（倫理面への配慮）

本研究は、参加各施設における倫理委員会の承認を受けた上で、患者からの文書による同意を得て行った。

C. 研究結果

1) ずり応力下血小板機能測定

超低体温（20℃）を用いて弓部全置換術を行った患者で、国立循環器病センターのサブスタディーとして解析可能であった症例における術前、人工心肺離脱直後（血小板輸血実施前）、ICU 帰室後における検体を平行板型フローチャンバー内に流し込み解析をおこなった。術前（n=18）における測定開始 10 分後の血小板血栓の高さは、23.3（平均）±6.9（1 S.D.）μm で、表面占有率は 68.0（平均）±15.1（1 S.D.）%あった。人工心肺離脱直後で血小板輸血実施前（n=15）の測定開始 10 分後の血小板血栓の高さは 5.8（平均）± 0.9（1 S.D.）μm で、表面占有率は 21.3（平均）±6.8（1 S.D.）%あった。ICU 帰室後（n=9）における測定開始 10 分後の血小板血栓の高さは、21.6（平均）±7.9（1 S.D.）μm で、表面占有率は 62.3（平均）± 11.4（1 S.D.）%あった。一方、中等度低体温（28℃）を用いて弓部全置換術を行った患者における結果は下記のとおりであった。術前（n=11）における測定開始 10 分後の血小板血栓の高さは、19.3（平均）±10. 1（1 S.D.）μm で、表面占有率は 55.4（平均）±17.2（1 S.D.）%であった。人工心肺離脱直後で血小板輸血実施前（n=9）の測定開始 10 分後の血小板血栓の高さは 5.6(平均)± 0.7（1 S.D.）μm で、表面占有率は 21.9（平均）± 7.5（1 S.D.）%であった。ICU 帰室後（n=5）における測定開始 10 分後の血小板血栓の高さは、11.0（平均）±8.1（1 S.D.）μm で、表面占有率は 39.1（平均）±20.8（1 S.D.）%であった。いずれの群においても、術前と比較して人工心肺離脱直後に明らかな血小板機能低下が認められ、ICU 帰室後には改善していた。中等度低体温（28℃）患者群で、術前の血小板機能が若干低く、人工心肺離脱直後で血小板輸血実施前では、両群にほとんど差が無く、ICU 帰室後では中等度低体温患者群の方が、血小板機能が低い傾向が認められた。

2) 術中輸血量

輸血量について検討してみると、超低体温（20℃）を用いて弓部全置換術を行った患者（n=28）では、赤血球製剤は、14.5 単位 ±11.3 単位、新鮮凍結血漿 17.1 単位 ± 10.7 単位、濃厚血小板製剤 22.9 単位 ± 19.1 単位であった。一方、中等度低体温（28℃）を用いて弓部全置換術を行った患者(n=25)では、赤血球製剤 6.0 単位 ±6.9 単位、新鮮凍結血漿 6.5 単位 ± 7.7 単位、濃厚血小板製剤 4.0 単位 ±10.4 単位であった。赤血球製剤、新鮮凍結血漿、濃厚血小板製剤、いずれの製剤においても輸血量は、中等度低体温群で少ない傾向にあった。また、血小板製剤輸血を必要とした症例は、超低体温（20℃）群では、71%（20/28）であったが、中等度低体温（28℃）症例では、16%（4/25）であった。

超低体温群（20℃）において、中等度低体温群と比較して ICU 帰室後の血小板機能が高かったのは、血小板製剤輸血量が超低体温群で多かったことの影響であると考えられた。

D. 考案

従来までの超低体温を用いた弓部全置換術に比較して、生理的条件に近付けた 28℃中等度低体温下手術では、（超）低体温の弊害である体外循環時間の延長、臓器の温度較差、非生理的環境、それに基づく全身浮腫、肺障害、出血傾向などが回避でき、早期回復や出血が少ないなど「warm surgery」の利点が期待できうる。

本研究では、中等度低体温下弓部全置換術と超低体温下弓部全置換術、それぞれの手術における血小板機能の推移を測定し、輸血量との関連を含めた解析を行うことにより、低体温の血小板機能、止血機能に与えるインパクトを検討した。生理的条件に近付けた 28℃中等度低体温下手術にて、すべての血液製剤（赤血球製剤、新鮮凍結血漿、濃厚血小板製剤）の輸血量が少ない傾向にあった。術前、人工心肺離脱直後で血小板輸血実施前の血

小板機能を両群で比較した場合、超低体温群で、血小板血栓の高さは、術前 23.3μm から人工心肺離脱直後で血小板輸血実施前に 5.8μm へ、表面占有率は、65.3%から 21.3%への低下であったが、中等度低体温弓部全置換術群では、血小板血栓の高さは、術前 19.3μm から人工心肺離脱直後で血小板輸血実施前に 5.6μm へ、表面占有率は、55.4%から 21.9%への低下であり、中等度低体温（28℃）弓部全置換術群で若干血小板機能低下割合が少ない（特に表面占有率において）傾向となっていた。しかしながら、このような体温の違いによる若干の血小板機能の相違だけで、観察されたようなすべての製剤における輸血量の明らかな相違を説明することは困難であり、血小板機能以外の凝固線溶系、炎症など他の因子が複雑に関与している可能性が高いと考えられる。

また、超低体温群（20℃）において、血小板製剤輸血量や血小板輸血割合が高く、中等度低体温群と比較して ICU 帰室後の血小板機能が高かったのは、超低体温群では、血小板機能、凝固線溶系、炎症などの影響により、出血傾向が強く、血小板製剤輸血等により血小板機能をより改善させないと止血が完了できないことを反映しているものと考えられた。

今後、中等度低体温（28℃）弓部全置換術において輸血量が少ない因子について、さらに詳細な検討を加えていく予定である。

E. 結論

- 中等度低体温（28℃）弓部全置換術群では、超低体温（20℃）群と比較して、輸血量が少ない傾向が見られた。
- 中等度低体温では超低体温と比較して血小板機能低下が軽減されている可能性が示唆された。しかしながら、血小板機能以外の因子（凝固線溶系、炎症など）が輸血量の変化に対してより強く関与しているものと考えられた。
- 超低体温群では、血小板機能、凝固線溶系、炎症などの影響により出血傾向が強く、血小板製剤輸血等により血小板機能をより改善させないと止血が完了できないものと考えられた。

F. 健康危険情報

特になし

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H. 知的財産権の出願・登録状況（予定を含む）

なし

厚生労働科学研究補助金（循環器疾患等生活習慣病対策総合研究事業）
総合研究報告書

弓部大動脈全置換術における超低体温療法の中等度低体温療法の多施設共同前向き調査研究：弓部大動脈全置換術における超低体温療法と中等度低体温療法のランダム化比較試験に関する研究

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研究要旨：超低体温療法を標準手段としてきた弓部全置換術において、最近になり生理的な選択的順行性脳灌流下で中等度低体温下手術が試みられている。第一段階として28℃中等度低体温と20℃超低体温における各々の特徴を明らかにするための多施設共同前向き調査研究(JSTAR I)を行った。 JSTAR Ⅰの結果を踏まえて、総輸血量の差を主要評価項目に、死亡・合併症の発生割合や術後人工呼吸管理期間などを副次的評価項目として設定し、より厳密に二群間でランダム化比較試験（JSTAR II）を行った。

