017. Patients who needed device replacement because of device-related infection or lead malfunction/fracture were excluded.

2.2. Criteria for downgrade from CRT-D to CRT-P

Patients were deemed eligible for a downgrade from CRT-D to CRT-P if they met the following criteria: LVEF >45% on echocardiography at the time of battery depletion; initial ICD implantation for primary prevention; no VT/VF events since initial CRT-D implantation; and

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臨床経験

重症大動脈弁狭窄症を有する開腹手術症例に対する術前IABP挿入の経験

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大動脈弁狭窄症は周術期リスクが高い心疾患とされており、重症例では非心臓手術を中止するか、もしくは大動脈弁治療を先行させることが望ましいとされているが、緊急手術・悪性腫瘍手術では開腹手術を先行せざるをえない状況も存在する。今回われわれは、当院で術前に心臓超音波検査で重症大動脈弁狭窄症と診断され、IABP挿入下に開腹手術を施行した5例について検討した。平均年齢は72.2歳で、男性3例、女性2例であった。緊急手術症例が1例であり、悪性腫瘍手術が4例であった。心臓超音波検査での収縮期平均圧較差は平均33.68mmHgで平均弁口面積は平均0.722cm²であった。IABPの平均留置期間は3.4日で、IABP留置による合併症は認めなかった。1例に在院死を認めたが、心合併症は認めなかった。重症大動脈弁狭窄症を合併した開腹手術症例に対する術前IABP挿入は、周術期管理の面で有用な手技である可能性が示唆された。

索引用語：IABP、開腹手術、重症大動脈弁狭窄症

緒 言

開腹手術を必要とする患者の高齢化により、術前に様々な合併症を有する場合が多くなってきている。合併症の中でも心疾患は術中、周術期を含めて生命的危機をきたす可能性があり注意を要する。さらに、大動脈弁狭窄症 (aortic valve stenosis; 以下, AS) は周術期リスクが高い心疾患とされており、非心臓手術における周術期死亡率が約10%との報告もある¹⁾。非心臓手術における合併心疾患の評価と管理に関するガイドラインでは、重症ASを合併する症例では非心臓手術を中止するか、もしくは大動脈弁治療を先行させることが望ましいとされている²⁾。しかしながら、消化管出血・穿孔などの緊急手術例や悪性腫瘍症例など、開腹手術を先行して施行せざるを得ない状況も存在する。今回われわれは、重症ASを合併した開腹手術先行症例に対して術前に大動脈内バルーンポンピング (intra aortic balloon pumping; 以下, IABP) を挿入し、その有用性と安全性をretrospectiveに検討した。

対象と方法

2011年1月から2015年12月末までの5年間で経胸壁心臓超音波検査で重症ASと診断し、術前IABP留置後に開腹手術を施行した5例を対象とし、IABP挿入に伴う問題点を含めた合併症ならびに転帰につき検討した。

患者の年齢は63～79歳 (平均72.2歳)、男女比は3:2であった。開腹手術の原疾患は胃穿孔、S状結腸癌 (T3N1M0 Stage IIIa)、肝細胞癌 (T3N0M0 Stage III)、回盲部悪性リンパ腫、肝細胞癌 (T3N0M0 Stage III) であった。胃穿孔の1例は緊急手術であった。肝細胞癌の1例は門脈右枝の腫瘍栓を伴っており、悪性リンパ腫症例は出血と閉塞性イレウスをきたしており、いずれも進行癌症例であった (Table 1)。

ASの程度は経胸壁心臓超音波検査で判定した。左室駆出分画 (ejection fraction; 以下, EF) は40.3～73.7% (平均60.88%)、左室内径短縮率 (fractional shortening; 以下, FS) は25.7～40.8% (平均37.23%) と比較的保たれていた。収縮期大動脈平均圧較差は22.6～40.9mmHg (平均33.68mmHg)、収縮期大動脈最大圧較差は50.8～72.2% (平均64.55mmHg) で弁口面積は0.58～0.80cm² (平均0.723cm²) であった。症例①については詳細不明であった (Table 2)。

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腹腔鏡下鼠径ヘルニア修復術が有用であった再発鼠径ヘルニア嵌頓の1例*

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[外科 80 巻 12 号 : 1278 ~ 1281, 2018]

はじめに 成人再発鼠径ヘルニアに対する治療方針は再発部位の確実な診断、修復が可能である点から、近年腹腔鏡下手術の有用性に対する報告が散見されるようになってきた^{1~4)}。鼠径部ヘルニア診療ガイドライン 2015⁵⁾では、既往手術が腹膜前修復法での再発では鼠径部切開法が推奨されているが、腹膜前修復法で治療されていない場合には腹腔鏡下ヘルニア修復術は手技に十分習熟した外科医が実施する場合において再発ヘルニアに適しているとされている（推奨度 B）。Mesh plug 法による両側鼠径ヘルニア術後の左鼠径ヘルニア嵌頓に対して、用手環納後腹腔鏡下に両側再発鼠径ヘルニア、右大腿鼠径ヘルニアと診断し修復した1例を経験したため報告する。

症 例

症 例 82 歳、男性

主 訴：左鼠径部膨隆、左鼠径部痛

既往歴：特記すべきことはない

現病歴：2002 年ごろ他院で両側鼠径ヘルニアに対して mesh plug 法による両側鼠径ヘルニア修復術を施行されていた。2017 年 6 月、突然左鼠径部の膨隆と強い疼痛を自覚したため近医を受診した。左鼠径ヘルニア再発による嵌頓を疑われ当科を紹介された。

来院時所見：身長 157 cm、体重 58.6 kg、両側鼠径部に手術瘢痕を認め、左鼠径部に手拳大の膨隆と圧痛を認めた。右鼠径部には手術瘢痕以外の明らかな異常を認めなかった。

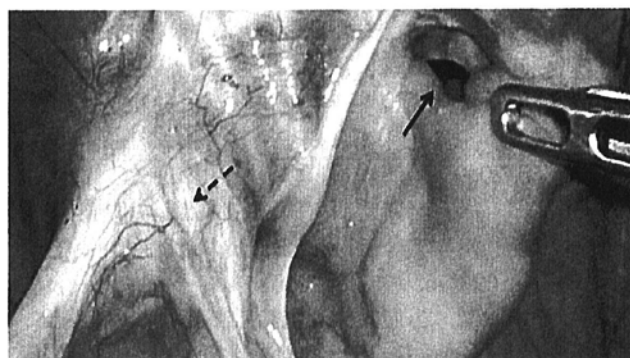


図1 腹腔鏡挿入時（左）

前回手術で挿入したプラグによる腹膜の膨隆（破線矢印）を認め、その内側にヘルニア門（実線矢印）を認める。

経 過：嵌頓症状発症から約2時間と早期であったため、まず用手的還納を行い入院での経過観察とした。腹部所見の悪化がないことを確認し、発症5日目に手術を行った。


手術所見：全身麻酔下に腹腔鏡下ヘルニア修復術（transabdominal preperitoneal repair : TAPP）を施行した。臍部に open method で 12 mm トロカールを挿入後炭酸ガスで気腹し、右側腹部に 12 mm、左側腹部に 5 mm のトロカールをそれぞれ挿入した。腹水は認めなかった。小腸、結腸を観察し、虚血性変化がないことを確認した。左内鼠径輪から腹腔側に突出するプラグを認め、その内側にヘルニア門を確認した。日本ヘルニア学会（Japanese Hernia Society : JHS）のヘルニア分類で Rec II-1 型と診断した（図1）。また、

キーワード：再発鼠径ヘルニア、腹腔鏡手術、鼠径ヘルニア嵌頓

* A case of incarcerated recurrence inguinal hernia treated by transabdominal preperitoneal repair

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Long-term survival after transcatheter versus surgical aortic valve replacement for aortic stenosis: A meta-analysis of observational comparative studies with a propensity-score analysis

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Abstract

Objectives: To synthesize evidence regarding long-term survival after transcatheter aortic valve implantation (TAVI) versus surgical aortic valve replacement (SAVR) for severe aortic stenosis (AS) from real-world clinical practice, we performed a meta-analysis of observational studies with a propensity-score analysis and ≥ 3 -year follow-up.

Methods: Databases including MEDLINE and EMBASE were searched through April 2017 using PubMed and OVID. Eligible studies were observational comparative studies with a propensity-score analysis of TAVI versus SAVR enrolling patients with severe AS and reporting ≥ 3 -year all-cause mortality as an outcome. A hazard ratio (HR) with its 95% confidence interval (CI) of follow-up (including early) mortality for TAVI versus SAVR was extracted from each individual study.

Results: Our search identified 14 eligible studies enrolling a total of 4,197 patients. A pooled analysis of all the 14 studies demonstrated a statistically significant 54% increase in mortality with TAVI relative to SAVR (HR, 1.54; 95% CI, 1.31–1.81; P for effect < 0.00001 ; P for heterogeneity = 0.14; $I^2 = 30\%$). Several sensitivity analyses did not substantially change the statistically significant benefit for SAVR. There was no evidence of significant publication bias.

Conclusions: On the basis of a meta-analysis of 14 observational comparative studies with a propensity-score analysis including a total of $> 4,000$ patients, TAVI is associated with worse ≥ 3 -year overall survival than SAVR.

KEYWORDS

aortic stenosis, long-term survival, meta-analysis, propensity-score analysis, surgical aortic valve replacement, transcatheter aortic valve implantation

1 | INTRODUCTION

To the best of our knowledge, five randomized controlled trials (RCTs) (Placement of Aortic Transcatheter Valves [PARTNER] 1 [1], PARTNER 2 [2], CoreValve US Pivotal [3], Nordic Aortic Valve Intervention [NOTION] [4], and Surgical Replacement and Transcatheter Aortic

Valve Implantation [SURTAVI] [5]) of transcatheter aortic valve implantation (TAVI) versus surgical aortic valve replacement (SAVR) for severe aortic stenosis (AS) reported ≥ 2 -year all-cause mortality. Although there is no statistically significant difference in follow-up mortality between TAVI and SAVR in all the five RCTs [1–5], ≥ 3 -year mortality is available in only two RCTs (PARTNER 1 [1] with 5-year follow-up and CoreValve US Pivotal [3] with 3-year follow-up). Furthermore, patients enrolled in RCTs may not be representative of those typically seen in real-world clinical practice. Indeed, approximate 80% (77.5% in

Hisato Takagi and Shohei Mitta contributed equally to this study and share the first authorship.

Meta-Analysis of the Prognostic Value of Psoas-Muscle Area on Mortality in Patients Undergoing Transcatheter Aortic Valve Implantation



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We performed a meta-analysis of currently available studies assessing prognostic value of psoas-muscle area (PMA) on mortality in patients who underwent transcatheter aortic valve implantation (TAVI). MEDLINE and EMBASE were searched through May 2018 to identify studies reporting ≥ 1 -year all-cause mortality in PMA-stratified TAVI patients. A hazard ratio of follow-up (including early) mortality for “lowest-quantile” versus “higher-quantiles” PMA. Study-specific estimates were combined in the random-effects model. Our search identified 6 eligible studies enrolling a total of 1,237 TAVI patients with 1-year to 2-year (midterm) follow-up. A primary meta-analysis pooling all hazard ratios for “lowest-quantile versus higher-quantiles” PMA demonstrated significantly higher mortality in “lowest-quantile” than “higher-quantiles” patients ($p < 0.0001$). A subgroup meta-analysis indicated no significant difference in mortality between “ < 50 th- and ≥ 50 th-percentile” patients ($p = 0.95$), but significantly higher mortality in “lowest-tertile” than “higher-tertiles” patients ($p = 0.0009$) and in “lowest-quartile” than “higher-quartiles” patients ($p = 0.0003$). A secondary meta-analysis revealed significantly higher mortality in “lowest-tertile” than “mid-tertile” patients ($p = 0.01$) and in “lowest-tertile” than “highest-tertile” patients ($p = 0.01$). A gender-stratified meta-analysis showed significantly higher mortality in “lowest-quantile” than “higher-quantiles” patients in both men ($p = 0.0008$) and women ($p = 0.01$). In conclusion, low PMA, especially “lowest-tertile/quartile” PMA, is a predictor of high all-cause mortality at midterm follow-up after TAVI for both men and women. However, PMA categorization into 50th percentiles may be invalid to predict mortality. © 2018 Elsevier Inc. All rights reserved. (Am J Cardiol 2018;122:1394–1400)

Sarcopenia means decreased muscle-tissue volume and function, as it ages and generally refers to the physiologic-reserve reduction in the body.¹ Psoas-muscle area (PMA), which is a core muscle and can reflect the skeletal-muscle status in the whole body,^{2,3} has been recently known as a sarcopenia marker.⁴ Low PMA may be associated with high postoperative mortality in patients who underwent endovascular and open (abdominal aortic) aneurysm repair (EVAR and OAR),⁵ whereas low psoas-muscle density, but not low PMA, may be a prognostic factor for survival in patients who underwent open cardiovascular surgery.⁶ Although results of a few studies have been published to date, it remains unclear whether low PMA is associated with mortality after transcatheter aortic valve implantation (TAVI) for severe aortic stenosis (AS). In the present study, we performed a meta-analysis of currently available studies assessing prognostic value

of PMA on mortality in patients who underwent TAVI.s

Methods

All studies investigating prognostic value of PMA on mortality after TAVI for severe AS were identified using a 2-level search strategy. First, databases including MEDLINE and EMBASE were searched through May 2018 using Web-based search engines (PubMed, OVID). Search terms included *psoas* and *aortic valve*. Second, relevant studies were identified through a manual search of secondary sources including references of initially identified studies and a search of reviews and commentaries. All references were downloaded for consolidation, elimination of duplicates, and further analyses.

