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A systematic review of transcatheter aortic valve implantation via carotid artery access

Thomas Stonier [a,b], Michael Harrison [c,d], Andrew M.T.L. Choong [e,f,g,*]

[a] Royal Free Hospital, London, United Kingdom
[b] University College London School of Medicine, London, United Kingdom
[c] Deparment of Cardiology, Hammersmith Hospital, London, United Kingdom
[d] Imperial College School of Medicine, London, United Kingdom
[e] Department of Cardiac, Thoracic and Vascular Surgery, National University Heart Centre, Singapore
[f] School of Medicine, University of Queensland, Brisbane, Queensland, Australia
[g] School of Medicine, Griffith University, Gold Coast, Queensland, Australia

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ABSTRACT

Background: The carotid artery is a novel access route for transcatheter aortic valve implantation (TAVI). This may represent a viable alternative in patients unsuitable for TAVI via traditional transfemoral access, up to 20%, as well as other access routes such as subclavian, transapical and aortic. This systematic review summarises the current evidence for its safety and feasibility.
Methods: A systematic review was conducted as per the Preferred Reporting Instructions for Systematic Reviews and Meta-analysis (PRISMA) guidelines using five electronic databases.
Results: 16 studies were identified, including three prospective cohort studies, one retrospective cohort study, three case series and eight case reports. Data on 74 patients (mean age 76.9 years) was extracted including pre-operative work-up, technical procedure details and outcomes.
This found 1 intraoperative death, 2 further deaths within 30 days, two incidences of transient ischaemic attack, no incidences of stroke, myocardial infarction, carotid access site complications or infection, 1 patient required new dialysis and 1 patient had an intraoperative dissection which resolved. Follow-up from 30 days to 1 year showed symptomatic improvement and echocardiographic improvement in line with those seen in transfemoral TAVI.
Conclusions: The available data on TAVI via carotid access demonstrate technical feasibility with comparable outcomes to other traditional access routes. A low number of patients, heterogeneous clinical endpoints and relatively short follow-up periods limit formal meta-analysis and firmer conclusions. For patients in which other access routes are impossible, TAVI via carotid access represents a viable and potentially crucial alternative in patients who might otherwise be untreatable.

1. Introduction

Patients with severe symptomatic aortic stenosis or regurgitation were classically managed with a valve replacement during open surgery. In the last 15 years, since the first description in 2002 [1], transcatheter aortic valve implantation (TAVI) is a viable alternative for those patients with multiple comorbidities considered at high risk for open surgery [2].

Transfemoral access is the most widely used access route for TAVI, is the least invasive and now also allows for a complete percutaneous procedure [3–5]. However, approximately 20% of patients approved for TAVI are not suitable for transfemoral access [6]. There are relative and absolute contraindications to the use of this access route such as iliofemoral arteriopathy, tortuosity, severe calcification, abdominal aortic aneurysm or previous vascular surgery. Alternative access routes to the aortic valve include transapical, transaortic and subclavian/axillary access.

The transapical approach is currently the second choice access route in many institutions [7]. However, the need for a left anterior minithoracotomy and a left ventricular apical puncture makes this is a far more invasive procedure. This is often still not suitable for patients with some significant comorbidities, which also exclude them from open surgery such as severe respiratory disease or left ventricular dysfunction.

The transaortic approach offers similar drawbacks through the need for a general anaesthetic and an upper ministernotomy [8]. It can be challenging from a surgical perspective in patients who have undergone

* Corresponding author at: Department of Cardiac, Thoracic and Vascular Surgery, National University Heart Centre, Level 9, NUHS Tower Block, 1E Kent Ridge Road, Singapore 119228.
E-mail address: andrew_choong@nuhs.edu.sg (A.M.T.L. Choong).

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a previous coronary artery bypass graft (CABG) with patent venous grafts. It is likewise unsuitable in patients with severe respiratory disease and those with a 'porcelain aorta'.

Subclavian (or transaxillary) access has been shown to be a safe approach but can also be precluded by previous CABG as with the transaortic approach and also by size of the artery and calcification at the aortic arch [9].

In 2010 Modine and colleagues published the first case report on TAVI via a carotid access route offering a further alternative [10]. The purpose of this systematic review is to summarise the current evidence available on TAVI via carotid access and assess its feasibility and safety as an alternative access route.

2. Methods

The review was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) checklist for systematic reviews [11].

2.1. Literature search

Medline (via PubMed), OvidSP, Embase, Google Scholar and Cochrane databases were searched to identify all reports describing TAVI via carotid access. The following 'Medical Subject Headings' (MeSH) search terms were used: "TAVI", "TAVR", "PAVR", "aortic valve replacement", "aortic valve implantation", "aortic valve insertion", "aortic heart valve replacement", "aortic heart valve implantation", "aortic heart valve insertion".

