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Systematic Review/Meta-analysis

Transfemoral vs Non-transfemoral Access for Transcatheter Aortic Valve Implantation: A Systematic Review and Meta-analysis

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See editorial by Dorval, pages 1415–1417 of this issue.

ABSTRACT

Background: Transcatheter aortic valve implantation (TAVI) is the definitive therapy for high-risk patients with severe aortic stenosis. The aim of this study was to determine the effect of non-transfemoral access on clinical outcomes in TAVI.

Methods: We conducted a computerized literature search on SCOPUS and selected all studies published in the English language, from 2002 until March 12 2014, that compared transfemoral access with a non-transfemoral access cohort. Two independent reviewers evaluated the studies and extracted data for analysis.

Results: A total 17,020 patients (11,079 transfemoral, 5941 non-transfemoral) encompassing 28 studies underwent TAVI between 2007 to 2013. Overall, the 30-day mortality was 4.7% with the transfemoral approach and 8.1% with a non-transfemoral approach (odds ratio [OR], 0.56; 95% confidence interval [CI], 0.49-0.64; $P < 0.01$). The 1-year mortality was 16.4% with transfemoral access and 24.8% with non-transfemoral access (OR, 0.68; 95% CI, 0.60-0.75; $P < 0.01$). Transfemoral access was associated with a greater incidence

RÉSUMÉ

Introduction : L'implantation valvulaire aortique par cathéter (IVAC) est le traitement définitif des patients exposés à un risque élevé ayant une sténose aortique grave. L'objectif de la présente étude était de déterminer les conséquences de l'accès non transfémoral sur les résultats cliniques de l'IVAC.

Méthodes : Nous avons réalisé une recherche documentaire informatisée dans la banque de données SCOPUS et sélectionné toutes les études publiées en langue anglaise de 2002 au 12 mars 2014, qui comparaient la cohorte par accès transfémoral à la cohorte par accès non transfémoral. Deux examinateurs indépendants ont évalué les études et extrait les données pour procéder à l'analyse.

Résultats : Un total de 17 020 patients (11 079 par accès transfémoral, 5941 par accès non transfémoral) provenant de 28 études ont subi une IVAC de 2007 à 2013. Dans l'ensemble, la mortalité à 30 jours était de 4,7 % pour l'approche par voie transfémorale et de 8,1 % pour l'approche par une voie non transfémorale (ratio d'incidence approché [RIA], 0,56; intervalle de confiance [IC] à 95 %, 0,49-0,64;

Transcatheter aortic valve implantation (TAVI) is the definitive therapy for high-risk patients with severe aortic valve stenosis.[1] Five-year outcomes from the **P**lacement of **A**ort**i**c Tra**n**s-cathet**e**r Valves (PARTNER) trial have shown significant benefit with the Edwards Sapien TAVI compared with standard therapy in extreme-risk patients.[2] Furthermore, the recent US Medtronic CoreValve trial showed a significantly lower mortality rate with TAVI compared with surgical aortic valve replacement for high-risk patients.[3] Thus, with increasing experience, a spectrum of patients, from intermediate to extreme risk, are being treated. Although transfemoral access remains the gold standard, several other access routes have been successfully used, including, transapical, direct aortic, subclavian, and axillary. Arguably, the true definition of 'alternative' access entails yet other approaches that have been used in small observational series of so called no-access patients.[4,5] Although experience and skills with non-transfemoral approaches remain centre-specific, new technologies allow increased availability of transfemoral access, and the proportional need for transthoracic approaches might have decreased overall.[6,7]

There are no randomized trial data that compare outcomes by transfemoral vs non-transfemoral access. Data from the single randomized controlled trial (RCT) comparing transfemoral and transapical access showed a higher mortality rate with transapical access.[1] However, in all-comers, historically the transapical approach has been adopted in patients with greater comorbidities including peripheral

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of vascular complications (OR, 2.1; 95% CI, 1.48-2.99; $P < 0.01$) but a lower rate of surgical conversion (OR, 0.59; 95% CI, 0.42-0.81; $P < 0.01$) and similar bleeding (OR, 1.01; 95% CI, 0.81-1.27; $P = 0.91$) compared with non-transfemoral access. The incidence of cerebrovascular events was similar in both groups (1.6% vs 2.1%; OR, 0.86; 95% CI, 0.64-1.15; $P = 0.31$).

Conclusions: Transfemoral access was associated with lower rate of 30-day and 1-year mortality compared with non-transfemoral access for TAVI. Randomized studies are needed to ascertain the effect of alternative access sites on clinical outcomes in prohibitive-risk, high-risk, and intermediate-risk populations, using currently available technologies.