Studies considered for inclusion met the following criteria: the study population was patients who underwent TAVI for severe AS; and main outcomes included ≥ 1 -year all-cause mortality in PMA-stratified patients. A hazard ratio (HR) with its 95% confidence interval (CI) of follow-up (including early) mortality for “lowest-quantile” PMA versus “higher-quantiles” PMA was extracted from each patient’s study (Table 1). In studies not reporting an HR with its 95% CI, it was calculated from Kaplan-Meier curve data (survival rates and patient numbers of at risk) or summary data (numbers of deaths and a log-rank, Mantel


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See page 1399 for disclosure information.

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A meta-analysis of ≥ 5 -year mortality in randomized controlled trials of off-pump versus on-pump coronary artery bypass grafting

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Abstract

Objectives: We sought to determine whether off-pump coronary artery bypass grafting (CABG) increases long-term mortality, by performing a meta-analysis of randomized controlled trials (RCTs) of off-pump versus on-pump CABG with ≥ 5 -year follow-up.

Methods: MEDLINE and EMBASE, and the Cochrane Central Register of Controlled Trials were searched through July 2018. Hazard, risk, or odds ratios (HRs, RRs, or ORs) of long-term (≥ 5 -year) mortality for off-pump versus on-pump CABG were extracted from each individual trial. Study-specific estimates were combined using inverse variance-weighted averages of logarithmic HRs in the random-effects model.

Results: Our search identified eight medium- to large-size RCTs at low risk of bias with long-term follow-up of off-pump versus on-pump CABG enrolling a total of 8780 patients. Combining four RCTs reporting actual HRs generated a statistically significant result favoring on-pump CABG (HR, 1.21; $P = 0.02$). A pooled analysis of all eight RCTs demonstrated a statistically significant increase in mortality with off-pump CABG (HR/RR, 1.19; $P = 0.01$). There was no evidence of significant publication bias in the meta-analysis of all eight RCTs. In a sensitivity analysis, extracting RRs or ORs from all eight RCTs and pooling them demonstrated a statistically significant increase in mortality with off-pump CABG (RR, 1.17; $P = 0.01$; OR, 1.20; $P = 0.007$). Eliminating 2 RRs and combining six HRs still generated a statistically significant result favoring on-pump CABG (HR, 1.19; $P = 0.05$).

Conclusions: Off-pump CABG increases long-term (≥ 5 -year) mortality compared with on-pump CABG.

KEYWORDS

coronary artery bypass grafting, long-term mortality, meta-analysis, off-pump, on-pump, randomized controlled trial

1 | INTRODUCTION

Previous studies have shown no difference in short-term (30-day) mortality between off-pump beating and on-pump coronary artery

bypass grafting (CABG).^{1–3} Off-pump CABG may reduce the incidence of postoperative stroke,^{1,2} renal dysfunction,³ mediastinitis,³ and atrial fibrillation.¹ Off-pump CABG has also been associated with a reduction in the length of ventilation^{1,3} and intensive care unit and hospital

A meta-analysis of valve-in-valve and valve-in-ring transcatheter mitral valve implantation

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Objectives: We performed a meta-analysis of transcatheter mitral valve implantation (TMVI) for deteriorated bioprosthetic valves (valve-in-valve [VIV]-TMVI) and/or failed annuloplasty rings (valve-in-ring [VIR]-TMVI), comparing observed early (30-day) mortality with predicted operative mortality.

Background: It remains unclear whether VIV/VIR-TMVI reduces mortality as compared with redo MVS.

Methods: MEDLINE and EMBASE were searched current through 24 July 2018 using Web-based search engines (PubMed and OVID) to identify studies including ≥ 10 patients undergoing VIV/VIR-TMVI. For each study, data regarding observed 30-day mortality and predicted operative mortality (Society of Thoracic Surgeons Predicted Risk of Mortality [STS-PROM]) were used to generate risk ratios (RRs) and 95% confidence intervals (CIs). Study-specific estimates were combined using the inverse variance-weighted average of logarithmic RRs in the random-effects model. One-group meta-analyses of 30-day/late (including 30-day) mortality rates were also performed in the random-effects model.

Results: Of 270 potentially relevant articles screened initially, 17 eligible studies including a total of 1017 patients undergoing VIV/VIR-TMVI were identified. In all but four studies, the STS-PROM was available and varied from 7.7% to 22.0% (weighted mean, 11.5%). Pooled analyses of all VIV/VIR-TMVI studies demonstrated the 30-day mortality rate of 5.4% (95%CI, 4.0-6.8%), the midterm (1- to 5-year) mortality rate of 13.7% (95%CI, 9.0-18.5%), and significantly lower observed 30-day mortality than predicted operative mortality (RR, 0.67; 95%CI, 0.49-0.91; $P = 0.01$).

Conclusions: VIV/VIR-TMVI brought about relatively low early and midterm (1- to 5-year) mortality, and observed 30-day mortality was significantly lower than predicted operative mortality.

KEYWORDS

meta-analysis, mortality, transcatheter mitral valve implantation, valve-in-ring, valve-in-valve

Transcatheter mitral valve replacement for mitral regurgitation—A meta-analysis

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Abstract

Objectives: We performed a meta-analysis to determine the outcomes in patients undergoing transcatheter mitral valve replacement (TMVR) for mitral regurgitation (MR).

Methods: Databases including MEDLINE and EMBASE were searched through April 2018 using Web-based search engines (PubMed and OVID) to identify single-arm observational (case series) studies of TMVR enrolling ≥ 5 patients with MR. For each study, data regarding observed 30-day mortality and predicted operative mortality (Society of Thoracic Surgeons Predicted Risk of Mortality) were used to generate risk ratios (RRs) and 95% confidence intervals (CIs). Study-specific estimates were combined using the inverse variance-weighted average of logarithmic RRs in the random-effects model. One-group meta-analyses of 30-day and >30-day (including 30-day) mortality were also performed in the random-effects model.

Results: Of 222 potentially relevant articles screened initially, nine eligible studies enrolling a total of 146 patients with MR undergoing TMVR were identified. In all but two studies, STS-PROM was available and varied from 3.3% to 15.4% (arithmetic mean, 7.6%). Pooled analyses demonstrated 30-day mortality of 20.4% (95%CI, 9.6-31.2%), >30-day mortality of 32.0% (95%CI, 19.8-44.2%), and non-significantly higher observed 30-day mortality than predicted operative mortality (RR, 1.70; 95%CI, 0.85-3.42; $P = 0.14$). There was no evidence of significant publication bias.

Conclusion: TMVR for patients with MR results in increased early and late mortality.

KEYWORDS

meta-analysis, mitral regurgitation, mortality, transcatheter mitral valve replacement

1 | INTRODUCTION

Available percutaneous options for mitral valve (MV) repair and replacement for high surgical-risk patients are increasing.¹ The shape of the MV is oval and saddle-like, and the annulus is not stiff, which makes it challengeable to implant a prosthesis within the MV.² Several biologic self-expanding prostheses have been currently and clinically

developed.³⁻¹⁰ Although transcatheter aortic valve replacement (TAVR) for low-to-moderate or moderate-to-high-risk patients with severe aortic stenosis (AS) is an established therapy,^{11,12} transcatheter mitral valve replacement (TMVR) for patients with severe symptomatic mitral regurgitation (MR) is still considered to be an evolving less-invasive alternative to open MV surgery (MVS) including repair and replacement.¹³ Neither observational comparative studies nor

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

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Thorac Cardiovasc Surg

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 meta-analysis 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 stroke (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 time-dependent cascade of events resulting in brain cell injury is initiated.¹ 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 of Valve-in-Valve Transcatheter versus Redo Surgical Aortic Valve Replacement

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Thorac Cardiovasc Surg

Abstract

Objective The objective of this study was to determine whether valve-in-valve 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 \geq 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 in-hospital) (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.

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.

Keywords

- ▶ degenerated aortic valve bioprostheses
- ▶ meta-analysis
- ▶ redo surgical aortic valve replacement
- ▶ valve-in-valve transcatheter aortic valve implantation

Introduction

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 STUDIES

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 aortic-valve 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, \geq 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 meta-analysis 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 \geq 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, \geq 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-analyses^{1–4} suggest that concurrent \geq 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 \geq 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

Meta-Analysis of Impact of Anemia and Hemoglobin Level on Survival After Transcatheter Aortic Valve Implantation



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To establish evidence whether baseline anemia and decreases in baseline hemoglobin levels affect survival after transcatheter aortic valve implantation (TAVI), we performed a meta-analysis of available studies. Studies considered for inclusion met the following criteria: the design was a comparative study of patients with baseline anemia versus those without baseline anemia or a cohort study investigating baseline anemia (as a dichotomous variable) or baseline hemoglobin levels (as a continuous variable) as one of prognostic factors of mortality; the study population was patients who underwent TAVI; and main outcomes included early (30-day or in-hospital) or late (including early) all-cause mortality. Study-specific estimates were combined in the random-effects model. Our search identified 15 eligible studies including a total of 11,657 TAVI patients. Pooled analysis demonstrated that baseline anemia was associated with a statistically significant increase in early ($p = 0.003$) and midterm mortality ($p < 0.0001$) and that incremental decreases in baseline hemoglobin levels were associated with a statistically significant increase in midterm mortality ($p < 0.00001$). Pooled analysis of only adjusted estimates indicated that anemia was independently associated with a statistically significant increase in early ($p = 0.02$) and midterm mortality ($p < 0.0001$) and that incremental decreases in baseline hemoglobin levels were independently associated with a statistically significant increase in midterm mortality ($p < 0.00001$). In conclusion, baseline anemia and lower baseline hemoglobin levels may be associated with increased early and midterm mortality after TAVI. © 2018 Elsevier Inc. All rights reserved. (Am J Cardiol 2019;123:306–314)

Baseline anemia is associated with increased early mortality, acute kidney injury, and infection after surgery and with increased early mortality also after cardiac surgery.¹

Anemia in percutaneous coronary intervention (PCI) is independently associated with twofold increased mortality, major adverse cardiovascular events (MACE), and major bleeding, with risk elevation related to incremental decreases in hemoglobin levels.² Because blood transfusion is more frequent in patients with anemia, diagnosis of anemia may change clinical practice in surgery and intervention. Blood transfusion also is independently associated with threefold increased mortality and MACE after PCI with dose-dependent adverse influence on mortality.³ Although several studies reported impact of baseline anemia and hemoglobin levels on survival after transcatheter aortic valve implantation (TAVI) for patients with severe aortic stenosis, no meta-analysis of

them has been conducted to date. In the present article, to establish evidence whether baseline anemia and decreases in baseline hemoglobin levels affect survival after TAVI, we performed a meta-analysis of available studies.

Methods

All studies investigating impact of anemia and hemoglobin levels on survival after TAVI were identified using a 2-level search strategy. First, databases including MEDLINE and EMBASE were searched through June 2018 using Web-based search engines (PubMed, OVID). Second, relevant studies were identified through a manual search of secondary sources including references of initially identified articles, reviews, and commentaries. All references were downloaded for consolidation, elimination of duplicates, and further analysis. Search terms included *anemia*, *anaemia*, *anemic*, *anaemic*, *hemoglobin*, *haemoglobin*, *hematocrit*, or *haematocrit*; *percutaneous*, *transcatheter*, *transluminal*, *transarterial*, *transapical*, *transaortic*, *transcarotid*, *transaxillary*, *trans-subclavian*, *trans-subclavian*, *transiliac*, *transfemoral*, *transiliofemoral*, or *transcaval*; *aortic valve*; and *implantation* or *replacement*.