A. 研究目的

弓部大動脈全置換術において、選択的順行性脳灌流（SCP）が安全に施行されるようになり、今までは脳保護を含めた臓器保護のために用いられていた超低体温が不可欠ではなくなってきたと考えられている。臨床的には術中最低温が経験的に徐々に上げられ、本邦では多くの施設で中等度低体温下弓部全置換術が試みられてきている。この二群を厳密に比較し、それぞれの長所短所を明確にする目的で本研究は開始された。第一段階として、まず中等度低体温下手術と超低体温下手術における多施設共同前向き調査研究（JSTAR I）を行った。引き続いて、その解析データから総輸血量の差を主要評価項目に、死亡・合併症の発生割合や術後人工呼吸管理期間などを副次的評価項目として設定し、多施設（８施設）でより厳密に二群間でランダム化比較試験（JSTAR II）を行った。

B. 研究方法

第一段階として、SCP を脳保護手段とした弓部全置換術において、28℃中等度低体温と 20℃超低体温における多施設共同前向き調査研究(JSTAR I)を行った。手術は、胸骨正中切開下にSCP を脳保護手段として、4分枝人工血管を用いた弓部分枝個別再建法により弓部全置換を行った. 各群の SCP 圧、SCP 量は① 膀胱温 20℃ SCP 圧 30-50 mmHg → 10 ml/kg/min、 ② 膀胱温 28℃ SCP圧 ≧50 mmHg → 15～25 ml/kg/min. 評価項目は、1) 術後 30 日以内死亡、および脳･脊髄障害、心臓障害、肺障害、腎障害、出血、感染、などの合併症の発生割合、および2) 臨床データ: ① 手術方法 ②出血量 ③循環動態計測 ④呼吸状態 ⑤脳神経機能 ⑥腎機能、肝機能 ⑦凝固機能 ⑧その他 であった。第二段階として。 28℃前後中等度低体温下弓部全置換術と 20℃前後超低体温下弓部全置換術における多施設（８施設）ラ

ンダム化比較試験研究(JSTAR II)を行った。80歳未満の待機的弓部全置換術患者を対象とし、弁置換術や冠動脈バイパス手術等の併施手術を行う患者は除外された。また、緊急患者、再手術患者も除外された。総輸血量の差を主要評価項目に、死亡・合併症の発生割合や術後人工呼吸管理期間などを副次的評価項目として設定した。ランダム化のために、登録された適格患者を上記二群に 1:1 に中央登録で割り付けた。

C. 研究結果

JSTAR I では、本院では 34 例の症例登録がなされた。7 例で有害事象を認めた。このうち、心不全が 2 例、呼吸不全が 2 例、脳神経障害が 2 例、出血が 1 例であった。心不全の 1 例が多臓器不全に陥り死亡し、脳神経障害の 1 例に後遺症を残したが、残る 5 例は軽快した。いずれも研究との因果関係は無し、あるいは不明であった。現時点において未だデータは完全には統計処理が終了していないが、それぞれの弓部全置換術の特徴、すなわち、中等度低体温群で死亡、合併症を含めた有害事象の発生頻度が低く、輸血量も少なく、人工呼吸管理も短い傾向が示唆された。JSTAR II では、15 例の症例登録がなされた。症例登録数は厳密な除外基準を設けたことで予想された数よりも大幅に減少した。その大きな原因は症例の高齢化と症例の複雑化であろうと考えられた。弓部全置換術自体の症例数は減ることはないものの、その大多数の症例で冠動脈バイパス術や大動脈弁置換術の併施が術前より予定され、JSTAR II の除外基準に触れてしまった。同様に登録した 3 例で術式の変更を術中に余儀なくされ、登録を中止した。有害事象の発生は 2 例で、1 例で縦隔炎と腹膜炎の発症を来たし、また 1 例で術後の血栓による動脈閉塞を来した。いずれも軽快し、有害事象は本研究と因果関係は無し、あるいは不明であると考えられ、いずれも軽快退院された。その他の主要評価項目、副次的評価項目ともに現時点においてデータの集計、解析中である。

D. 考察

超低体温法に代わり中等度低体温下弓部全置換術が、特に本邦において幅広く行われつつあるが、未だエビデンスとなる報告が乏しいのが現実である。欧米の専門家からは本法に対して未だ批判が少なくなく、その安全性の根拠となるデータの提出を期待されている。したがって、本研究は EBM 時代における中等度低体温下弓部全置換術の安全性を示すための一翼を担う重要なものと考えられた。しかしながら、大動脈手術における臨床研究、とりわけランダム化比較試験(JSTARII)においてはその患者登録が厳密に遂行しようとすればするほど困難であった。症例数が本稿執筆時には未だ 15 例しかなく、更なる期間延長をもって症例数が増加することを期待したい。

E. 結論

JSTAR I と JSTAR II を分担施設として共同研究を行った。JSTAR I において中等度低体温法で期待された長所が確認されたが、超低体温法との厳密な比較を行った JSTAR II の統計処理が待たれる。

F. 健康危険情報

なし

G. 研究発表

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H. 知的財産権の出願・登録状況

1. 特許取得

なし

2. 実用新案登録

なし

3. その他

なし

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総合研究報告書

弓部大動脈全置換術における超低体温療法と中等度低体温療法のランダム化比較試験に関する研究
統計解析およびデータマネジメントに関する研究

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研究要旨：28℃中等度低体温下弓部全置換術と20℃超低体温下弓部全置換術の特徴を明らかにするために、多施設共同前向き調査研究と多施設共同ランダム化比較試験が段階的に計画され、実施、解析が進められた。その各段階において統計的な観点から検討を行った。前向き調査研究の症例登録が終了し、術後3週までのデータの集計より、ランダム化比較試験の研究計画を検討した。主要評価項目として輸血量を設定し、独立したデータ安全性評価委員会を設け、安全性と評価項目の妥当性を確認することとした。

その後、前向き調査研究の症例観察が終了した段階で、データのクリーニングを行い、統計解析計画書を固定した後、解析を実施した。解析では、交絡要因の評価と調整した方法を検討した。また両研究のデータ管理、進捗管理を行った。

A. 研究目的

28℃中等度低体温下弓部全置換術と 20℃超低体温下弓部全置換術について、適切なデザインの研究によりそれらの特徴を明らかにし、有効性や安全性を評価することが重要である。そのために、多施設共同前向き調査研究を適切に計画、実施し、その評価をもとに、多施設共同ランダム化比較試験の研究計画を検討する。

両研究においてデータマネジメントを行うとともに、解析計画の詳細を明確にし、それに基づき解析を実施する。

B. 研究方法

1)前向き調査研究のデザインなどを検討し、データマネジメント関連の実施体制を整備する。

2)前向き調査研究の症例登録が終了し、術後3週までのデータが収集された段階で、ランダム化比較試験の計画を検討する。

3)前向き調査研究の症例観察が終了した段階で、データのクリーニングを行い、解析を実施する。解析では、交絡要因の評価と調整した方法を検討する。

4)両研究において、研究の進捗およびデータ管理を各実施医療機関、事務局、データセンターが協力して効率的に進めていく。

（倫理面への配慮）

前向き調査研究およびランダム化比較試験は、ヘルシンキ宣言、および臨床研究に関する倫理指針に従い実施する。データを解析する際には個人情報の取り扱いに留意する。

C. 研究結果

1)前向き調査研究の計画

対象集団は、待機的胸骨正中弓部全置換術患者とし、緊急患者、再手術患者を除外とした。

評価項目として、術後 30 日以内死亡（手術死亡）、および脳・脊髄障害、心臓障害、肺障害、腎障害、出血、感染などの合併症の発生割合を設定した。その他に、手術、出血、循環、呼吸、脳、血液などに関する項目を設定し、それぞれの弓部全置換術の特徴を明らかにすることを目的とした。

2)前向き調査研究からランダム化比較試験の計画

前向き調査研究は、2006 年 12 月に被験者登録を終了した。5 施設から症例が登録され、術後 3 週までの症例報告書が回収された 52 例について集計を行った。