The 'related articles' function was used to broaden the search. Based on the title and abstract, cases were sought in which carotid access was used to perform a TAVI. References of the articles selected were also searched manually. No language restrictions were used. Articles published before 1st January 2002 were excluded as TAVI via any route was not performed before this time. The latest date for this search was 29th March 2016 (the full search strategy can be obtained from TS on request).

2.2. Inclusion criteria for review

Any article was included that used either of the common carotid arteries as the primary access vessel for aortic valve replacement.

2.3. Exclusion criteria for review

Studies published prior to 2002 were excluded.

2.4. Data extraction and validation of studies

Three reviewers (TS, MH, AC) independently extracted the following data from each study: first author, year of publication, number of patients in study, mean age of patients, sex of patients, co-morbidities, pathology being treated, co-morbidities, contraindications to open surgical repair, contraindications to TAVI via a transfemoral, transapical, transaortic or subclavian approach, approach taken and reason for this, pre-operative work-up, carotid assessment, anaesthetic, equipment used, cerebral monitoring used, qualitative statements on procedure, valve assessment post-procedure, paravalvular regurgitation, mortality, complications, follow-up and outcome at follow-up. Data were also retrieved on the following outcomes of interest: valve assessment post-operatively, paravalvular regurgitation, mortality, neurological complications, vascular access site complications, other complications according to the Valve Academic Research Consortium (VARC-2) criteria [12], follow-up and outcome at follow-up.

2.5. Data analysis

The outcome measures were mortality, immediate complications, valve function and follow-up of patients. Data regarding valve function were sometimes unavailable whilst those involving follow-up involved dissimilar time spans between reports and was also sometimes unavailable. Overall the data were heterogeneous and formal meta-analysis could not be performed on any extracted data.

3. Results

3.1. Systematic search strategy

The systematic search of the databases revealed 712 publications for possible inclusion. Following the removal of duplicates and publications from before 2002, the remaining titles and abstracts were reviewed and irrelevant publications were excluded. This left 36 publications, which were reviewed in their entirety. Of these, 21 were excluded on more detailed inspection of the full text. No additional articles were added from manual review of the references. A total of 16 papers or abstracts were scrutinised and data extracted. The 16 reports comprised three prospective cohort studies, one retrospective cohort study, four case series and eight case reports. Three of the case series had sufficient detail for the data to be extracted as individual cases [6,13,14]. One group, Azmoun et al., presented or published the same content with increasing patients in their series [15]. We selected the published article for data extraction as it provided the most detail on patient characteristics and outcomes. One case series was presented as an oral presentation [16]. The search strategy is shown in Fig. 1 and is based upon the PRISMA flow diagram for systematic review [11].

3.2. Patient demographics, comorbidities and contraindications to open or other TAVI access options

In the 16 reports, 74 patients underwent TAVI via carotid access. The mean patient age was 76.9 years (range 27–91 years), with 59.5% of patients being male (ratio M 44:30 F). 69 procedures were performed for severe aortic stenosis, whilst five were performed for aortic regurgitation. One report was in a failed aortic bioprosthesis [17].

All patients were considered unfit for an open procedure. Transfemoral access was contraindicated due to vessel disease, calcification, tortuosity, significant risk of rupture and risk of distal emboli. The transapical approach was contraindicated chiefly due to severe pulmonary disease or previous coronary artery bypass graft (CABG). Finally the subclavian route was mostly precluded due to difficult anatomy such as angulation, stenosis and calcification; or again from previous CABG.

A summary of baseline patient characteristics, comorbidities, risk stratification scores and reasons for avoidance of other traditional endovascular techniques is presented in Tables 1 and 2.

3.3. Procedural technique

Three types of TAVI device were used in all studies found; the CoreValve porcine pericardial device (Medtronic, Inc., Minneapolis, Minnesota), the balloon-expandable Edwards SAPIEN bovine pericardial device (Edwards Life Sciences, Irvine, California) and in one case the Evolut R valve (Medtronic, Inc., Minneapolis, Minnesota). The left common carotid are was used for access in 41 cases, with the right side used in 33. Where reported the procedure was done under local anaesthetic in 22 cases (41.5% of those reported), and general anaesthetic in 31 cases (58.4% of those reported), with no cases requiring conversion from local to general anaesthetic. In one case general anaesthetic was used for placement of the Dacron prosthesis prior to the TAVI procedure performed under local anaesthetic [17]. Individual procedure techniques are detailed in Table 3.