Studies considered for inclusion met the following criteria: the design was a comparative study of patients with baseline anemia versus those without baseline

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Meta-Analysis of Impact of Baseline N-Terminal Pro-Brain Natriuretic Peptide Levels on Survival After Transcatheter Aortic Valve Implantation for Aortic Stenosis



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We performed a meta-analysis of currently available studies investigating impact of baseline N-terminal pro-brain natriuretic peptide (NT-proBNP) on mortality after transcatheter aortic valve implantation (TAVI) for aortic stenosis (AS). MEDLINE and EMBASE were searched through August 2018 using PubMed and OVID. Studies considered for inclusion met the following criteria: the design was a study researching impact of baseline NT-proBNP levels on survival; the study population was patients underwent TAVI for AS; outcomes included all-cause mortality. For each study, we directly extracted odds ratio (ORs) or hazard ratios (HRs) of mortality (for high vs low baseline NT-proBNP); and generated ORs using mortality rates in both patients with high and low levels of baseline NT-proBNP. Study-specific estimates were combined using inverse variance-weighted averages of logarithmic ORs/HRs in the random-effects model. We identified 16 eligible studies including a total of 3,679 patients who underwent TAVI for AS. Pooled analyses demonstrated that high levels of baseline NT-proBNP were associated with a statistically nonsignificant increase in early (30-day or 2-month) mortality (pooled OR, 1.60; 95% confidence interval, 0.84 to 3.04; $p = 0.15$) and a statistically significant increase in midterm (6-month to 4-year) mortality (pooled OR/HR, 1.88; 95% confidence interval, 1.54 to 2.28; $p < 0.00001$). Although funnel-plot asymmetry suggesting publication bias was detected, adjusting for funnel-plot asymmetry indicated an association of high levels of baseline NT-proBNP with a still significant increase in midterm mortality. In conclusion, high levels of baseline NT-proBNP predict increased midterm, not early, mortality after TAVI for AS. © 2018 Elsevier Inc. All rights reserved. (Am J Cardiol 2019;123:820–826)

In patients with asymptomatic and symptomatic aortic stenosis (AS), brain natriuretic peptide (BNP), and its N-terminal pro-form (NT-proBNP) are independently associated with outcomes.¹ Preoperative BNP and NT-proBNP also are predictors of outcomes after surgical aortic valve replacement for AS.^{2,3} A number of studies have recently investigated associations of BNP and NT-proBNP with outcomes after transcatheter aortic valve implantation (TAVI). A meta-analysis⁴ (published in 2014) showed that preprocedural proBNP predicted 30-day and 1-year mortality after TAVI; however, extremely wide confidence intervals (CIs) of pooled odds ratios (ORs) suggest low statistical power of the analysis probably due to inclusion of few studies and events. In the present article, we

performed a meta-analysis of currently available studies researching impact of baseline NT-proBNP on survival after TAVI.

Methods

We performed a meta-analysis in accordance with the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guideline (available from <http://www.prisma-statement.org>). All studies investigating impact of baseline NT-proBNP levels on mortality after TAVI for AS were identified using a 2-level search strategy. First, databases including MEDLINE and EMBASE were searched through August 2018 using Web-based search engines (PubMed and OVID). Search terms included *natriuretic peptide(s)*; *percutaneous, transcatheter, transluminal, transarterial, transapical, transaortic, transcarotid, transaxillary, trans-subclavian, transubclavian, transiliac, transfemoral, transiliofemoral, or transcaval; aortic valve; and implantation(s) or replacement(s)*. Second, relevant studies were identified through a manual search of secondary sources including references of initially identified articles, reviews, and commentaries. All references were downloaded for consolidation, elimination of duplicates, and further analyses.

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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 (in-hospital/30-day) mortality ($P = 0.28$), but a statistically significant association of liver disease with increases mid-term (1–2-year) mortality (hazard ratio 1.87, $P < 0.00001$) in

TAVI patients, and no statistically significant difference in in-hospital 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.¹ 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 liver-related 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,³ 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.⁴ 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 (MEDLINE, EMBASE, and the Cochrane Central Register of Controlled Trials) through July 2018 by use of Web-based 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 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

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]. Postprocedural \geq 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 and Meta-Regression of Transcatheter Aortic Valve Implantation for Pure Native Aortic Regurgitation

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Q4 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-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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Impact of low-flow/low-gradient aortic stenosis on survival after transcatheter aortic valve implantation --Manuscript Draft--

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Abstract:	<p>Aims To determine whether low-flow/low-gradient (LF/LG) aortic stenosis (AS) 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 (1) classical LF/LG (C/LF/LG) AS versus normal-flow/high-gradient (NF/HG) AS, (2) paradoxical LF/LG (P/LF/LG) AS versus NF/HG AS, and (3) C/LF/LG AS versus P/LF/LG AS were included. Study-specific estimates, risk and hazard ratios (RRs and HRs) of mortality, were combined in the random-effects model. Results Our search identified 9 eligible studies including a total of 5512 TAVI patients. Pooled analysis demonstrated significantly higher early mortality in C/LF/LG AS than NF/HG AS (RR, 1.72; P = 0.02) and no statistically significant difference in early mortality between P/LF/LG AS and NF/HG AS (P = 0.67) and between C/LF/LG AS and P/LF/LG AS (P = 0.51). Midterm mortality in C/LF/LG (RR/HR, 1.73; P = 0.0003) and P/LF/LG AS (RR/HR, 1.48; P < 0.0001) was significantly higher than that in NF/HG AS. There was no statistically significant difference in midterm mortality between C/LF/LG AS and P/LF/LG AS (P = 0.63). Conclusion After TAVI, C/LF/LG AS is associated with increased early mortality compared with NF/HG, and C/LF/LG and P/LF/LG AS is associated with increased midterm mortality compared with NF/HG AS despite no difference in early mortality between P/LF/LG AS and NF/HG AS. There is no difference in early and midterm mortality between C/LF/LG AS and P/LF/LG AS.</p>



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

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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 pacemaker 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.¹ 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.² Alternative approaches include transsubclavian (synonym for transaxillary) (TSc/TAx),

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

Abbreviations: TAo, transaortic; TAp, transapical; TAVI, transcatheter aortic valve implantation; TF, transfemoral; TSc/TAx, transsubclavian (synonym for transaxillary)

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

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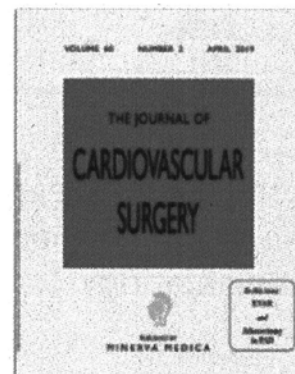
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Suppression of aortic expansion and contractile recovery in a rat abdominal aortic aneurysm model by biodegradable gelatin hydrogel sheet incorporating basic fibroblast growth factor

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Abstract

Biodegradable gelatin hydrogel sheet (BGHS) incorporating basic fibroblast growth factor (bFGF) may inhibit the progression of abdominal aortic aneurysm (AAA). We investigated whether AAA in a rat model treated with BGHS soaked with bFGF can suppress aortic expansion and recover the contractile response of aneurysmal aortic wall. Experimental AAA was induced in 10-week-old male Sprague–Dawley rats with intra-aortic elastase infusion. Aortas of these rats were assigned to 4 groups ($n = 6$ each) as follows: Control group, aortas infused with saline; Elastase only group, aortas infused with elastase; Hydrogel group, aortas wrapped with saline-soaked BGHS after elastase infusion; and bFGF group, aortas wrapped with bFGF (100 μ g)-soaked BGHS after elastase infusion. Preoperatively and on postoperative day (POD)7 and POD14, mean aortic maximal diameter was measured ultrasonographically. Aortic expansion ratio was calculated as: (post-infusion aortic diameter on POD14/pre-infusion aortic diameter $\times 100$). Aortas were stained with Elastica van Gieson and α -smooth muscle actin to measure the ratio of elastic fibers and α -smooth muscle actin-positive cells area to the media area. Aortas on POD14 were cut into 2-mm rings and treated with contractile agent, then tension was recorded using myography. Maximum aorta diameters were significantly greater in Elastase only group, Hydrogel group, and bFGF group than in Control group (on POD14). Maximum diameter was significantly lower in bFGF group (3.52 ± 0.4 mm) than in Elastase only group (6.21 ± 1.4 mm on POD14, $P < .05$). On histological analysis, ratio of the area staining positively for elastic fibers was significantly greater in bFGF group ($7.43 \pm 1.8\%$) than in Elastase only group ($3.76 \pm 2.9\%$, $P < .05$). The ratio for α -smooth muscle actin-positive cells was significantly lower in Elastase only group ($38.3 \pm 5.1\%$) than in Control group ($49.8 \pm 6.7\%$, $P < .05$). No significant differences were seen between Elastase only group and bFGF group, but ratios tended to be increased in bFGF group. Consecutive mean contractile tensions were significantly higher in bFGF group than in Elastase only group. Maximum contractile tension was significantly higher in bFGF group (1.3 ± 0.4 mN) than in Elastase only group (0.4 ± 0.2 mN, $P < .05$). Aortic expansion can be suppressed and contractile responses of aneurysmal aortic wall recovered using BGHS incorporating bFGF.

Keywords Abdominal aortic aneurysm · Basic fibroblast growth factor · Angiogenesis · Vascular function

Introduction

Abdominal aortic aneurysm (AAA) is a potentially deadly disorder that has traditionally been treated primarily by surgical aortic replacement (SAR). In recent years, endovascular aortic repair (EVAR) has become more commonly utilized [1]. Unlike SAR that require laparotomy under general anesthesia, EVAR can be performed with an incision to the groin area to expose the artery (or insertion of a catheter) alone under local anesthesia. However, while the lesion site is resected in SAR, aneurysmal aortic wall is conserved

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Is Transcatheter Aortic Valve Replacement Better Than Surgical Aortic Valve Replacement in Patients With Chronic Obstructive Pulmonary Disease? A Nationwide Inpatient Sample Analysis

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Background—Chronic obstructive pulmonary disease (COPD) patients are at increased risk of respiratory related complications after cardiac surgery. It is unclear whether transcatheter aortic valve replacement (TAVR) or surgical aortic valve replacement (SAVR) results in favorable outcomes among COPD patients.

Methods and Results—Patients were identified from the Nationwide Inpatient Sample database from 2011 to 2014. Patients with age ≥ 60 , COPD, and either went transarterial TAVR or SAVR were included in the analysis. A 1:1 propensity-matched cohort was created to examine the outcomes. A matched pair of 1210 TAVR and 1208 SAVR patients was identified. Respiratory-related complications such as tracheostomy (0.8% versus 5.8%; odds ratio [OR], 0.14; $P < 0.001$), acute respiratory failure (16.4% versus 23.7%; OR, 0.63; $P = 0.002$), reintubation (6.5% versus 10.0%; OR, 0.49; $P < 0.001$), and pneumonia (4.5% versus 10.1%; OR, 0.41; $P < 0.001$) were significantly less frequent with TAVR versus SAVR. Use of noninvasive mechanical ventilation was similar between TAVR and SAVR (4.1% versus 4.8%; OR, 0.84; $P = 0.41$). Non-respiratory-related complications, such as in-hospital mortality (3.3% versus 4.2%; OR, 0.64; $P = 0.035$), bleeding requiring transfusion (9.9% versus 21.7%; OR, 0.38; $P < 0.001$), acute kidney injury (17.7% versus 25.3%; OR, 0.63; $P < 0.001$), and acute myocardial infarction (2.4% versus 8.4%; OR, 0.19; $P < 0.001$), were significantly less frequent with TAVR than SAVR. Cost (\$56 099 versus \$63 146; $P < 0.001$) and hospital stay (mean, 7.7 versus 13.0 days; $P < 0.001$) were also more favorable with TAVR than SAVR.

Conclusions—TAVR portended significantly fewer respiratory-related complications compared with SAVR in COPD patients. TAVR may be a preferable mode of aortic valve replacement in COPD patients. (*J Am Heart Assoc.* 2018;7:e008408. DOI: 10.1161/JAHA.117.008408.)

Key Words: chronic obstructive pulmonary disease • surgical aortic valve replacement • transcatheter aortic valve replacement • transcatheter aortic valve implantation

Chronic obstructive pulmonary disease (COPD) is a common comorbidity that portends significant impact on decision making among candidates undergoing aortic valve replacement for severe, symptomatic aortic stenosis.¹ Surgical aortic valve replacement (SAVR), compared with transcatheter aortic valve replacement (TAVR), may require longer duration of mechanical ventilation, thus adversely affecting patients' outcomes especially among those with COPD.

Therefore, TAVR may confer added advantage over SAVR in COPD patients requiring aortic valve replacement. The negative impact of COPD has been evaluated in both TAVR and SAVR for those with and without COPD.^{2–5} However, comparative outcome data between TAVR versus SAVR have not been extensively investigated.