その結果、輸血量、術後 30 日以内の合併症の発生、人工呼吸管理時間などに 28℃群と 20℃群による特徴が見られた。

これらをもとに、ランダム化比較試験の研究計画を検討した。

対象集団について、主に安全性と評価可能性を考慮し、前向き調査研究より詳細に選択・除外基準を設定した。

選択基準：

(1)弓部全置換術単独の患者（解離症例を含む）

(2)80 歳未満の患者

(3)弓部～遠位弓部瘤で下行大動脈への伸展が少なく正中到達が可能な患者

除外基準：

(1)緊急患者（大動脈瘤破裂、急性大動脈解離など）

(2)広範囲大動脈病変：手術適応に近い大動脈基部、下行大動脈（正中から到達困難なもの）、胸腹部大動脈、腹部大動脈瘤病変を合併する患者

(3)上行、弓部、弓部分枝に著しい粥状硬化性病変を有する患者

(4)高安病、Behcet病、Marfan症候群、Ehlers-Danlos症候群などの特殊大動脈病変患者

(5)重症閉塞性動脈硬化症合併患者

(6)再手術（再胸骨正中切開）患者

(7)脳、心、肺、肝、腎、血液・凝固機能に中等度以上の異常（合併疾患）を認める患者

(8)感染所見のある患者

(9)担癌患者

(10)痴呆（認知症）、精神疾患患者

(11)その他、担当医師が不適当と判断した患者

主要評価項目は、輸血量(MAP＋FFP)とした。副次的評価項目として、術後 30 日以内死亡（手術死亡）、および脳・脊髄障害、心臓障害、肺障害、腎障害、出血、感染などの合併症の発生割合を設定した。さらに、その他の評価項目として、血小板輸血を行った症例の割合、無輸血症例の割合、死亡および副次的評価項目の各合併症の発生割合、人工呼吸管理時間（抜管時期）などを評価する。

症例数は、前向き調査研究をもとに主要評価項目から設定し、1 群 50 例、合計 100 例を目標とした。

また、第三者の委員によるデータ安全性評価委員会を設置する。委員会は、登録開始後 5 ヶ月、登録終了後、及び追跡終了後に開催し、安全性と評価項目の妥当性を確認する。

3)前向き調査研究の終了とランダム化比較試験の進捗

前向き調査研究は、2007 年 12 月に観察を終了した。温度群については、20℃群が 28 例、28℃群が 25 例であった。施設により温度の選択に偏りがあり、両方の温度群が選択されたのは 1 施設のみであり、他の 2 施設は 20℃群のみ、残りの 2 施設は 28℃群のみの登録であった。また、CABG をあわせて実施した症例は、20℃群で 9 例、28℃群で 3 例あった。

輸血量（MAP＋FFP）について、CABG の実

施の有無別に示すと、CABG を実施しない層において 20℃群は 23.4±13.2 単位（n=19）、28℃群では 12.7±15.1 単位(n=22)であった。CABG を実施した層においては、20℃群では 49.0±23.7 単位（n=9）と多く、28℃群では 11.3±6.1 単位(n=3)であった。CABG の実施の有無で輸血量の結果が異なったため、これらをわけて評価した。CABG を実施しなかった層において性別、年齢、呼吸機能、クレアチニンで調整した結果、両群の差（20℃群－28℃群）の点推定値は 5.1 単位（p=0.314）であった。

要因を調整する propensity score による方法は、まず温度(20℃/28℃)について性別、年齢、呼吸機能、クレアチニンなどを要因としたロジスティックモデルを用いて propensity score を算出し、次に propensity score のみを説明変数とする一般線型モデルを用いた。その結果、点推定値は 4.9 単位（p=0.312）であり、一般線型モデルによる結果と大きな違いは認められなかった。

合併症は、20℃群で 9 例（32%）、28℃群で 1 例(4%)発生した。内容は、20℃群で脳障害 2 例、心臓障害 2 例、肺障害 4 例、出血 1 例、28℃群で脳障害 1 例であった。重篤な有害事象は、20℃群で 4 例（14%）、28℃群で 1 例（4%）であった。

ランダム化比較試験は、2007 年 5 月に登録を開始した。2008 年 3 月までに、7 施設から 38 例が登録され、そのうち実施しなかった症例が 2 例、中止した症例が 2 例あった。有害事象は 4 件報告された。この試験では独立安全性評価委員会を設置しており、これらの有害事象は独立安全性委員会へ報告された。

D. 考察

28℃中等度低体温下弓部全置換術と 20℃超低体温下弓部全置換術の特徴を明らかにするための評価項目は未だ確立されていない。本研究グループでは、前向き調査研究で得られた情報をもとに評価項目を設定し、ランダム化比較試験で評価するべく進めている。

前向き調査研究においては、温度群の設定をランダムに割り付けていないため、施設により温度群の選択に偏りがあった。その他の要因も両群間で異なっている可能性があり、評価項目を検討する際には要因の調整が重要となる。影響が強いと考えられる CABG 実施の有無は、輸血量の比較において層による違いが認められたため、層をわけて検討した。28℃群で輸血量が少ない様子がみられたが、要因を調整した結果有意な減少ではなかった。

要因の影響を考慮する方法について、一般線型モデルでは、要因の結果への影響をモデル化している。したがって、各要因の効果を評価することが可能であるが、このモデルが正しくないと温度群の影響を正確に評価できない。一方、propensity score による方法は要因の温度群へ影響をモデル化しており、各要因の効果を直接調べられないが、各要因の結果への影響をモデル化していないため、モデルに対する仮定が緩い。今回の 2 つの結果は大きく異ならなかったことから、モデル誤特定による影響は少なく、要因を調整した温度群の効果の大きさを評価できると考えられる。

合併症、重篤な有害事象では、20℃群より 28℃群の方が発生が少なかった。これらの結果に加え、副次的評価項目の結果も総合的に評価し、ランダム化比較試験で厳密に比較検討していく必要がある。

また、確かなエビデンスを示していくためにはデータマネジメントが大切である。クリニカル・データマネジメントは、研究データを統一して評価できる情報にまとめることであり、研究の計画段階から最終の報告書が完成するまでの各段階でおこなわれる。本研究では、前向き調査研究とランダム化比較試験でほぼ同様の手順で登録、症例報告書の収集、管理を行っている。

E. 結論

28℃中等度低体温下弓部全置換術と 20℃超低体温下弓部全置換術の特徴を明らかにするため

に、多施設共同前向き調査研究と多施設共同ランダム化比較試験が段階的に計画され、実施、解析が進められた。その各段階において統計的な観点から検討を行った。

前向き調査研究の症例登録が終了し、術後3週までのデータの集計より、ランダム化比較試験の研究計画を検討した。主要評価項目として輸血量を設定し、独立したデータ安全性評価委員会を設け、安全性と評価項目の妥当性を確認することとした。

その後、前向き調査研究の症例観察が終了した段階で、データのクリーニングを行い、統計解析計画書を固定した後、解析を実施した。解析では、交絡要因の評価と調整した方法を検討した。また両研究のデータ管理、進捗管理を行った。

F. 健康危険情報

なし

G. 研究発表

1. 論文発表

なし

2. 学会発表

なし

H. 知的財産権の出願・登録状況

1. 特許取得

なし

2. 実用新案登録

なし

3. その他

なし

III. 研究成果の刊行物・別刷

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How-to-do-it

Total arch replacement using a stepwise distal anastomosis for arch aneurysms with distal extension☆

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Abstract

A total of 120 patients having arch to distal arch aneurysm with downstream extension underwent total arch replacement, with individual arch-vessel reconstruction through median sternotomy using a novel 'stepwise' distal aortic anastomosis. Cardiopulmonary bypass was established by cannulating the right axillary artery and the ascending aorta or femoral artery. Hypothermia was at 22–28 °C. Through the aneurysm, the descending aorta was divided. Distal anastomosis using the stepwise technique was performed; a tube graft of length 7–12 cm was inserted into the descending aorta and anastomosed by running suture. The distal end of the inserted graft was extracted, and a further four-branched arch graft was joined to it. Selective cerebral perfusion was used for cerebral safety during arch repair. There were three hospital deaths (2.5%). Two patients (1.7%) developed permanent neurological dysfunction and three patients (2.5%) suffered transient cerebral deficits. Three patients (2.5%) required reentry for postoperative bleeding although in none of them bleeding was from the distal anastomosis site with the stepwise technique. Stepwise anastomosis is a useful and secure alternative for distal anastomosis in total arch replacement for arch to distal arch aneurysms with distal extension.