$P < 0,01$). La mortalité à 1 an était de 16,4 % pour l'accès transfémoral et de 24,8 % pour l'accès non transfémoral (RIA, 0,68; IC à 95 %, 0,60-0,75; $P < 0,01$). L'accès transfémoral était associé à un plus grand nombre de complications vasculaires (RIA, 2,1; IC à 95 %, 1,48-2,99; $P < 0,01$), mais à un plus faible taux de conversion chirurgicale (RIA, 0,59; IC à 95 %, 0,42-0,81; $P < 0,01$) et à des saignements similaires (RIA, 1,01; IC à 95 %, 0,81-1,27; $P = 0,91$) comparativement à l'accès non transfémoral. La fréquence des événements vasculaires cérébraux était similaire dans les deux groupes (1,6 % *vs* 2,1 %; RIA, 0,86; IC à 95 %, 0,64-1,15; $P = 0,31$).

Conclusions : L'accès transfémoral était associé à un taux plus faible de mortalité à 30 jours et à 1 an comparativement à l'accès non transfémoral lors d'IVAC. Des études à répartition aléatoire sont nécessaires pour vérifier les conséquences des autres sites d'accès sur les résultats cliniques des populations exposées à un risque prohibitif, à un risque élevé et à un risque intermédiaire au moyen des technologies actuellement disponibles.

arterial disease (PAD), which might independently affect outcomes. However, early experience with trans-subclavian access suggests a mortality comparable with transfemoral access.[8] For other access sites, smaller observational data and case reports exist, indicating feasibility of these techniques; but direct comparisons with transfemoral access are as yet lacking.[4,5,9-11]

In light of the evolving TAVI experience and concomitant improvement in TAVI technologies, we sought to conduct a meta-analysis to determine if there was a difference in mortality between transfemoral and non-transfemoral approaches at 30 days.

Methods

Literature search

In development of our research question we predefined the population, intervention, comparison, and outcome of interest. The population of interest was patients with severe aortic valve stenosis who underwent TAVI, comparing transfemoral vs non-transfemoral access for 30-day mortality.

We performed a computerized literature search on SCOPUS for all English language studies from 2002 up to March 12, 2014. We searched for the terms 'alternative access AND transcatheter aortic valve implantation,' 'alternative access

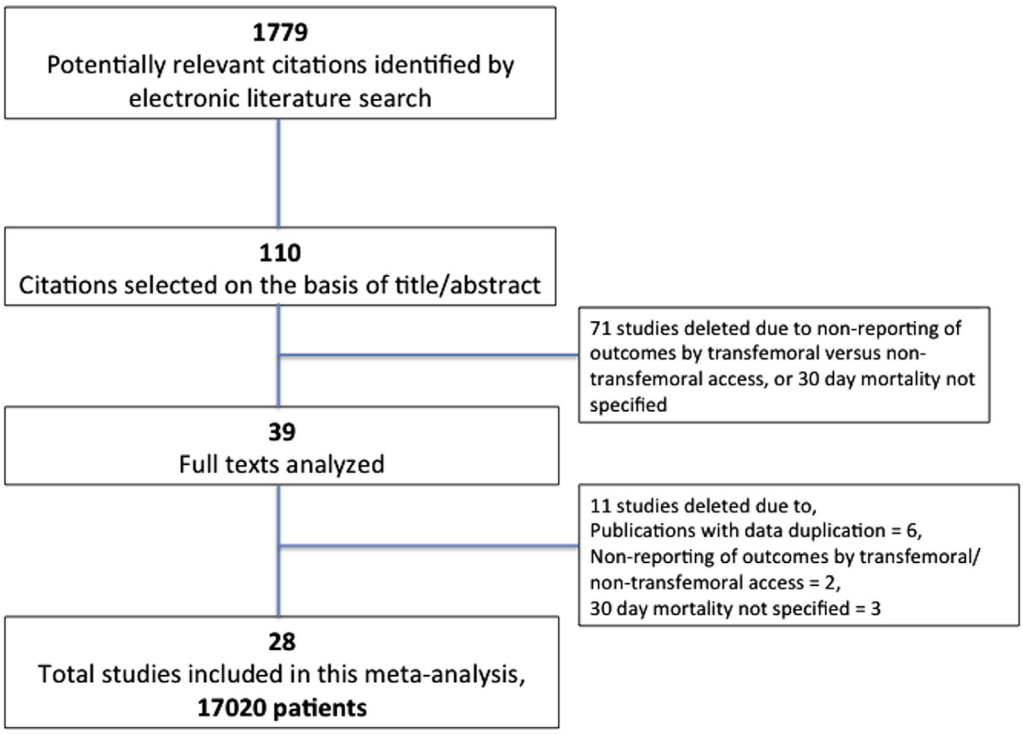

Figure 1. Flow diagram of studies included for the meta-analysis.