TAVR could potentially offer clinical benefit especially in COPD patients given that it could be performed under local or

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Accompanying Data S1 and Tables S1, S2 are available at <http://jaha.ahajournals.org/content/7/7/e008408/DC1/embed/inline-supplementary-material-1.pdf>

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Clinical End Points of Transcatheter Aortic Valve Implantation Compared With Surgical Aortic Valve Replacement in Patients <65 Years of Age (From the National Inpatient Sample Database)

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It is unknown if transcatheter aortic valve implantation (TAVI) is a safe alternative to surgical aortic valve replacement (SAVR) in patients <65 years old. Data from the National Inpatient Sample database were utilized. Patients from 2011 to 2015, ages 18 to 64 years old (inclusive) who underwent TAVI and SAVR were included. Patients who underwent SAVR and who also received a concomitant nonaortic valve surgery were excluded. A propensity score analysis was used. A total of 18,970 (528 TAVI and 18,442 SAVR) patients were identified. Patients who underwent TAVI were older (57 ± 7 vs 54 ± 10 years old, $p < 0.001$) with more frequent co-morbidities. Overall in-hospital mortality was similar between TAVI and SAVR (odds ratio [OR] = 0.52, $p = 0.12$). Postprocedure stroke (OR = 0.50, $p = 0.24$), acute kidney injury (OR = 0.98, $p = 0.89$), acute myocardial infarction (OR = 0.48, $p = 0.08$), and vascular complication requiring surgery (OR = 0.20, $p = 0.11$) were similar between patients who underwent TAVI and SAVR. Bleeding requiring transfusion (OR = 0.32, $p < 0.01$) was less frequent in patients who underwent TAVI, but new pacemakers (OR = 1.7, $p = 0.02$) were more frequent in these patients. Patients who underwent TAVI had shorter hospital stays (7.9 vs 10.0 days, $p < 0.001$) and were more likely to be discharged to home. Cost between TAVI and SAVR was similar (\$49,014 vs \$42,907, respectively, $p = 0.82$). In the <65 years old patient population, TAVI also conferred similar overall in-hospital mortality compared with patients who underwent SAVR. TAVI resulted in fewer major complications, shorter hospital stay, and more frequent discharge to home, but higher rates of pacemaker implantation compared with SAVR. Therefore, TAVI appears to be a safe alternative to SAVR in patients <65 years old. © 2018 Elsevier Inc. All rights reserved. (Am J Cardiol 2018;122:279–283)

Severe aortic stenosis is primarily a disease of the advanced aged population. Therefore, transcatheter aortic valve implantation (TAVI) has been primarily investigated in the advanced age population. The mean age of patients enrolled in the landmark trials was near or over 80 years old for both high and intermediate surgical risk patients.^{1–3} Age is one of the key factors in determining the surgical risk and prognosis. With the interest in TAVI moving toward lower surgical risk patients, the end points of TAVI versus surgical aortic valve replacement (SAVR) in patients <65 years old are becoming more relevant. Little is known about the safety

and efficacy of TAVI compared with SAVR in patients <65 years of age. Younger patients typically have lower surgical risk; however, paradoxically younger patients who are considered for TAVI often have unique co-morbidities that elevate their surgical risk. To date there is no clear data on the periprocedure outcomes in patients <65 years of age who underwent TAVI compared with SAVR. Therefore, we performed this study using a large national database to investigate the in-hospital clinical end points, cost, and length of hospital stay in patients <65 years of age who underwent TAVI or SAVR.

Methods

The National Inpatient Sample (NIS) database of the Health Care Utilization Project sponsored by the Agency for Healthcare Research and Quality (AHRQ) was queried from 2011 to 2015. The NIS database samples 20% of over 7 million hospital stays every year in the United States. Patient demographics, co-morbidities, in-hospital procedures and clinical end points, and disposition are available among many other patient and hospital variables. From the NIS database we identified patients (1) who were ages 18 to 64 years old (inclusive), (2) who underwent transarterial TAVI, or (3) SAVR. We excluded patients who (1) were diagnosed with aortic

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See page 283 for disclosure information.

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Failure to Rescue, Hospital Volume, and In-Hospital Mortality After Transcatheter Aortic Valve Implantation



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Failure to rescue (FTR), death after major complications, has been well described in the surgical literature as a source of different outcomes in different hospitals. However, FTR has not been investigated in transcatheter aortic valve implantation (TAVI). Our aim was to assess the difference of in-patient mortality and FTR in different TAVI volume hospitals. We queried the Nationwide Inpatient Sample database from 2011 to 2015 to identify patients who had transarterial TAVI. FTR was calculated as those who had in-patient mortality with at least one with major perioperative complications. Hospitals were divided into three groups according to annual TAVI volume, the lowest quintile (≤ 30 /year), second to fourth quintile (31 to 130/year), and highest quintile (≥ 130 /year). Multivariate analysis was used to calculate risk adjusted in-patient mortality rate and FTR and was compared between these different volume hospitals. A total of 48,886 TAVI procedures were identified (10,407, 28,811, and 9,668 in low, intermediate, and high volume centers, respectively). Mean age, percentage of woman, and Elixhauser co-morbidity index was similar across different TAVI volume hospital. The incidence of major perioperative complications did not differ in different volume hospitals. Adjusted rate of in-patient mortality (2.3%, 1.87%, and 1.57% for low, intermediate, and high volume center, respectively, $p < 0.001$) were significantly less with greater hospital volume but FTR (8.24%, 8.20%, and 6.12% for low, intermediate, and high volume center, respectively, $p = 0.29$) were the same in the three groups. Our results suggest that FTR does not explain the variation of in-hospital mortality in different hospital volumes. © 2018 Elsevier Inc. All rights reserved. (Am J Cardiol 2018;122:828–832)

Failure to rescue (FTR), characterized as in-patient mortality with at least one with major perioperative complication, has been well described in the surgical literature as a source of variation in hospital outcomes.^{1–5} Transcatheter aortic valve implantation (TAVI) is associated with certain periprocedural complications that negatively impact the outcomes and therefore assessing the rate of FTR would have incremental value in addition to evaluating periprocedural complication and mortality rate post-TAVI. With increase in-hospital procedural volume, better outcomes have been reported in the past for various surgical and percutaneous procedures.^{6–13} Previous studies have reported similar trends, with decreasing adverse outcomes with

increased hospital volume after TAVI.^{14,15} However, these analyses reflected early United States commercial TAVI experience. With its rapid expansion and center experience, TAVI has become a safer procedure and the outcomes of volume-outcome relation may have dramatically changed. Our aim was to assess the FTR in different TAVI volume hospital including the most recently available Nationwide Inpatient Sample (NIS) database.

Methods

Data were obtained from the Agency for Healthcare Research and Quality Healthcare Cost and Utilization Project (HCUP)—NIS files between 2011 and 2015. The data were queried to identify patient demographics and TAVI procedure recipients in the United States using the International Classification of Diseases-Ninth Revision-Clinical Modification (ICD-9-CM). The NIS was created by the HCUP as a discharge database and is maintained by the Agency for Healthcare Research and Quality. NIS data are extracted from a random sample of approximately 20% of all nonfederal, general, and specialty specific hospital inpatient admissions. Approximately 97% of hospitals in the United States are represented by the NIS, making it the largest all-payer inpatient discharge database in the United States. Criteria used for stratified sampling of hospitals into the NIS include hospital ownership, patient volume, teaching status, urban or rural location, and geographic region.¹⁶

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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 4125 patients (1268 transfemoral [TF]-TAVR, 1261 Non-TF TAVR [transcatheter aortic valve replacement, transapical or transaortic], and 1596 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	Transfemoral-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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ORIGINAL STUDIES

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 mortality 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).^{1,2} 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 2015.³ 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

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.

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 ≥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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Incidence, Predictors, and In-Hospital Outcomes of Transcatheter Aortic Valve Implantation After Nonelective Admission in Comparison With Elective Admission: From the Nationwide Inpatient Sample Database



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Candidates for transcatheter aortic valve implantation (TAVI) are generally older with multiple co-morbidities and are therefore susceptible to nonelective admissions before scheduled TAVI. Frequency, predictors, and outcomes of TAVI after nonelective admission are under-explored. We queried the Nationwide Inpatient Sample database, an administrative database, from January 2012 to September 2015 to identify hospitalization in those age ≥ 50 who had transarterial TAVI. A propensity-matched cohort was created to compare the outcomes between nonelective and elective admission who had TAVI. The primary outcome was in-hospital mortality. A total of 9,521 TAVI admissions were identified during the study period. Of these admissions, 22.3% were nonelective admissions. Pulmonary circulation disorders (adjusted odds ratio [aOR] 1.38), anemia (aOR 1.54), congestive heart failure (aOR 1.37), chronic kidney disease (aOR 1.28; all $p < 0.001$), and atrial fibrillation (aOR 1.17, $p = 0.006$) were independent risk factors for nonelective admission. In a propensity-matched cohort (1,683 admissions in each cohort), in-hospital mortality was similar (4.0% vs 2.8%, $p = 0.052$). Nonelective admissions had higher rates of acute myocardial infarction (5.2% vs 0.7%), fatal arrhythmia (9.4% vs 6.0%), acute kidney injury (25.9% vs 17.1%), respiratory failure requiring intubation (0.26% vs 0.19%), cardiogenic shock (5.1% vs 2.1%; all $p < 0.001$), and bleeding requiring transfusion (13.1% vs 10.1%, $p = 0.006$) during the index-hospitalization. Hospital length of stay (11.4 days vs 6.5 days, $p < 0.001$) and hospital cost (\$68,669 vs \$57,442, $p < 0.001$) were both increased in nonelective admissions. Nonelective admission accounted for approximately one-fifth of total TAVI with significantly different cohort profiles. Our results suggest that nonelective TAVI has higher adverse outcomes and increased health resource utilization. Expedition in TAVI process in high-risk cohorts may result in better outcomes. © 2018 Elsevier Inc. All rights reserved. (Am J Cardiol 2019;123:100–107)

Candidates of transcatheter aortic valve implantation (TAVI) often have atherosclerosis-related and non-related co-morbidities (i.e., lung disease, malignancy) and are thus vulnerable to clinical events requiring emergency department visit before undergoing scheduled TAVI.¹ Even after

TAVI, 30 days readmissions rate remains relatively as high as 18%.² Patient awaiting TAVI could be even at higher risk of nonelective medical visit and admission. Kolte et al have reported the outcomes of TAVI as a rescue therapy for decompensated severe aortic stenosis.³ However, it remains under-explored how often TAVI candidates are admitted in a nonelective manner (i.e., through the emergency department), its predictors, and the outcomes compared with those who had TAVI after elective admission. We used the Nationwide Inpatient Sample (NIS) database to explore outcomes of TAVI between elective and nonelective admission.

Methods

Our study was performed using data from Healthcare Cost and Utilization Project (HCUP)—NIS from January 2012 to September 2015. NIS is the largest publically accessible database of all-payer inpatient care in the United

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Acute Myocardial Infarction Outcomes in Systemic Lupus Erythematosus (from the Nationwide Inpatient Sample)



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One of the major causes of mortality in systemic lupus erythematosus (SLE) is acute myocardial infarction. Whether in-hospital outcomes and management of ST-segment elevation myocardial infarction (STEMI) and non-STEMI (NSTEMI) are different in SLE patients compared with those without SLE from large, recent dataset is unclear. We queried the Nationwide Inpatient Database from 2005 to 2014 and identified STEMI and NSTEMI admissions with and without SLE. The primary outcome was in-hospital mortality. Secondary outcomes were revascularization strategy (percutaneous coronary intervention, coronary artery bypass surgery, or thrombolytics), medical therapy rates (no reperfusion), and major adverse clinical events. A propensity-matched cohort was created to compare these outcomes. Odds ratio (OR) was calculated from the propensity-matched cohort. A total of 321,048 STEMI admissions, of which 1,001 (0.31%) and 572,971 NSTEMI admissions, of which 2,134 (0.37%) were SLE, were identified. In those with STEMI, 882 SLE and non-SLE admissions were propensity-matched. In-hospital mortality (9.1% vs 11.8%, OR 0.75, $p = 0.07$), revascularization strategy, medical therapy rates, and major adverse events were similar. Similarly, in those with NSTEMI, 1,770 SLE and 1,775 non-SLE were matched. In-hospital mortality (4.1% vs 4.50%, OR 0.90, $p = 0.51$), coronary artery bypass surgery, medical therapy rates, and major adverse events were mostly similar but the rate of percutaneous coronary intervention was higher in SLE (32.9% vs 29.6%, OR 1.16, $p = 0.04$). For both STEMI and NSTEMI, hospital cost and length of stay were similar between SLE and non-SLE cohorts. From a large administrative database in the United States, revascularization strategies and in-hospital outcomes of acute coronary syndrome were mostly similar between SLE and non-SLE. © 2018 Elsevier Inc. All rights reserved. (Am J Cardiol 2019;123:227–232)

One of the major causes of mortality in systemic lupus erythematosus (SLE) patients is cardiovascular disease from accelerated atherosclerosis caused by both traditional and disease-specific risk factors.^{1,2,3} A population-based study showed that acute myocardial infarction (AMI) hospitalizations increased from 1996 to 2012 in SLE while they decreased in the general population.⁴ The incidence of AMI in SLE was higher compared with non-SLE.⁴ Outcomes of AMI in SLE cohorts have been reported in the past^{5,6} but several clinically important questions remain not fully addressed. First, a previous study that reported SLE presenting with AMI had worse in-hospital outcomes⁶ was not reflective of the recent advances in the management of AMI and did not differentiate ST-segment elevation myocardial infarction

(STEMI) and non-STEMI (NSTEMI). Second, whether those with SLE presenting as AMI received different revascularization strategies due to more advanced coronary artery disease from additional disease-specific atherosclerosis risk factors (i.e., steroid use, chronic inflammation, lupus nephritis) is not clear.^{7–10} We queried Nationwide Inpatient Sample (NIS) database to address these clinically relevant issues.