Keywords: Aortic arch; Aneurysm; Aortic dissection; Aortic surgery

1. Introduction

For arch to distal arch aneurysms, it is not agreed whether a median or lateral approach is better, particularly for aneurysms with distal extension [1–7]. The median approach aims to provide cerebral and cardiac safety [1–4]. However, the distal anastomosis is often difficult and bleeding from it is a serious problem [6,7]. We have therefore used a novel stepwise technique providing a technically easy and secure anastomosis.

2. Patients and methods

Between 1999 and 2003, 120 patients (74 years old) having an arch to distal arch aneurysm underwent total arch replacement. Of these, 112 patients had non-dissecting and two had dissecting aneurysms. The other six had a combined pathology. Ten patients required emergency surgery.

The aneurysm was approached through median sternotomy (Fig. 1A). After full heparinization, a 10–16 Fr straight thin-wall cannula was inserted into the right axillary artery (RAxA) on the right armpit [8]. Cardiopulmonary bypass (CPB) was established by cannulation involving also the femoral artery or the ascending aorta. The patients were cooled to 22–28 °C. Following hypothermic circulatory arrest, selective cerebral perfusion (SCP) was begun through the RAxA perfusion by clamping the brachiocephalic artery (BCA). The arch was opened and a 12 Fr SCP balloon cannula was inserted into the left common carotid artery (LCCA) (Fig. 1B). In recent series with moderate hypothermia at 25–28 °C, the left subclavian artery (LSCA) was also perfused. With SCP, the descending aorta was divided through the aneurysm. Distal aortic anastomosis was done using a stepwise technique. First, an invaginated tube graft of length 7–12 cm (a piece of the quadrifurcated arch graft) was inserted into the descending aorta (Fig. 1C). The position of the proximal end of the invaginated graft was adjusted to match the level of the divided end of the descending aorta. The anastomosis was then easy to perform, with a good surgical view, using an over and over running suture of 3-0 or 4-0 polypropylene, with reinforcement by Teflon felt strip (Fig. 2A). The distal end of the inserted graft was extracted proximally. For arch reconstruction, a further four-branched arch graft was attached to this stepwise graft using a running 3-0 polypropylene suture (Fig. 2B). Antegrade aortic perfusion was initiated. The LSCA was reconstructed with a branch graft.

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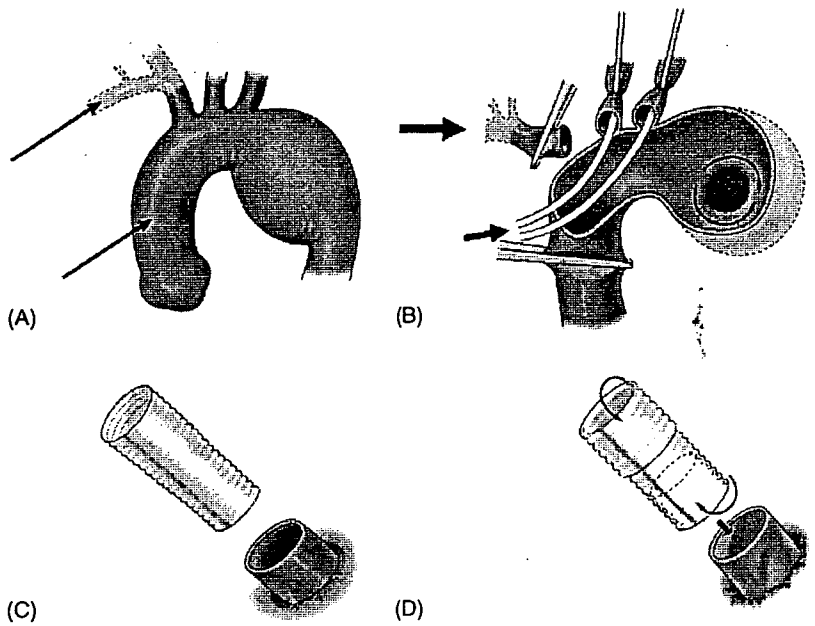

Fig. 1. Total arch replacement using selective cerebral perfusion and stepwise distal anastomosis. (A) Distal arch aneurysm: black arrows show cannulation sites on the right axillary artery and the ascending aorta for cardiopulmonary bypass. (B) Brain protection with antegrade selective cerebral perfusion (SCP): large (right axillary artery perfusion) and small (left common carotid and left subclavian artery perfusion) arrows show SCP. The descending aorta was divided from the inside through the aneurysm. (C) An invaginated tube graft was inserted into the descending aorta. (D) Recent refined technique (mini-elephant trunk technique): 2–3 cm of the proximal end was left without invagination so as to reinforce the anastomosis from the inside by a 'sandwich' technique with the outside Teflon felt strip. The distal end was also tucked inside to shorten the length of the graft, in order to prevent dislodge of the mural atheroma.

Rewarming was then initiated. The proximal anastomosis was done above the sinotubular junction. Finally, the LCCA and the BCA were reconstructed (Fig. 2C). The RAxA perfusion was discontinued. In recent cases, our stepwise technique was refined to reinforce the anastomosis and prevent bleeding from the anastomosis (Fig. 1D). In making the stepwise graft, 2–3 cm of the proximal end was left without invagination so as to reinforce the anastomosis from the inside by a 'sandwich' technique with the Teflon felt strip. We call this 'mini-elephant trunk technique'. Coronary artery bypasses grafting in 23, aortic valve replacement in one, and mitral valve plasty in one were also performed.

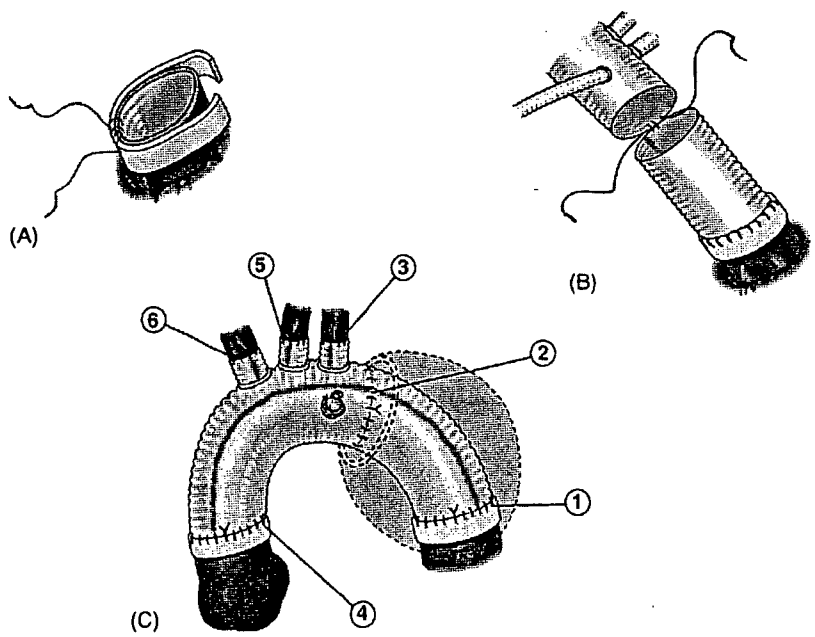

Fig. 2. Stepwise distal anastomosis. (A) Stepwise distal anastomosis with the reinforcement of outside Teflon felt strip using a running suture. (B) The distal end of the inserted graft was extracted and a quadrifurcated arch graft was connected to this end. (C) Total arch replacement using a stepwise anastomosis: the numbers show the turn of anastomosis.