Methods

Data were obtained from the Agency for Healthcare Research and Quality Healthcare Cost and Utilization Project–NIS files between 2005 and 2014. The data were queried to identify patients (≥ 18 years) who underwent either percutaneous coronary intervention (PCI), coronary artery bypass graft (CABG), thrombolytic therapy, or medical therapy (no reperfusion) using the International Classification of Diseases, Ninth Revision, Clinical Modification. The NIS is the largest all-payer inpatient database in the United States, and it includes a 20% sample of US community hospitals from up to 45 states and approximates 20% of all US community hospitals. Hospitals are short-term, nonfederal general and specialty hospitals selected based on 5 sampling strata, and once selected, include 100% of their hospitalizations.¹¹

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Meta-Analysis Comparing the Incidence of Infective Endocarditis Following Transcatheter Aortic Valve Implantation Versus Surgical Aortic Valve Replacement



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Infective endocarditis (IE) after transcatheter aortic valve implantation (TAVI) and surgical aortic valve replacement (SAVR) is a rare but life-threatening complication. Paravalvular regurgitation, compression of native leaflets, and space between transcatheter valve prosthesis and native valves could dispose TAVI recipients at increased risk of IE compared with SAVR. To assess the comparative risk of IE between TAVI and SAVR, we performed a systematic review and meta-analysis. A literature search of PUBMED and EMBASE was performed to identify randomized controlled trials that reported the event rate of IE in both TAVI and SAVR. A Mantel-Haenszel method and a random-effects model was used to calculate the odds ratio (OR) and 95% confidence interval (CI). The studied outcomes were early (at 1-year), late (>1-year), and overall IE (post-procedure to longest follow-up) in TAVI versus SAVR. We performed subgroup analysis based on valve-type (self or balloon-expandable) and surgical risk (high or intermediate). A total of 4 studies with 3,761 (1,895 TAVI and 1,866 SAVR) patients were included. The incidence of early IE, (3 studies, 0.86% vs 0.73%, OR 1.17, 95% CI 0.51 to 2.65, $p = 0.71$, $I^2 = 0\%$), late IE (mean follow-up 2.0 years) (3 studies, 1.3% vs 0.6%, OR 1.85, 95% CI 0.81 to 4.20, $p = 0.42$, $I^2 = 0\%$), and overall IE (mean follow-up 3.4 years) (4 studies, 2.0% vs 1.3%, OR 1.44, 95% CI 0.85 to 2.43, $p = 0.18$, $I^2 = 0\%$) was similar between TAVI and SAVR. Subgroup analysis suggested that in intermediate surgical risk cohort, there was a trend toward increased risk of overall IE in TAVI (2.3% in TAVI and 1.2% in SAVR, OR 1.92, 95% CI 0.99 to 3.72, $p = 0.05$, $I^2 = 0\%$). In this meta-analysis, we did not find an increased risk of IE in TAVI compared with SAVR. Appropriate preventative measure and early recognition of IE in these cohorts are important. © 2018 Elsevier Inc. All rights reserved. (Am J Cardiol 2019;123:827–832)

Infective endocarditis (IE) post-transcatheter aortic valve implantation (TAVI) is a complication that remains less investigated owing to its low incidence and challenges in diagnosis. Transcatheter heart valve prosthesis contains a significant amount of metal because of the stent frame housing the leaflets and may have higher risk of IE compared with surgical aortic valve replacement (SAVR) recipients. Paravalvular regurgitation, which occurs more frequently in TAVI, as well as space between the native and transcatheter prosthetic valve could function as a nidus

for IE.^{1–3} Furthermore, the initial damage of calcific native valve compression from valve insertion and higher incidence of subclinical valve leaflet thrombosis compared with a surgical prosthetic valve⁴ may also increase the risk of IE in TAVI. Although staphylococcus species was the leading etiology of IE post-SAVR, enterococcus was the major cause of IE post-TAVI, implicating potentially different entry of pathobiologic mechanisms.^{1,5} It is not well investigated whether TAVI have higher risk of IE compared with SAVR. The main aim of this systematic review and meta-analysis was to assess whether the risk of IE in TAVI recipients are higher compared with SAVR patients.

Methods

We searched the PUBMED and EMBASE from January 1st, 2002 to September 26th 2018. We used (TAVI OR TAVR OR transcatheter aortic valve replacement OR transcatheter aortic valve implantation) and (endocarditis OR infectious endocarditis OR infective endocarditis OR randomized OR randomized) as the search term. Two independent authors' (TA and HT) reviewed the search results separately to select the studies based on preset inclusion and exclusion criteria. There was no language restriction. A reference list of included studies for meta-analysis was

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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 complications may reduce TAVI-related costs. © 2019 Elsevier Inc. All rights reserved. (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).¹ In addition, TAVI had higher hospitalization costs compared with SAVR when factoring readmission costs.² 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.

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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Should patients become obese before transcatheter aortic valve implantation?

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Article Tokarek et al., see p. 190

Obesity is highly prevalent in economically advanced countries and incurs a substantial burden on health care. It has been reported to be associated with comorbidities such as hypertension, diabetes mellitus, and dyslipidaemia, as well as diseases such as cardiovascular and cerebrovascular disease [1]. Despite these associations, the so-called obesity paradox, a phenomenon indicating that obese patients actually have better survival, has been repeatedly reported in various conditions [2–7].

Tokarek et al. [8] have recently presented outcomes of transcatheter aortic valve implantation (TAVI) among 148 consecutive patients classified according to the body mass index (BMI) into normal-weight (18.5–24.9 kg/m²), overweight (25.0–29.9 kg/m²), and obese (≥ 30 kg/m²). After excluding one patient with a low BMI, the final analysis comprised 147 subjects. The proportion of obese patients was 25.2%, and in an adjusted model patients with normal BMI had higher all-cause mortality compared with the obese cohorts (hazard ratio 3.86). BMI was also associated with lower all-cause mortality (hazard ratio 0.91, per 1 kg/m² increase). While this work constitutes another piece of evidence on the existence of the obesity paradox in post-TAVI patients, we still do not have a clear idea of the mechanisms of this phenomenon. The present study adds important insights by assessing the frailty score using several scales in patients with different BMI values. Interestingly, although there was no statistical difference, most of the frailty indices were lower in the obese cohorts and the duration of the five-metre walk test was significantly shorter in obese patients (indicating lower frailty). Various frailty scales were not included in the multivariate analysis, but it would have been interesting to see how their inclusion would have affected the results, because frailty is one of the well-known predictors of mortality following TAVI [9]. Of note, there was no significant difference in the rate of myocardial infarction or cerebrovascular events, and these events

were unlikely to be the cause of the obesity paradox in this study. Observing the Kaplan-Meier curve for all-cause mortality in the present study, it can be seen that the curve diverges rapidly at an early stage and stabilises later in the normal BMI cohort, whereas the event occurs more frequently after two years or so in the obese group, after an initially low mortality rate during follow-up. This finding may support one of the theories behind the obesity paradox discussed by the authors, i.e. that the metabolic reserve in obese cohorts may have a protective effect in acute morbidities and procedural stress.

In light of the previous studies relating to the obesity paradox post-TAVI, this study adds to the current literature, proving that BMI is a useful variable for further risk stratification in post-TAVI patients. Should nutritional assessment be part of a routine evaluation in TAVI patients regardless of BMI? Should patients try to gain weight prior to the procedure? While patients with low BMI gaining weight through nutritional referral and assessment prior to TAVI appears to be a plausible perioperative management, should patients with normal BMI try to gain weight and become obese prior to TAVI? Further studies are required to elucidate the mechanism of the obesity paradox.

Conflict of interest: none declared

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Can we assess which is better?—transcatheter or surgical aortic valve replacement in intermediate or lower risk patients with chronic obstructive pulmonary disease

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We appreciate the editorial by Lv *et al.* on our published manuscript in the *Journal of American Heart Association*, entitled “Is Transcatheter Aortic Valve Replacement Better Than Surgical Aortic Valve Replacement in Patients With Chronic Obstructive Pulmonary Disease? A Nationwide Inpatient Sample Analysis” (1). We read the editorial with great interest and therefore would like to expand the discussion on whether the similar results could be expected in lower surgical risk patients, which was pointed by them.

As pointed out by Lv *et al.*, the next important clinical question is whether these results could be replicated in intermediate and further down the road, in low surgical risk patients. In order to examine these questions, a database with a large cohort with clinical outcomes of interest specific for a respiratory system such as pneumonia, tracheostomy, use of non-invasive ventilation, and respiratory failure examined in our study are required. Because the Nationwide Inpatient Sample database does not capture commonly used surgical risk scores in evaluating aortic valve replacement candidates such as the Society of Thoracic Surgeons score (STS) and the EuroSCORE, it is difficult to identify those at intermediate or low surgical risk cohort from the more recently released version of the Nationwide Inpatient Sample database. Furthermore, the decision of surgical risk is not solely based on the risk score but many other

considerations come into play and ultimately determined by the multi-disciplinary heart team.

Large registry such as the Transcatheter Valve Treatment Registry do capture information regarding the history of chronic lung disease with its severity (mild, moderate, or severe), which was not available in our study, but do not have respiratory specific outcomes (2). In large randomized trials assessing the outcomes between transcatheter aortic valve replacement (TAVR) and surgical aortic valve replacement (SAVR) such as the PARTNER 2 and SURTAVI trials likely do not collect these outcomes because respiratory specific outcomes are not defined in the Valve Academic Research Consortium-2 (3).

Those considered at intermediate and low surgical risk patients will less likely have a severe chronic obstructive pulmonary disease (COPD) because then those patients will likely be considered as high surgical risk and therefore, the benefit of TAVR will likely be attenuated when these two replacement modalities are compared in mild or moderate COPD.

For these reasons, currently, we consider that it is difficult to assess the perioperative respiratory specific outcomes between TAVR and SAVR in COPD patients at intermediate or low surgical risk patients from a large database.



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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].

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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Perforation of a Peptic Ulcer in a Hiatal Hernia Into the Left Ventricle With Systemic Air and Food Embolism

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Abstract: Perforation of a peptic ulcer into the ventricle is uncommon, and the definitive diagnosis is difficult in living patients. We herein report a case of perforation of a peptic ulcer in a hiatal hernia into the left ventricle with systemic air and food embolism. This is the first case report of the perforation diagnosed by computed tomography and confirmed by autopsy. Computed tomography was useful for the diagnosis of perforation into the ventricle.

Key Words: systemic air and food embolism, a hiatal hernia, perforation of a peptic ulcer into the left ventricle

(*J Comput Assist Tomogr* 2018;42: 767–770)

CASE REPORT

A 76-year-old woman was brought to the emergency room of our hospital by an ambulance in a state of cardiopulmonary arrest. She had repeatedly suffered from a high fever of 40°C for several days. She was in severe distress in the morning of the day of admission and was found unconscious and short of breath by her daughter in the afternoon. According to her daughter, she had rarely visited the hospital and had no remarkable medical history.

Tracheal intubation was performed, and cardiopulmonary resuscitation was started. A blood examination revealed an elevated white blood cell count (17,300/μL; reference range, 4000–9000/μL) and increased C-reactive protein (8.52 mg/dL; reference range, 0.00–0.28 mg/dL). There was no visible hematemesis nor melena.

Computed tomography (CT) of the head and body was performed. Head CT images (Fig. 1A) revealed multiple air bubbles in the cerebral arteries. Body CT images (Fig. 1B–D) revealed a paraesophageal hiatal hernia. The thickened anterior wall of the herniating stomach protruded into the pericardium, where the pericardial fat tissue disappeared. There were air bubbles in the left ventricle, coronary arteries, and hepatic arteries. Communication between the stomach via the hiatal hernia and the left ventricle was suspected.

Despite cardiopulmonary resuscitation, an electrocardiogram showed the continuation of asystole. The patient was pronounced dead 1.5 hours after her admission. An autopsy was performed.

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METHOD

The autopsy was performed approximately 8 hours after death was pronounced. After the autopsy, the organs were fixed in formalin, and tissue blocks were embedded in paraffin.

RESULTS

A large peptic ulcer was noted in the anterior wall of the stomach in a paraesophageal hiatal hernia (Fig. 2B). The ulcer fused the pericardium and the myocardium of the left ventricle with severe fibrosis and formed a small fistula into the lumen of the ventricle (Fig. 2A). The fistulous tract was less than 5 mm in diameter. There was no hemorrhaging in the stomach.

A microscopic examination confirmed a chronic benign peptic ulcer with massive fibrosis. Many meningeal and intracerebral arteries contained emboli of foodstuff and aggregations of bacteria (Fig. 2C). Many small arteries in the heart (Fig. 2D), liver, spleen, and kidney contained food and bacteria emboli similar to those in the brain. These findings suggested systemic embolism of the contents in the stomach via the fistula between the stomach and the left ventricle.

DISCUSSION

Penetration/perforation of a benign peptic ulcer into the pericardium or the heart is uncommon, although there have been several previous reports. West et al¹ and Porteous et al² reported such cases with a large series of reviews in the 20th century. There are 2 types of penetration/perforation of a peptic ulcer into the pericardium or the heart: with a hiatal hernia and without a hiatal hernia (Fig. 3). Without a hiatal hernia, intra-abdominal gastric fundic ulcers communicate into the pericardium and the heart via the diaphragm. With a hiatal hernia, intrathoracic ulcers at the anterior wall of the stomach directly communicate into the pericardium and the heart. The most commonly affected sites are the pericardium and the inferior wall of the left ventricle.

Hiatal hernias are common, being reported to affect 10% to 50% of the population.³ There are basically 2 types of hiatal hernias: a sliding hernia and a paraesophageal hernia. The incidence of paraesophageal hiatal hernias is reported to range between 3.5% and 5%.³ In this type, although the gastroesophageal junction remains in the normal position, the anterior wall of the stomach protrudes into the thoracic cavity and comes close to the pericardium and the left ventricle.

Peptic erosions/ulcerations located at the level of the diaphragmatic hiatus are described as Cameron lesions, having first been reported by Cameron and Higgins⁴ in 1986. Weston⁵ reported the prevalence of Cameron lesions in patients with hiatal hernias to be 5.2% in 1996. Gray et al⁶ similarly reported the prevalence to be 3.3% in 2015. Both stated the prevalence to be dependent on the size of the hernia sac. In addition, Gray et al⁶ reported that nonsteroidal anti-inflammatory drug use was a significant independent risk factor for Cameron lesions and treatment using

Letters to the Editor

Repeat Contrast Medium Administration for Patients with Mild Immediate Hypersensitivity Reaction to Iodinated Contrast Media

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Editor:

I read with great interest the article by Dr Park and colleagues in the September 2018 issue of *Radiology* (1) on the strategy of repeat contrast material administration for patients with mild immediate hypersensitivity reaction (HSR) to iodinated contrast media (ICM).

The authors state in the introduction that two recent studies revealed the potential benefits of changing the culprit agent for the prevention of recurrent HSR, providing two references. However, a study regarding the protective effect of changing the culprit agent was omitted (2).

In addition, Dr Park and colleagues state that the precise recurrence rate of HSRs to low-osmolar ICM without premedication is not currently known. In the series by Abe et al (2), the reported rate was 28%. In the same report, the recurrence rate of hypersensitivity reaction to the low-osmolar ICM other than the culprit agent without premedication was 8%. The results of the study by Dr Park and colleagues are similar to those of Abe et al, with recurrence rates of 31.1% and 12%, respectively, with reexposure to the culprit agent without premedication.

I congratulate Dr Park and colleagues on publishing the article based on a large-scale serial database and obtaining good efficacy with a combination of changing the culprit agent and antihistamine premedication without corticosteroids for patients who experienced mild HSR to ICM. A remaining question is whether we have to wait for 30 minutes after intravenous administration of antihistamine. A large-scale prospective study is also still needed.

Disclosures of Conflicts of Interest: disclosed no relevant relationships.

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Response

From
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We sincerely appreciate Dr Abe's interest in our recent article (1).

As noted, Abe et al (2) were the first to report the effect of changing ICM. We discussed the importance of their work in our article. However, in their study, only one patient had a moderate to severe previous reaction in the control group; thus, it was difficult to conclude whether the effect of changing ICM was valid in those with moderate to severe index reaction. In addition, other groups, such as the premedication alone group ($n = 3$), changing ICM alone group ($n = 12$), and premedication and changing ICM group ($n = 16$), were also limited in the numbers of moderate to severe reactions. A multicenter study by Park et al (3) successfully complemented the prior findings by comparing the result of ICM change among patients with moderate to severe previous reactions to ICM. Based on these two articles, the American College of Radiology guideline has been changed regarding the usefulness of changing ICM (4).

Abe et al compared the recurrence rate in 58 unpremedicated cases in which the ICM was changed (5.2%) with that in 220 unpremedicated cases using the same ICM (27.7%) (2); however, these results were mostly from subjects with faint and mild reactions (there was only one moderate reaction and there were no severe reactions). Many were not allergic-like reactions. According to our literature review, the accurate recurrence rate of allergic-like reactions to ICM remains unknown (4), especially in unpremedicated patients with moderate or severe ICM reactions. However, it is unlikely that we could investigate the recurrence rate by readministering the culprit contrast media without premedication in those with moderate or severe index reactions because of ethical limitations.

There are limited data regarding the onset time of intravenously administered prophylactic chlorpheniramine. A study regarding allergic rhinitis reported that the initial response of chlorpheniramine occurred at 30 minutes (5). Our study also proved the preventive effect of chlorpheniramine administered 30 minutes before ICM exposure. Although there has been a small study showing the effectiveness of intravenous chlorpheniramine administered 15 minutes before exposure (6), evidence for an administration less than 30 minutes before exposure is insufficient and further studies are needed.

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CASE REPORT

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Trousseau syndrome in a patient with advanced oral squamous cell carcinoma: a case report

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Abstract

Background: Trousseau syndrome is known as a variant of cancer-associated thrombosis. Trousseau syndrome commonly occurs in patients with lung or prostate cancer. Hypercoagulability is thought to be initiated by mucins produced by the adenocarcinoma, which react with leukocyte and platelet selectins to form platelet-rich microthrombi. This is the first report of Trousseau syndrome in a patient with oral cancer.

Case presentation: Here, we describe the case of a 61-year-old Japanese man diagnosed as having advanced buccal carcinoma (T4bN2bM1; the right scapula, erector spinae muscles, and the right femur), who experienced aphasia and loss of consciousness. Although magnetic resonance imaging showed cerebral infarction, carotid invasion by the tumor and carotid sheath rupturing, cardiovascular problems, and bacterial infection were not present, which indicated Trousseau syndrome.

Conclusions: Trousseau syndrome in oral cancer is rare, but we must always consider cancer-associated thrombosis in patients with advanced stages of cancer regardless of the primary site of the cancer and take steps to prevent it.

Keywords: Trousseau syndrome, Oral squamous cell carcinoma, Cancer-associated thrombosis

Background

It is well known that patients with advanced malignant disease are at risk of a hypercoagulable condition, and may develop cancer-associated thrombosis (CAT) [1].

Trousseau syndrome (TS) is a known state of CAT and often occurs in patients with advanced solid cancers [2]. TS is defined as chronic disseminated intravascular coagulation (DIC) associated with non-bacterial thrombotic endocarditis. Recovery is rare in patients with TS and there is no established evidence regarding the effects of anticoagulant treatment on this condition [1, 3]. TS is currently used to describe a hypercoagulation disorder in patients with malignancy, similar to CAT [1, 3]. TS commonly occurs in pulmonary, digestive, gynecology, or urinary cancer [1, 3, 4], and no such condition has been reported in a patient with oral cancer.

Here, we described a case of TS in a patient with buccal squamous cell carcinoma (SCC).

Case presentation

In 2017, a 61-year-old Japanese man was referred to an oral and maxillofacial surgeon in Tokai University Hospital, Isehara, Japan, because of trismus and general fatigue. He complained of gradually worsening trismus and a painful ulcerated wound in the right buccal mucosa that had failed to heal for the past 6 months. He was on medication for hypertension and had no other specific systemic disease. On physical examination, facial swelling without redness was observed on the middle right side of his face, and trismus was noted (inter-incisor distance was 17 mm). Ulceration was observed in the right buccal mucosa, and an indurated mass could be palpated on the skin of his right cheek. Multiple palpable cervical lymphadenopathies were observed. He underwent workup for suspected malignancy of the

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伝家の宝刀となるか(小児抗菌薬適正使用支援加算)

静岡医療センター 薬剤部 滝 久司

小児抗菌薬適正使用支援加算:80 点(新設)

平成30年度の診療報酬改定率は、厳しい財政事情の中、医療機関の経営状況、賃金・物価の動向等が考慮され、本体として+0.55%(医科+0.63)となりました。薬剤耐性菌対策と抗菌薬適正使用は国際的な喫緊の課題であり、平成30年度診療報酬改定で、小児抗菌薬適正使用支援加算(80点)が小児科外来診療料と小児 かかりつけ診療料に新設されました。

日本では抗菌薬の90%は外来で処方されており、AMR対策アクションプランでは2020年までに2013年の使用量の50%まで削減することを目指しています。小児領域でまず加算が算定されたのは、小児科、耳鼻科での抗菌薬の処方割合が多いからです。また、日本では経口の第3世代セファロスポリン系抗菌薬、フルオロキノロン系抗菌薬、マクロライド系抗菌薬の使用量が多いことが指摘されています。外来患者数における15歳未満患者の割合は、この10年で全体の10%前後と横ばいですが、同年齢層への抗菌薬処方方は全体の25%と高くなっています。抗菌薬適正使用は、患者や家族の理解向上なしに進めることは困難です。厚生労働省の研究報告では、患者家族が抗菌薬の正しい情報を得ようとする際の情報源は医師が74%、薬剤師が42%でした。一方で抗菌薬を服用することになった理由の調査では、風邪45%、インフルエンザ12%、発熱、咳や咽頭痛が各10%前後で、多くが抗菌薬不要の疾患でした。正しい情報提供ができていないと言えない状態です。この加算新設は患者家族の理解向上のためにコミュニケーションと正しい説明を評価するための加算と言えます。

算定要件と施設基準について解説します。小児の急性上気道感染症と急性下痢症の初診で、問診と診察の結果、抗菌薬投与の必要性がなく、使用もしない場合に、説明と療養上の指導を行うことで算定できます。基礎疾患のない学童期以降は、「抗微生物薬適正使用の手引き」に則した診療を行うことを要件としています(次ページ参照)。急性上気道感染症では努力呼吸や頻呼吸がなく、中等症以上の鼻副鼻腔炎と溶連菌性咽頭炎でもなければ算定できます。急性下痢症では海外渡航歴や強い腹痛、血便がない事例にはウイルス性と判断しやすいです。

また施設基準には定期的な感染症研修会への参加が必要です。今後、静岡耐性菌対策チームが医師会で開催させていただいている抗菌薬適正使用研修会で参加証を発行できるように準備を進めます。是非ご参加ください。

参考:平成28年度 厚生労働科学研究:「国民の薬剤耐性に関する意識についての研究」

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滝 久司 たき ひさし

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この連載は・・・毎号ひとつの薬剤に関するトピックを取り上げ、その薬についての印象や思い入れなど、経験ベースでの知見を薬剤師ならではの視点から語るリレー連載です。

関東地方で風疹の届出数が増えています

2018年8月24日、厚生労働省のメールマガジン『感染症エクスプレス@厚労省』より、「現在、関東地方で風疹の届出数が大幅に増加しています。妊娠中の女性が風疹に感染すると、生まれてくる子どもが先天性風しん症候群を発症することがあるため注意が必要です」と発信された（続報あり）。私事であるが、以前に発信元の職場に在籍し、感染症エクスプレスを執筆していた関係から厚生労働省より発出される通知と紐づけてみた。平成30年8月14日付健感発0814第3号厚生労働省健康局結核感染症課長通知において、各都道府県・保健所設置市・特別区の衛生主管部（局）長宛に「特に妊婦を守る観点から、診療に関わる医療関係者、これまで風疹にかかっていない者、風疹の予防接種を受けていない者および妊娠を希望する女性などへの注意喚起など、風疹に対する一層の対策の実施をお願いします」との周知が図られていた。ふと2013年の流行時を含め、風疹に対する予防接種の必要性の認識やその対策を実践している薬剤師がどのくらいいるのだろうかと思いをめぐらせた。

薬剤耐性(AMR)対策アクションプラン²⁾

一方、2015年5月、世界保健総会では薬剤耐性に関するグローバル・アクション・プラン³⁾が採択され、加盟各国は2年以内に薬剤耐性に関する国家行動計画を策定することを求められた。また、厚生労働省では

2016年4月5日に薬剤耐性対策に関する包括的な取り組みについて議論され「国際的に脅威となる感染症対策関係閣僚会議」のもと、わが国として初めてのアクションプランが策定された。このなかで、抗微生物薬の適正使用は、薬剤耐性対策として日頃の臨床の現場で医療従事者および患者を含む医療に関わるすべての者が対応すべき最重要の分野の一つとされ、特に抗菌薬使用量に関する成果指標は2013年と比較して、2020年には全体として33%減、経口セファロスポリン・フルオロキノロン・マクロライド系薬の3系統は50%減、静注抗菌薬は20%減とすることが記載されたことは記憶に新しい。また、2017年6月1日には厚生労働省健康局結核感染症課より『抗微生物薬適正使用の手引き』の第一版が発刊され、適正な感染症診療にかかわる指針を明確にし抗微生物薬の適正使用を推進していくことが示された³⁾。さらに、平成30年度診療報酬改定では、薬剤耐性対策の推進、特に抗菌薬の適正使用推進の観点から抗菌薬適正使用支援チームの組織を含む抗菌薬の適正使用を支援する体制の評価として抗菌薬適正使用支援加算が新設された。当院でも感染症治療の早期モニタリングとフィードバック、微生物検査室・臨床検査の利用の適正化、抗菌薬適正使用にかかわる評価、抗菌薬適正使用の教育・啓発などを行うことによる抗菌薬の適切な使用の推進を目的に抗菌薬適正使用支援チームが始動したところであり、われわれ薬剤師にとっても身近な話題であった。

(学 術)

血管撮影装置における透視画像の評価方法について

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【背景】

近年、増加する医療被ばくに対応するために、医療被ばくに関連する学会・行政・産業界などから構成される医療被ばく研究情報ネットワーク (J-RIME) から、日本初となる医療被ばくの線量指標を示した診断参考レベル (DRLs2015) が発表された¹⁾。

Interventional Radiology (IVR) の分野では患者照射基準点における透視線量率20mGy/min となっているが、画質については言及されていない。透視線量率が DRLs 2015を下回っていても画質が悪ければ IVR 手技の延長に繋がり、かえって被ばく線量の増加になり得る。つまり我々放射線技師は DRLs2015を参考しつつ画質を担保する必要があるといえる。しかし、透視線量率は線量計を用いて測定を行えば求めることが出来るが、透視画像を評価する方法については未だに確立していない²⁻⁵⁾。そこで、血管撮影装置の透視画像を評価する方法について検討を行う必要があると考える。