3. Results

The median duration of lower body circulatory arrest, SCP, CPB, and surgery were 68, 147, 209, and 415 min, respectively. The median transfusion volume was 2400 ml. There were three hospital deaths (2.5%) from perioperative myocardial infarction, low cardiac output with bowel necrosis, and mediastinitis. Two patients (1.7%) developed permanent neurological dysfunction (small stroke), and three patients (2.5%) suffered from transient cerebral deficits. Three patients (2.5%) required reentry for bleeding. In none of them, bleeding from the distal anastomosis was found. Other complications occurred: low cardiac output in 5.0%, respiratory failure in 10.0%, renal failure in 3.3%, hepatic failure in 0.8%, bowel necrosis in 1.7%, and sepsis in 0.8%.

4. Discussion

The most common approach for arch to distal arch aneurysms is currently through median sternotomy [1–4]. This approach aims to provide cerebral and cardiac safety. However, the distal anastomosis tends to be difficult because of poor, distant, and limited view [6,7]. In our technique, the arch aneurysm is not incised to prevent injury to the nerves and lung. Through the aneurysm, the descending aorta is divided and the distal anastomosis takes place. Subsequently, the surgical view is limited. Furthermore, bleeding from this anastomosis is a major concern. We have therefore evolved a novel stepwise technique, which made the distal anastomosis around the hilum feasible in our experience.

The end of the descending aorta is often fragile with much atherosclerosis. Even with the stepwise technique, we experienced bleeding from the anastomosis in seven patients. The stepwise technique was therefore refined by the "mini-elephant trunk". With this refinement, we have not experienced any major bleeding from the distal anastomosis.

The stepwise technique has some drawbacks. Graft insertion carries a risk of dislodging mural atheroma. We experienced one case of bowel necrosis. To prevent this problem, in the refined technique, the distal end was tucked inside to shorten the graft length. Graft insertion must be done carefully into the atheromatous descending aorta. Direct anastomosis of a short-length graft without graft insertion is a good alternative. Another disadvantage is the need for a graft–graft anastomosis, which is fortunately easy with a good view taking 5–10 min.

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Is Emergency Total Arch Replacement With a Modified Elephant Trunk Technique Justified for Acute Type A Aortic Dissection?

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Background. We assess the outcome of emergency total arch replacement with a modified elephant trunk technique for acute type A aortic dissection to clarify whether our aggressive approach is justified in certain patients.

Methods. Between 2000 and 2006, 54 patients (55.1% of all) underwent emergency total arch replacement for acute type A aortic dissection. The surgery was performed using open distal anastomosis with selective antegrade cerebral perfusion under hypothermia. Total arch replacement with individual arch-vessel reconstruction was applied in the following settings: the intimal tear in the transverse arch or the proximal descending aorta, massive arch dissection, Marfan syndrome, arch aneurysm, and atheromatous arch. At the distal anastomosis, a modified elephant trunk procedure was added for secure anastomosis and early thrombosed closure of the false channel in the descending aorta.

Results. Only 2 patients (3.7%) died of low cardiac output, in whom cardiac arrest had developed preoperatively owing to rupture of the arch or to left coronary artery malperfusion. There were 4 late deaths from non-aortic events. On the follow-up computed tomographic scanning, a high incidence of early thrombosed closure of the false channel in the dissected descending aorta was found. Only 2 patients, whose tear had not been resected in the first surgery, required reoperation of the descending aorta.

Conclusions. Total arch replacement with an elephant trunk procedure, which permits immediate survival and provides early thrombosed closure of the distal false channel, is justified in certain patients with acute type A dissection.

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Acute type A aortic dissection is a potentially catastrophic event and requires surgical repair on an emergency basis. Despite recent favorable outcomes by leading centers [1, 2], the surgery still has a high mortality rate of 14% to 32.5% [3–6]. In these circumstances, limited ascending aortic or hemiarch replacement is widely accepted to permit a primary goal of immediate survival by preventing secondary cardiac events. However, the residual dissection's behavior in the aortic arch or thoracoabdominal aorta after the limited repair is still unclear. In the long term, repeated surgery for the residual dissection of the arch, descending thoracic aorta, and abdominal aorta would be necessary in some instances [7, 8]. Extended total arch repair is then more advantageous for complete resection of the intimal tear and the massively dissected arch [9]. In particular, with a modified elephant trunk technique, total arch repair might be more beneficial to prevent late enlargement of the residual aortic dissection.

In this study, we evaluated the early and midterm outcome of emergency total arch replacement with a modified elephant trunk technique for acute type A aortic dissection to clarify whether our aggressive approach is justified in certain patients who would have potential for enlargement of the distal dissection.

Patients and Methods

Patients

Between 2000 and 2006, a total of 98 patients underwent emergent or urgent surgery for acute type A aortic dissection in the National Cardiovascular Center, Japan. Extended total arch replacement was performed in 54 patients (55.1%) of them (Table 1). One patient had previous history of type B dissection. Another patient developing significant distal anastomotic leak immediately after emergent hemiarch replacement was also included, although patients having iatrogenic dissection were excluded. Other 40 patients underwent hemiarch replacement and 4 patients partial arch replacement with reconstruction of the innominate artery. The institutional

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Table 1. Preoperative Patient Characteristics

Characteristic	Value
Age (years)	66 (28–86)
Sex (male/female)	30/24
Marfan syndrome (n)	3
Onset to surgery (n)	
Within 6 hours	24
6–24 hours	22
1–7 days	4
1–2 weeks	4
Surgery (n)	
Emergent	51
Urgent	3
Persistent malperfusion (n)	11 (20.4%)
Brain	2
Heart (coronary)	1
Bowel (SMA)	1
Limb (arm/leg)	7 (4/3)
Cardiac tamponade (n)	16 (29.6%)
Aortic valve insufficiency, grade ≥III (n)	11 (20.4%)
Shock, blood pressure ≤80 mm Hg (n)	13 (26.3%)
Cardiac arrest on CPR	4
Rupture (n)	9 (16.7%)
Patent false channel (n)	48 (88.9%)
Range of dissection (n)	
Ascending–descending aorta	49 (90.7%)
Ascending aorta–arch	5
Location of the intimal tear (n)	
Ascending aorta	23
Arch	18
Descending aorta	13

CPR = cardiopulmonary resuscitation; SMA = superior mesenteric artery.

approval for this study was obtained, and each patient within the study gave informed consent for serving as a subject.

Surgical Technique

CARDIOPULMONARY BYPASS WITH ADDITIONAL AXILLARY ARTERY PERFUSION. With standard retrograde perfusion through the femoral artery, an additional right axillary artery perfusion was used for maintaining the true channel circulation and easy shift to selective antegrade cerebral perfusion (SCP [Fig 1]) [10]. The right axillary artery was quickly exposed and easily cannulated in the axilla, to where arterial dissection hardly extends. A 10F to 16F thin-wall cannula was inserted. The femoral artery was also cannulated with a 16F to 21F cannula. Bicaval venous drainage with left ventricular venting was used.

BRAIN PROTECTION. Patients were cooled to the range of 20°C to 28°C (Fig 1). With hypothermic circulatory arrest, SCP through the right axillary artery was quickly commenced by clamping the innominate artery. The ascending aorta was opened without aortic clamp. The site and extent of intimal tear was defined. A SCP balloon-tipped cannula was inserted into the left common carotid artery with the left subclavian artery clamped. During the SCP, the superficial temporal artery or the balloon-tip pressures were regulated in the range of 30 to 50 mm Hg by the SCP flow of approximately 10 to 12 mL · kg^{-1} · min^{-1}. Since 2003, the left subclavian artery perfusion has been included with moderate hypothermia. The SCP flow was also increased to maintain the pressure at approximately 50 mm Hg.

TOTAL ARCH REPLACEMENT WITH A MODIFIED ELEPHANT TRUNK TECHNIQUE. Ascending aortic or hemiarch replacement was the procedure principally performed for our tear-oriented surgery (Fig 1) [1, 2]. With hypothermic circulatory arrest, the ascending aorta was transected proximal to the innominate artery, excising a tear. With a tear in the minor arch curvature, the arch including a tear was beveled for hemiarch replacement. The false channel was closed with internal and external Teflon felt strips. A 22 mm to 26 mm single-branched Dacron graft was anastomosed with an open aortic technique. The antegrade distal aortic perfusion was commenced using the branch graft, and the patient was rewarmed. In contrast, extended total arch replacement with a modified elephant trunk technique [11] was attempted in the following settings: (1) tear (entry) in the arch (excluding the minor curvature); (2) tear in the descending aorta ("retrograde dissection"); (3) reentry in the arch or the proximal descending aorta; (4) Marfan syndrome; (5) arch aneurysm or dilatation; (6) atheromatous arch; (7) massive arch dissection; and (8) relatively young age less than 70 years [9, 12, 13].

In total arch replacement, the descending aorta was transected distal to the left subclavian artery. A modified elephant trunk technique was used for secure anastomosis with less anastomotic bleeding and early thrombosed

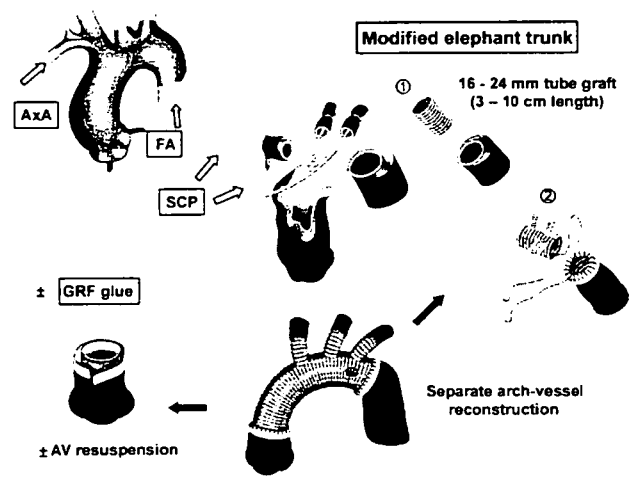

Fig 1. Total arch replacement with a modified elephant trunk technique using antegrade selective cerebral perfusion (SCP) with right axillary artery (AxA) perfusion. (AV = aortic valve; FA = femoral artery; GRF-glue = Gelatin-Resorcin-Formal glue.)

closure of the distal false channel [12, 13] . Depending on the size and condition of the true channel in the descending aorta, a prosthetic graft of 16 mm to 24 mm in diameter and 3 cm to 10 cm in length was carefully inserted into the distal true channel. The proximal end of the elephant trunk graft was attached to the completely divided descending aorta using a 4-0 polypropylene continuous suture. The anastomosis was reinforced by an external Teflon felt strip. Another quadrifurcated Dacron arch graft of 20 to 24 mm in diameter was anastomosed to this aortic stump with a 4-0 polypropylene continuous suture. The antegrade distal aortic perfusion was commenced with a branch graft of the arch graft.

By transesophageal echocardiography, good shape of the inserted elephant trunk graft without kinking was confirmed. The left subclavian artery was reconstructed using a branch graft with the reinforcement of an external felt. The patient was then rewarmed. At the proximal site, the ascending aorta was transected just around the sinotubular junction. The proximal false channel was closed with internal and external Teflon felt strips. When the commissures of aortic valve detached, they were attached using 5-0 polypropylene pledgeted mattress sutures in 25 patients. In most, the proximal false channel was fixed using Gelatin-Resorcin-Formal glue (Cardial, Sainte-Etienne, France) [3]. In a recent 5 patients, an adventitial inversion technique was used without Gelatin-Resorcin-Formal glue. The main graft was anastomosed to this end with a 4-0 polypropylene continuous suture. Finally, the other two arch vessels were reconstructed using branch grafts with 5-0 polypropylene continuous suture under SCP.

Data Collection and Statistical Analysis

Medical records were reviewed. All patients have been followed at our outpatient clinic at intervals of 3 to 12 months. The follow-up rate was 100%, and the mean duration was 2.9 ± 1.8 years. We reviewed the early and midterm outcomes and investigated risk factors for in-hospital mortality and for reoperation of the distal dissection by univariate and multivariate analyses, which were carried out using SPSS software (SPSS, Chicago, Illinois). Values are expressed as the mean ± SD or medians (range), with p values less than 0.05 considered significant. Univariate analysis was carried out using the χ^2 test or Fisher exact test. Stepwise logistic regression was used for multivariate analysis. A logistic regression model was used with p less than 0.10 as the limit for selecting variables for entry into the model. Kaplan-Meier estimates were used to calculate long-term survival and reoperation-free rates.

In the follow-up, enhanced computed tomography (CT) scanning of the entire aorta was undertaken annually to assess late enlargement of the distal dissection and the fate of the distal false channel. The diameter of the dissected aorta was measured on the short-axis view at four points of the proximal, middle, and distal descending aorta, and the abdominal aorta around the origin of the superior mesenteric artery. The conditions of the false lumen were evaluated using three grades: (1) thrombosed closure, (2) nearly closed with most of parts thrombosed, and (3) patent. The authors had full access to the data and take responsibility for its integrity. All authors have read and agree to the manuscript as written.

Results

Total arch replacement was performed in certain patients with the following settings: tear in the arch (n = 18), tear in the descending aorta (13), massive arch dissection (17), Marfan syndrome (2), arch aneurysm (1), atheromatous arch (1), distal end of dissection in the arch (2), arch rupture (1), and descending aortic rupture (1). Concomitantly, aortic valve resuspension (n = 25), composite root replacement (2), valve-sparing root surgery (3), aortic valve replacement (1), mitral valve plasty (1), coronary artery bypass grafting (5), and ascending aorta to external iliac or femoral artery bypass for limb ischemia (2) were performed. The median duration of open distal anastomosis, cardiac arrest, SCP, cardiopulmonary bypass, and surgery was 55.5 minutes (range, 34 to 130), 136.5 minutes (84 to 379), 167.5 minutes (50 to 455), 236 minutes (124 to 789), and 462.5 minutes (237 to 1,375). The stay in the intensive care unit and the hospital was 5 days (range, 1 to 52) and 31.5 days (16 to 130), respectively. The amount of transfusion was 3,780 mL (range, 0 to 20,000 mL).