【目的】

血管撮影装置における透視画像の評価方法につ

いて検討する。

【使用機器】

- ・血管撮影装置：PHILIPS AlluraClarity FD20
- ・JSGI ファントム
- ・Primus L
- ・動画用ファントム
- ・アクリル板：35×35×20cm
- ・半導体線量計：RTI Piranha657 CB2-12020217
- ・Image J

【方法】

1、患者照射基準点に線量率の測定

①アクリルファントム20cmを使用して、「IVR 基準点における測定マニュアル」に則って患者照射基準点 (図1) における透視線量率を測定した。透視条件は通常使用している心臓カテーテル検査のプランを使用した (透視フレームレート15f/s)。

2、ファントムの測定

②①と同じジオメトリにて、透視用ファントムである JSGI (図2) をインチサイズを19インチと10.5インチとし、透視条件 (フレームレート) を15f/s・7.5f/s・3.75f/sと変化させて、表示さ

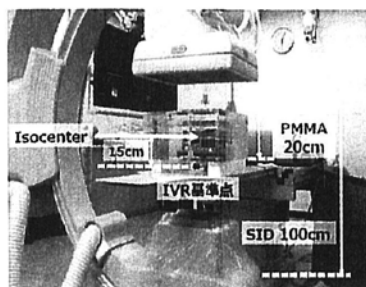
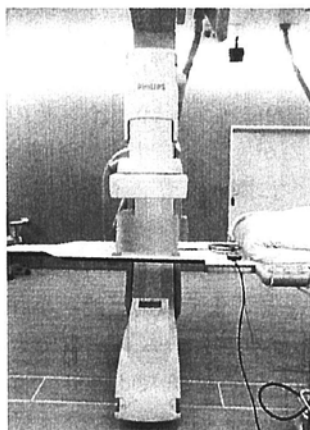


図1 患者照射基準点

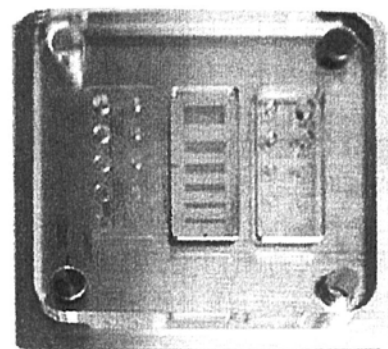


図2 JSGI ファントム

Safety and efficacy of exercise training in patients with abdominal aortic aneurysm: A meta-analysis of randomized controlled trials

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ABSTRACT

Objective: Low exercise capacity preoperatively leads to increased postoperative complications, perioperative mortality, length of stay, and inpatient costs among patients going through elective abdominal aortic aneurysm (AAA) surgery. Therefore, exercise training may be extremely important for reducing perioperative adverse events in AAA patients. This paper aimed to perform a meta-analysis of randomized controlled trials to evaluate the safety of exercise training and its effects on exercise capacity in AAA patients.

Methods: We searched for randomized controlled trials published up to December 2017 that compared exercise training vs usual care without exercise training in AAA patients. The primary outcome was safety, specifically the occurrence of cardiovascular adverse events during the study. Secondary outcomes were changes in AAA diameter, inflammation markers, and exercise capacity based on peak oxygen consumption (peak $\dot{V}O_2$) and anaerobic threshold (AT).

Results: We identified 341 trials, and after an assessment of relevance, 7 trials with a combined total of 489 participants were analyzed. There were a total of two cardiovascular adverse events during the exercise test and training, and the cardiovascular event rate and its 95% confidence interval (CI) were 0.8% and 0.2% to 3.1%. Exercise training did not tend to increase AAA diameter, and it also tended to decrease high-sensitivity C-reactive protein level in patients with AAA. All studies that evaluated the changes in AAA diameter or high-sensitivity C-reactive protein level involved patients with AAA diameter <55 mm at baseline; there was no study involving participants with AAA diameter \geq 55 mm at baseline. Exercise training significantly increased peak $\dot{V}O_2$ (pooled mean difference, 1.67 mL/kg/min; 95% CI, 0.69-2.65; $P < .001$) and AT (pooled mean difference, 1.98 mL/kg/min; 95% CI, 0.77-3.19; $P < .001$) in AAA patients. The result of meta-regression suggested that the effects of exercise training on peak $\dot{V}O_2$ and AT were not modulated by the exercise duration.

Conclusions: Our analyses suggested that exercise training among AAA patients is generally safe, although future research should be carried out to further clarify the safety among patients with large AAAs. Exercise training improved peak $\dot{V}O_2$ and AT in AAA patients. More data are required to identify the optimal exercise duration for improving exercise capacity in patients with AAA. (J Vasc Surg 2018;■:1-11.)

Keywords: Abdominal aortic aneurysm; Exercise training; Safety; Exercise capacity

Abdominal aortic aneurysm (AAA) is a degenerative condition of the abdominal aorta and is frequently lethal if it ruptures.¹ The incidence of AAA is high in Japan in comparison with other countries because of the high prevalence of hypertension, a large proportion of elderly in the population, and the high availability of computed tomography, which facilitates the diagnosis of aortic

diseases.² More than 13,000 open or endovascular AAA repairs are performed in Japan each year.³

AAA typically develops in elderly persons with arteriosclerosis. AAA is found in 5% to 7.5% of men and 1.5% to 3% of women older than 65 years.¹ In elderly AAA patients, exercise capacity is often poor as a consequence of comorbid diseases, sedentary lifestyle, and age.⁴ Exercise capacity is known to be associated with AAA repair outcomes: low exercise capacity preoperatively leads to increased postoperative complications, perioperative mortality, length of stay, and inpatient costs.⁵⁻⁷ Therefore, to reduce perioperative adverse events, exercise training may be extremely important for AAA patients. However, exercise training in AAA patients has received little attention in the literature. Some small randomized controlled trials (RCTs) have reported that exercise training is safe and leads to increased exercise capacity in AAA patients, but no systematic review or meta-analysis has been carried out to date. Given the limited evidence, physicians and other health care providers may hesitate to recommend

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Author conflict of interest: none.

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Original Article

Characteristics of respiratory muscle fatigue upon inhalation resistance with a maximal inspiratory mouth pressure of 50%

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Abstract. [Purpose] Considering that respiratory muscle fatigue is a cause of respiratory failure, we aimed to clarify the characteristics of respiratory muscle fatigue under inhalation load and investigate its impact on individual respiratory muscles. [Participants and Methods] The study included 14 healthy adult male volunteers. Maximal inspiratory and expiratory mouth pressures were measured under inhalation load and while at rest. The statuses of the trapezius, sternocleidomastoid, pectoralis major, diaphragm, rectus abdominis, and external and internal abdominal oblique muscles were also assessed using electromyographic frequency analysis. [Results] The maximal inspiratory and expiratory mouth pressures decreased over time and recovered after rest. The median power frequency decreased significantly in the sternocleidomastoid and rectus abdominis muscles at maximal inspiratory and expiratory mouth pressures, respectively, under inhalation load. [Conclusion] As a characteristic of respiratory muscle fatigue, there is a possibility that decreases in maximal inspiratory and expiratory mouth pressures as a result of the inhalation load affect muscle fatigue in the sternocleidomastoid and rectus abdominis muscles.

Key words: Respiratory muscle fatigue, Maximal mouth pressure, Surface electromyogram

(This article was submitted Nov. 13, 2018, and was accepted Jan. 3, 2019)

INTRODUCTION

Respiratory muscle fatigue was first described in 1977 by Roussos and Macklem¹⁾ it was identified as a cause of the onset of ventilatory impairment, which is often accompanied by the onset of hypoxemia and hypercapnia. In 1990, the Respiratory Muscle Fatigue Workshop Group²⁾ defined respiratory muscle fatigue as “a condition in which there is a loss in the capacity for developing force and/or velocity of a muscle, resulting from muscle activity under load and which is reversible by rest.” Moreover, respiratory muscle fatigue has been identified as one of the major causes of respiratory failure³⁾. The load causing respiratory muscle fatigue is reportedly caused by respiration under mechanical load due to external resistance²⁾, and loads with a maximal pressures of $\geq 40\%$ are important factors related to the onset of respiratory muscle fatigue⁴⁾.

Respiratory muscle fatigue is the cause of respiratory failure in several cases of chronic obstructive pulmonary disease (COPD), which is a typical target for respiratory rehabilitation⁵⁾. The decrease in the contraction power of the respiratory muscles associated with this condition is thought to play a crucial role in numerous respiratory diseases; it is also assumed to be a major cause of restriction on exercise⁶⁾. Thus, training techniques, which are collectively known as ventilatory muscle training (VMT), designed to increase the contraction power of fatigued respiratory muscles and to recover their stamina are often conducted for such patients^{6, 7)}. However, the importance of respiratory muscle fatigue may not be sufficiently recognized in the clinical setting⁸⁾ resulting in the present state of affairs, whereby respiratory muscle fatigue is almost never

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Original Article

Relationship between advanced glycation end-product accumulation in the skin and pulmonary function

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Abstract. [Purpose] This study aimed to evaluate the relationship between advanced glycation end-product accumulation and pulmonary function in a general population with normal spirometry results. [Subjects and Methods] A total of 201 subjects (mean age, 56 ± 11 years; males, 58%) enrolled in this study. Subjects were classified into two groups (younger group [<65 years old] and elderly group [≥ 65 years old]). Skin autofluorescence was assessed as an estimate of advanced glycation end-product. Forced vital capacity and forced expiratory volume in one second were measured using a spirometer, and the forced expiratory volume in one second/forced vital capacity ratio (FEV1/FVC) was calculated. [Results] Skin autofluorescence was not an independent factor associated with FEV1/FVC in the younger group, but both skin autofluorescence and pack-years of smoking were significant independent factors associated with FEV1/FVC in the elderly group. [Conclusion] Advanced glycation end-product accumulation, assessed by skin autofluorescence, is an independent factor negatively associated with FEV1/FVC in elderly people with normal spirometry results.

Key words: Advanced glycation end product, FEV1/FVC, Elderly

(This article was submitted Nov. 17, 2017, and was accepted Dec. 12, 2017)

INTRODUCTION

Chronic obstructive pulmonary disease (COPD) remains a major public health problem and is projected to rank fifth in global disease burden by 2020¹⁾. COPD is induced by long-term cigarette smoking, and is primarily characterized by the presence of airflow limitations resulting from airway inflammation and remodeling and the development of emphysema²⁾. Chronic inflammation occurs not only in the airways of COPD patients, but throughout the body as well, given that inflammatory mediators are known to spread from the lung to the rest of the body²⁾.

According to recent studies, the level of advanced glycation end products (AGEs) increases with age and is higher in smokers and COPD patients^{3, 4)}. AGEs are bioactive molecules formed by the nonenzymatic glycation or peroxidation of proteins, lipids, and nucleic acids^{5, 6)}. AGEs increase inflammation by binding to receptors for AGE (RAGE), which are present on cell surfaces in tissues^{5, 7)}. Therefore, AGE accumulation may play a role in the pathogenesis of COPD by increasing inflammation⁸⁾.

Several AGEs, such as pentosidine and N ϵ -(Carboxymethyl)-L-lysine (CML), have been reported to emit a characteristic fluorescence in human skin⁹⁾. AGEs assessed by skin autofluorescence (SAF) could help in the rapid evaluation of AGE

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研究論文 (原著)

ストレッチング体操が植込み型除細動器あるいは 両心室ペーシング機能つき植込み型除細動器を 装着した運動習慣のない慢性心不全患者の 血管内皮機能と運動耐容能に与える影響*

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要旨

【目的】 植込み型除細動器 (以下, ICD) あるいは両心室ペーシング機能つき植込み型除細動器 (以下, CRT-D) を装着した慢性心不全 (以下, CHF) 患者に対するストレッチング体操が, 血管内皮機能と運動耐容能に与える影響を検討した。【方法】 対象を ICD あるいは CRT-D が植え込まれた運動習慣のない CHF 患者 32 名 (男性 27 例, 平均年齢 69 ± 9 歳) とし, ストレッチング体操を実施するストレッチング群と対照群に無作為に分類した。4 週間の介入前後の反応性充血指数 (以下, RHI) と 6 分間歩行距離 (以下, 6MWD) を評価した。【結果】 ストレッチング群の RHI と 6MWD は, 介入前と比較して介入後に有意に増加した ($P < 0.01$, $P < 0.01$)。介入前後の RHI と 6MWD の変化量は, 有意に正相関 ($r = 0.53$, $P < 0.05$) を示した。【結論】 ICD あるいは CRT-D 患者に対するストレッチング体操の効果として, 血管内皮機能障害と運動耐容能の改善が考えられた。

キーワード 植込み型除細動器, 両心室ペーシング機能つき植込み型除細動器, 慢性心不全, 血管内皮機能, 運動耐容能

はじめに

植込み型除細動器 (以下, ICD) あるいは両心室ペーシング機能つき植込み型除細動器 (以下, CRT-D) を装着した慢性心不全 (以下, CHF) 患者に対する持久力トレーニングは, 運動耐容能を増加することが報告されている¹⁾。しかし, ICD を装着した一部の CHF 患者は, 不整脈の出現による ICD の作動に強い不安を感じ

ていると報告されている²⁾。また, 最近の研究では, ICD あるいは CRT-D を移植した患者の約 14% が移植後 1 年以内に ICD の作動を経験するとされており³⁾, ICD の作動を経験した患者は, さらなる ICD の作動を受けることに対する恐怖感からうつ状態になりやすいことが知られている⁴⁾。先行研究によると, ICD の作動に対して不安を感じている患者や ICD の作動によりうつ状態になった患者は, 日常生活における身体活動を制限し, さらに持久力トレーニングも避けるようになることが報告されている⁵⁾。また, CRT-D を移植しても, 心不全症状が改善しない患者や, 逆に症状が悪化してしまう患者が一部に存在すると報告されている⁶⁾。このような患者は, 持久力トレーニングの実施により心不全の増悪を生じる可能性があり, 持久力トレーニングを処方することが難しい場合がある。これらのことから, ICD あるいは CRT-D を装着した CHF 患者の中には, 持久力トレーニングが適応とならない患者が存在し, このような患者に対しては運動耐容能の維持を目的とした代替の運動療法を提供する必要があると考える。

* Effects of Stretching Exercises on Vascular Endothelial Dysfunction and Exercise Capacity in Chronic Heart Failure Patients with an Implantable Cardioverter Defibrillator or Cardiac Resynchronization Therapy-defibrillator

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プレフレイルと静的立位バランスとの関係

Relationship between Pre-frailty and Static Standing Balance

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ABSTRACT: [Purpose] This study aimed to investigate the relationship between pre-frailty and static standing balance (Static balance). [Participants and Methods] A total of 187 outpatients enrolled in this study. They were divided into a healthy group (n=101), and a pre-frailty group (n=86). Appendicular skeletal muscle mass index (SMI) was measured using dual-energy X-ray absorptiometry (DXA). The rectangle area (REC AREA), a stabilometric parameter, was measured with subjects' eyes open and used as an estimate of static balance. [Results] SMI was significantly lower in the pre-frailty group than in the healthy group. REC AREA was significantly higher in the pre-frailty group than in the healthy group. REC AREA was a significant factor associated with pre-frailty according to multivariate logistic regression analysis. [Conclusion] The results suggest that static balance measured by REC AREA is a factor associated with pre-frailty.