The following complications occurred: bleeding in 5.6% (n = 3), cardiac in 5.6% (3), respiratory in 13.0% (7), renal in 1.9% (1), hepatic in 1.9% (1), gastrointestinal tract in 1.9% (1), limb (leg) ischemia in 3.7% (2), infection in 1.9% (1), and wound in 1.9% (1). Cerebral deficits occurred in 11.1% (6): temporary neurologic dysfunction in 5.6% (3) and permanent dysfunction in 5.6% (3). One severe permanent neurologic dysfunction was due to preoperative cardiac arrest in the anesthetic induction owing to rupture, and cardiac massage was required until the establishment of cardiopulmonary bypass. The other 2 permanent dysfunctions were presumably due to preoperative serious cerebral malperfusion caused by extended dissection of the innominate artery to the right common carotid artery. The surgery needed to be rushed for cardiac tamponade, although both of the patients were unconscious. These 2 patients rehabilitated eventually.

There were two 30-day deaths (3.7%) due to low cardiac output. Both of these 2 female patients with preoperative deep shock had fallen into cardiac arrest during the anesthetic induction owing to ascending aorta to aortic arch rupture in 1 patient or to coronary malperfusion in 1 patient. For the first patient, hemiarch replacement was initially attempted because all of the three intimal tears were located in the ascending aorta. However, rupture of the transverse arch close to the arch vessels was found after the proximal anastomosis so that total arch replacement was performed after recooling the patient. This patient had severe edema of the whole body and abdominal distension associated with severe acidosis; she did

Table 2. Univariate Analysis of Risk Factors for In-Hospital Mortality

Factor	*p* Value
Super acute (≤6 hours from onset)	0.872
Female	0.193
Age ≥70 years	0.508
Marfan syndrome	0.727
Cardiac tamponade	0.509
Shock (blood pressure ≤80 mm Hg)	0.055
Cardiac arrest before surgery	0.004[a]
Aortic valve insufficiency (≥III)	0.466
Rupture	0.308
Tear in arch/descending aorta	0.915
Malperfusion	0.370
Coronary malperfusion	0.037[a]
Patent false channel	0.610
Concomitant surgery	0.369
Open distal anastomosis ≥60 minutes	0.177
Cardiac arrest ≥180 minutes	0.039[a]
Cardiopulmonary bypass ≥5 hours	0.073
Surgery ≥10 hours	0.055
Blood transfusion ≥5,000 mL	0.161

[a] $p < 0.05$.

not recover despite cardiopulmonary support using femorofemoral circuit. In the second patient, having deep shock and severe pulmonary congestion due to left coronary malperfusion preoperatively, severe hypokinesis of the anteroseptal wall with left ventricular dilatation and mitral regurgitation of grade IV due to left coronary malperfusion were revealed on transthoracic echocardiography. Total arch repair was carried out because of the primary tear located in the transverse arch just close to the left common carotid artery. After that, at the proximal site, routine supracoronary anastomosis was done with Gelatin-Resorcin-Formal glue. However, after the anastomosis, rupture of the right coronary artery due to extension of the dissection was noticed. Full root repair was carried out using a porcine stentless valved graft. However, cardiac function did not recover despite intra-

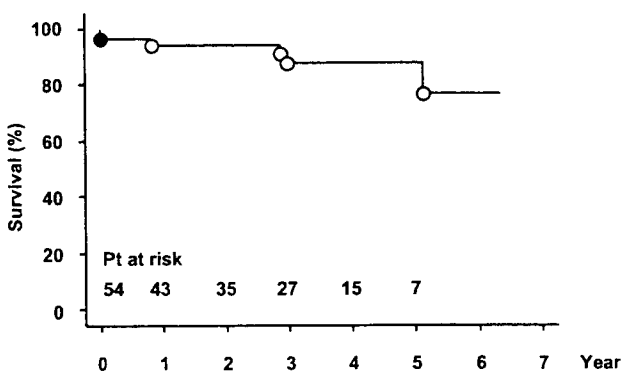

Fig 2. Midterm survival, Kaplan-Meier method. (Pt = patients.)

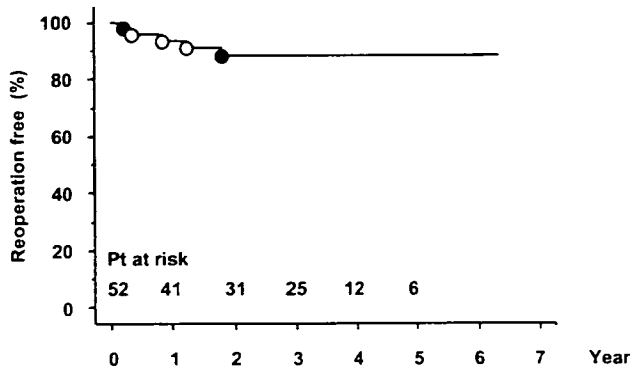

Fig 3. Freedom from reoperation, Kaplan-Meier method. (Open circles = replacement of root [2] or ascending aorta [1]; solid circles = replacement of descending aorta [2]; Pt = patients.)

aortic balloon pumping and percutaneous cardiopulmonary support using a femorofemoral circuit.

On the univariate analysis, significant risk factors for 30-day mortality were cardiac arrest before surgery, coronary malperfusion, and the duration of cardioplegic cardiac arrest more than 180 minutes (Table 2). In the following multivariate analysis, no independent predictors for mortality were found.

During the mean follow-up period of 2.9 ± 1.8 years, 4 late deaths (7.8%) occurred from nonaortic events such as pneumonia (n = 2), cancer (1), and suicide (1; Fig 2). The actuarial survival including hospital deaths was 87.8% ± 1.2% at 3 years. Five patients (9.6%) required reoperation: root replacement for recurrent aortic regurgitation (n = 2), ascending aortic replacement for proximal anastomotic stricture due to the internal felt strip (1), and descending replacement (2; Fig 3). Regarding the reoperation of the distal dissection with the incidence of 3.8%, 1 of the 2 patients had suffered from type B aortic dissection before acute type A dissection. In the total arch replacement for new type A dissection, the previous tear of old dissection in the descending aorta was not resected, resulting in the enlargement of the descending aorta. Another patient had the tear in the descending aorta, which was not noticed through a median approach. The tear was not resected in the total arch repair, resulting in the descending aortic dilatation. The overall reoperation-free rate was 88.4% ± 11.7% at 3 years. On univariate analysis, no resection of the tear in the de-

Table 3. Univariate Analysis of Risk Factors for Reoperation of the Descending Aorta

Factor	*p* Value
Patent false channel before surgery	0.610
Marfan syndrome	0.727
Tear in the descending aorta	0.427
No tear resection	0.004[a]
Patent false channel in the proximal descending aorta	0.144

[a] $p < 0.05$.

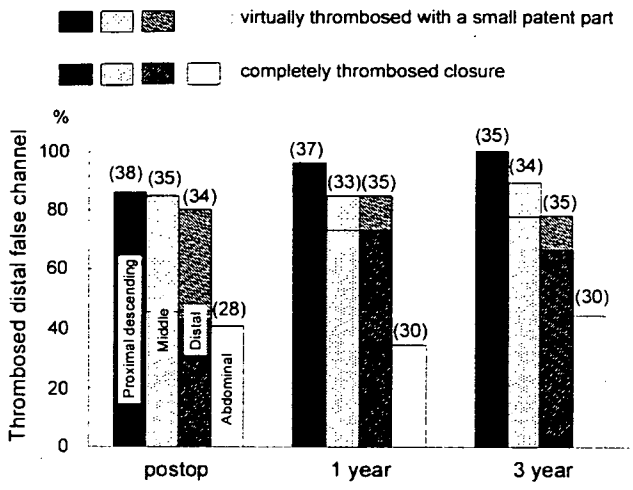

Fig 4. Behavior of distal false channels after total arch replacement with a modified elephant trunk technique on the follow-up computed tomography scans. Numbers in parentheses indicate median diameter of the distal dissected aorta including true and false channels. (Postop = postoperative, before discharge.)

scending aorta was a risk factor for distal aortic reoperation (Table 3).

The follow-up CT scans showed early thrombosed closure of the distal false channel (Fig 4). Particularly, in the proximal, middle, and distal descending aorta, the complete thrombosis was demonstrated at the incidence of 43.2%, 45.5%, and 43.2% immediately after the surgery (n = 49); 84.6%, 73.1%, and 77.8% in 1 year (n = 34); and 100%, 77.8%, and 66.7% in 3 years (n = 21). Including the condition of nearly closed with most of parts thrombosed, the rate of thrombosed closure of the distal false channel was 88.6%%, 84.1%, and 79.5% immediately after the surgery; 92.3%, 84.6%, and 84.6% in 1 year; and 100%, 88.9%, and 77.8% in 3 years.

Comment

The outcome of total arch replacement with a modified elephant trunk under SCP with axillary artery perfusion was satisfactory, with a low in-hospital mortality rate. The primary goal of emergency surgery for acute type A aortic dissection is to save patients' lives. Limited ascending aortic or hemiarch replacement is then widely recommended [1–6]. With recent advances of diagnosis and surgery, the outcome has improved to less than 10% mortality in the leading centers [1, 2]. In our institution, the overall mortality in emergency surgery for acute type A aortic dissection, including ascending or hemiarch repair, was 2.9% during the same period. The in-hospital mortality rate in extended total arch replacement was 3.7%, which did not increase dramatically. This satisfactory outcome is, we believe, based on our surgical background consisting of a large number of arch surgeries [10, 14, 15]. During the same period, a total of 458 patients underwent total arch replacement for a variety of aortic pathologies including chronic dissecting and nondissecting aneurysms. The in-hospital mortality rate for elective total arch replacement for nondissecting aneurysm in 305 patients was 2.3% [15].

For arch surgery, we have established an integrated circulatory support system consisting of axillary artery perfusion for cardiopulmonary bypass coupled with femoral artery or ascending aortic perfusion and of SCP [10, 14, 15]. In particular, we have advocated routine use of axillary artery perfusion [10]. The exposure of the distal part of axillary artery in the axilla is quicker and easier than that in the subclavicular region. Arterial dissection rarely extends to this portion of the axillary artery. Secure perfusion of the true channel can be commenced quickly, improving cardiac and cerebral safety. Furthermore, easy shift to the SCP is feasible by clamping the innominate artery without cannulation. Our increasing experiences with arch replacement using SCP with the axillary artery perfusion has led to our growing confidence in the safe application of this prompt approach of total arch replacement even on an emergency basis [10, 13–15].

Previous reports identified various risk factors for mortality such as early year operation, increasing age, history of aortic valve replacement, high New York Heart Association class, diabetes mellitus, shock, cardiac tamponade, rupture, coronary malperfusion, visceral malperfusion, limb malperfusion, root replacement, arch replacement, coronary artery bypass graft surgery, or longer circulatory arrest [4–6]. In the presented series, cardiac arrest before surgery as well as coronary malperfusion was a risk factor for in-hospital mortality in the univariate analysis. It was extremely difficult to rescue these 2 critical patients having serious coronary malperfusion or aortic arch rupture. Given a larger number of such critical patients, the outcome might have been much worse with a higher mortality.

Complete resection of the primary tear is a key to good early and long-term outcomes. In previous reports, no differences were recognized in mortality or reoperation rate whether the tear was resected or not [16, 17]. However, subsequent reports noted that the reoperation rate was significantly higher without tear resection [3, 18–20]. Since then, "tear-oriented surgery" has been widely recommended [1–6]. In previous studies, anastomotic leakage, no tear resection, younger age, Marfan syndrome, and severe aortic regurgitation were significant determinants for reoperation [3, 18–22]. Given a tear in the arch excluding the minor curvature site or in the proximal descending aorta, total arch replacement is then reasonable [3, 13, 18, 19, 21, 22]. Furthermore, in cases with massive arch dissection, complete arch replacement would be more beneficial to avoid bleeding, anastomotic leak, progression of aneurysmal dilatation, rupture, reoperation, and cerebral malperfusion [3, 18, 19]. Recently, the Mount Sinai group [22] described that repeated surgical intervention was most frequently required in the aortic arch and abdominal aorta in a large series. We believe our aggressive total arch replacement for complete resection of massive arch dissection as well as the primary tear can reduce the incidence of distal reoperation, in particular, for arch dilatation.

Coupled with the total arch repair, a modified elephant trunk technique was used for secure anastomosis and for early thrombosed closure of the distal false channel [11, 12]. Without the internal reinforcement by elephant trunk graft, the distal anastomosis would be more troublesome with bleeding because of a fragile dissected descending aorta. Literally, the patent false channel was recognized in the incidence of approximately 50% to 80% after the conventional ascending aortic replacement. In our series, having total arch repair with a modified elephant trunk, early thrombosed closure or obliteration of the false channel in the descending aorta was recognized frequently on the follow up CT scans. From this point of view, we believe this unique technique plays an important role or is essential for total arch replacement for acute type A dissection [12]. It does, however, have some shortcomings. The true channel in the descending aorta is generally too small to accept a large-size graft, making necessary the use of another smaller-size graft. With such a size mismatch, the inserted elephant trunk graft might be kinked or wrinkled, resulting in stenosis or hemolysis. Its adequate length is also unknown. The longer the graft is, the greater the impact of elephant trunk on closure or obliteration of the distal false channel is. However, with a too-long elephant trunk, the potential risk of spinal cord injury or new tear formation would increase [23]. Regardless, we propose as another advantage, with the elephant trunk, that the reoperation of the descending aorta would be much easier [11, 12]. The elephant trunk procedure should be coupled with total arch replacement.

The aim of the elephant trunk procedure was to reduce the reoperation rate by preventing enlargement of the distal dissected aorta. However, 2 patients, whose tear had not been resected in the first surgery, required descending aortic replacement in the late stage. In 1 patient having the tear in the descending aorta that was not noticed intraoperatively, the elephant trunk was 5 cm in length. It was subsequently too short to cover the tear. If the tear had been identified, we could have closed the tear using a longer elephant trunk. Kato and colleagues [24] and Ishihara and associates [25] reported greater impact of stent graft as an elephant trunk on closing the false channel, instead of standard prosthetic graft. However, in the use of stent graft for acute aortic dissection, a potential risk of new intimal tear formation exists [26]. More flexible stent graft might be preferable for such fragile aortic wall of acute dissection. For reoperation of the descending aorta, patent false channel, anastomotic leakage, no tear resection, younger age, and Marfan syndrome were reportedly risk factors [3, 18, 19]. In this series, reoperation of the descending aorta was required only in the 2 cases without resection of the tear in the descending aorta. For such patients having a potential risk of distal dilatation, meticulous follow up using CT scans is mandatory.

Postoperative cerebral morbidity remains one of the critical complications, particularly in total arch repair requiring longer SCP. Generally, the incidence is higher compared with ascending or hemiarch repair. In total, 3 patients had strokes due to brain damage during cardiac resuscitation or to preoperative cerebral malperfusion. Although 2 patients having cerebral malperfusion were unconscious before surgery, the surgery was indicated because brain CT scans did not reveal any infarction.

This retrospective study has some limitations. The number of patients might be too small to reach definitive conclusions. For that, a larger number of patients is necessary. There was no appropriate control group having ascending or hemiarch replacement, because the limited repairs were performed in the patient group having different conditions including the site of the primary tear. For definitive conclusions, a randomized controlled study is required between the extended and limited repairs in patients having homogenous aortic lesions.

In conclusion, total arch replacement with a modified elephant trunk procedure under SCP with right axillary artery perfusion, which permits immediate survival and can reduce the distal aortic reoperation rate, would be justified in certain patients with acute type A aortic dissection.

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