Key words: pre-frailty, static standing balance, skeletal muscle mass index

要旨: [目的] プレフレイルと静的立位バランス (静的バランス) との関係を検証すること。[対象と方法] 銀座医院を受診した187名を対象とし、健常群101名、プレフレイル群86名に分類した。調査項目は対象の背景、握力、骨格筋指数 (SMI)、静的バランスの指標である矩形面積とした。SMIは二重エネルギーX線吸収測定法 (DXA) を用いて算出し、矩形面積は重心動揺検査装置を用いて開眼にて30秒間計測した。[結果] プレフレイル群の男性の割合、握力、SMIは健常群と比較して有意に低値を認め、年齢と矩形面積は有意に高値を認めた。矩形面積はプレフレイル群に関係する因子として抽出された。[結語] プレフレイルの状態から静的バランスが低下している可能性が示唆された。

キーワード: プレフレイル、静的立位バランス、骨格筋指数

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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

慢性腎臓病患者の食事療法に対する意思決定バランス

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【目的】 保存期慢性腎臓病（CKD）患者において、食事療法に対する意思決定バランスを属性ごとに比較する。

【方法】 2016年2月～9月、都内1病院に通院するCKD患者54名を対象とし、食事療法に対する有益性、障害の項目を含む質問紙調査を実施した。初めに、各項目の人数分布を算出した。その後、有益性、障害の合計得点と性別、年齢、BMI、eGFR、糖尿病既往歴、調理担当者の項目でMann-Whitney U検定を用いて比較した。合計得点で有意差もしくは有意傾向のみられた属性は、各項目で得点を比較した。

【結果】 対象者54名中、男性は27名（50.0%）であった。有益性、障害の各々の合計得点と属性を比較した結果、有益性では有意差はみられなかったが、障害では、性別と調理担当者の2つの属性で、合計得点と有意差もしくは有意傾向がみられた（各々 $p=0.034$, $p=0.057$ ）。障害の項目別では、「食事療法を行うと、食事の準備や選択に手間がかかる」の項目で性別に有意差がみられ、女性（2.0（2.0, 4.0）点）よりも男性（4.0（3.0, 5.0）点）の方が（各々中央値（25, 75%タイル値））、食事の準備や選択に手間がかかると回答していた（ $p=0.02$ ）。

【結論】 保存期CKD患者において、食事療法に対する有益性では属性による差はないが、障害では性別や調理担当者により捉え方が異なることが示唆された。

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キーワード: 慢性腎臓病, 食事療法, 意思決定バランス

I. 緒言

我が国における20歳以上の慢性腎臓病（CKD: chronic kidney disease）患者は、推定1,330万人であり¹⁾、さらに慢性腎臓病による透析患者数は32万人（2014年12月現在）に達している²⁾。CKD患者では、糸球体濾過率を適切にコントロールできないと、不可逆的にCKDが進行し、透析に至る³⁾。透析患者では心房細動や脳血管疾患などの罹患リスクが高くなる^{4,5)}。現在、我が国の透析に関する医療費は国民総医療費の5%の1兆5千万円を超えていることより⁶⁾、末期腎不全に達する前の保存期CKDでの重症化予防が重要といえる。

CKDの治療は、薬物療法、運動療法、食事療法から成る。特にCKD患者の食事療法は、食塩制限やたんぱく質制限、エネルギー補給、さらに糖尿病など合併疾患に応じた複雑な管理が求められる。それゆえ、CKD患者では食事療法の順守率は他の慢性疾患と比べると概して低いことが示されている⁷⁻⁹⁾。この食事順守は障害や自己効力感などの認知が関係していることから¹⁰⁾、食事療法

を効果的に行うために、医療従事者は患者の行動に起因する認知を把握し、アプローチすることが求められる。

行動変容を進めていく上で必要なアセスメントの項目として、人の行動に起因する認知である、意思決定バランスが挙げられる¹¹⁾。意思決定バランスとは¹²⁾、人が新しい行動を取り入れるときに考える、その行動を行うことによる有益性と障害のことである。人は有益性が障害よりも高く評価された時、行動を実行する。すなわち、有益性を増強し、障害を減弱させることで、望ましい行動に導くことができる。慢性疾患患者を対象とした意思決定バランスの評価指標には、心不全患者を対象としたBennettらの「Beliefs About Dietary Compliance Scale」を始め^{13,14)}、いくつか開発されている^{15,16)}。また、意思決定バランスは、ヘルスビリーフモデル（HBM: Health Belief Model）^{17,18)}にも含まれ、慢性疾患のセルフケアのための介入とその評価に用いられている^{13-16,19-21)}。糖尿病患者においては、有益性の増加と障害の減少が血糖や、BMI（body mass index）を低下させるなど、セルフケアに関連していることが報告されている²²⁾。

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高齢糖尿病患者に対するフレイル予防介入プログラムの評価についての検討 —糖尿病教室を用いた多職種連携による介入—

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要旨

近年、要介護状態に移行する前の状態としてフレイルという概念が注目されている。糖尿病は、フレイルに至る要因を多く有しており、フレイルの予防には食事および運動療法が重要であると報告されている。

高齢者糖尿病患者のフレイル予防に繋がる介入プログラムを実施し、その効果を検証することを目的とした。

基本チェックリスト (Kihon Check List: KCL) 8点以上にてフレイルと判定された介護保険を使用していない65歳以上の糖尿病患者30名、75.3±4.8歳を対象にフレイル予防のための食事指導の講義、運動の講義および体操からなる10回の糖尿病教室を行った。また、自宅における運動をノートに記入してもらい、糖尿病教室参加時に毎回フレイル予防ノートを確認した。調査項目は、KCL25項目、介護保険の利用状況、握力、歩行速度、Time Up and Go (TUG) などの身体計測と認知機能評価、栄養評価および糖尿病データを調査した。

教室修了者14名平均年齢75.3±4.8歳、HbA1c7.9±0.9%、脱落者は16名 (53.3%) で平均年齢76.1±6.1歳、HbA1c7.9±0.8%であった。糖尿病教室参加中に転倒した者は5名 (35.7%)、介護保険利用開始者は、2名であった。教室の前後比較では、TUG値、前10.1 (8.8-12.3)、後9.5 (7.6-11.8) およびKCL得点前9.0 (8.0-10.0)、後6.0 (2.0-8.0) と有意に改善された。さらに、教室終了群と教室脱落群の教室前の比較では、握力値、TUG値、栄養評価得点は脱落群で有意に低下していた。教室終了群のアンケート調査では、脱落群と比較してより具体的な内

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Assessment of a Frailty Prevention Program for Elderly Patient with Diabetes: A Multidisciplinary Intervention with Diabetes Awareness Classes

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Key Words: frailty prevention, diabetes classes, elderly, multidisciplinary intervention

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〈旧Churg-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

疾患病態別心カテプロトコル

両心室ペーシング急性効果

acute hemodynamic effect of biventricular pacing

小鹿野道雄 (独立行政法人国立病院機構静岡医療センター循環器内科)

心カテのポイント

- 一部の施設でのみ行われている手技であるが、両心室ペーシング治療の効果予測判定に有用である。
- LV dP/dtが両心室ペーシング中にbaselineより10%以上上昇すれば慢性期の効果が期待できる。
- 心臓再同期療法(CRT)植込み前に、複数の冠静脈分枝から候補となる左室ペーシング部位(最遅延伝導部位)を同定でき、実際のペーシングによる血行動態変化を評価できるため、最適なCRTの導入が可能となり、かつ植込み術中の負担軽減につながる。

基本病態

- 両心室ペーシング治療：CRTは症候性慢性心不全患者に対し、人工ペーシングにより電気的心臓内非同期を是正する治療である¹⁾。
- わが国での適応はニューヨーク心臓協会(NYHA)分類Ⅲ～Ⅳ、左室駆出率(LVEF) < 35%, QRS > 120msecであるが、この適応基準を満たしていても約30～40%の患者では期待する効果が得られない、いわゆるnon-responderとなってしまう。
- non-responderの原因として、重症心不全患者の心臓内の電氣的興奮伝播は複雑でありペーシングに対する反応も患者ごとに多様性があることが挙げられる²⁾。
- 実際に適切な左室リード留置部位で両心室ペーシングを行い、血行動態の急性効果を測定することでCRTの適応をよりの確にできる³⁾。

心カテの適応

- CRTを検討している患者



話 題

遺伝性不整脈に対する 最新のデバイス治療*

小鹿野 道雄**

Key Words : subcutaneous intracardiac 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療法・デバイス治療などが行われる。本稿では、まず最新のデバイス治療について総論を述べ、その後遺伝性不整脈に対する適応について述べる。

皮下植込み型除細動器 (subcutaneous intracardiac cardioverter defibrillator : S-ICD)

従来の経静脈植込み型除細動器(transvenous intracardiac cardioverter defibrillator : T-ICD)は致死性不整脈である心室頻拍・心室細動(VT/VF)による突然死を予防する手段として一次予防・二次予防ともに確立された治療法として普及した¹⁾²⁾。しかし、T-ICDの除細動リードは鎖骨下静脈より挿入し、三尖弁を通過して右室心尖部や中隔に留置する必要がある。そのため、リードは肩関節の動作や心拍動を介して頻回の機械的刺激を受けることになり、長期の経過でリード損傷のリスクがある。また、植込み手技中のリード挿入に伴う合併症や植込み後の菌血症に伴うリードや本体の感染症のリスクもある。T-ICDシステムが感染した場合、システム全体の抜去が推奨されている³⁾。しかし、長期経過したT-ICDのリード抜去手技は困難であり、静脈損傷や心穿孔、弁障害、血胸などの合併症が多く報告

されている⁴⁾。これら経静脈的手技に関連するリスクを軽減させるために開発されたのがS-ICDである。

S-ICDはT-ICDと同様に本体と除細動リードで構成されているが、除細動リードは胸骨近傍の皮下に植え込まれ、本体は左中～後腋窩線レベルの前鋸筋と広背筋の間に植え込まれる(図1)。頻拍の感知・検出は胸骨近傍の除細動リードに装着されている14 cm離れた2つの電極とS-ICD本体の間で構成される3つの誘導から選択される⁵⁾。T-ICDでは心内膜に留置したリードで心房、心室それぞれの電位を感知するが、S-ICDでは皮下の電極で電位を感知する。そのためS-ICDでは12誘導心電図のような波形となりP波、QRS波、T波が同定される波形となる。しかし、得られる電位は振幅が低く、体位によっても変化しやすい。そのためS-ICD植込み術を検討する場合、感知・検出不良による不適切作動を予防するために術前の心電図スクリーニングを必ず行う。S-ICD後の最も多い不適切作動の原因はT波のオーバーセンシングであり、スクリーニングで安全性が確保できない患者ではS-ICDは不適となる(図2)。S-ICD候補となる患者の7～10%がスクリーニングでS-ICD不適と判断されており、肥大型心筋症や先天性心疾患合併の症例に多いことが報告されている⁶⁾。

S-ICDはショック作動後に30秒のバックアップペーシングが使用できるが、ショック作動後

* Current device therapies for inherited arrhythmia syndrome.

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編集後記

平成 30 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、勝又さん、薬剤師の薄先生、いつもありがとうございます。休日返上で研修や会議に出席し努力する姿に頭が下がります。また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。それから事務の渡邊光子さん。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。渡邊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。

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