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REVIEW

Editor's Choice – Arteriotomy Closure Devices in EVAR, TEVAR, and TAVR: A Systematic Review and Meta-analysis of Randomised Clinical Trials and Cohort Studies

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WHAT THIS PAPER ADDS

This paper updates earlier meta-analyses with additional information and increased applicability of outcome after percutaneous access of the common femoral artery. This is particularly important given the establishment of percutaneous procedures and the publication of several important studies reporting use of arteriotomy closure devices.

Objectives: Cardiac and vascular surgery benefit from percutaneous interventions. Arteriotomy closure devices (ACDs) enable minimally invasive access to the common femoral artery (CFA). The objective of this review was to assess the differences between ACDs and surgical cut down (SCD) of the CFA regarding the number of complications, duration of surgery (DOS), and hospital length of stay (HLOS).

Design: A systematic literature search with predefined search terms was performed using MEDLINE, Embase, and the Cochrane Library (2000–2016). All studies reporting on ACD and SCD for a puncture of the CFA of at least 12 French (Fr.) were assessed for eligibility.

Methods: Included were randomised controlled trials and cohort studies comparing both techniques. Patient characteristics, exclusion criteria, and conversion rates were evaluated. Complications, DOS, and HLOS were compared.

Materials: A total of 17 studies were included for meta-analysis, describing 7889 vascular access sites; four studies were randomised trials, two studies reported from a prospective database, and 11 studies reported retrospective cohorts.

Results: ACD was associated with fewer post-operative seromas (odds ratio [OR] 0.15, 95% confidence interval [CI] 0.06–0.35), less wound dehiscence (OR 0.14, 95% CI 0.03–0.78), and fewer surgical site infections (OR 0.38, 95% CI 0.23–0.63). Post-operative pseudoaneurysms were significantly more common in the ACD group (OR 3.83, 95% CI 1.55–9.44). In five of 17 studies, DOS and HLOS were not reduced in the ACD group. When all studies reporting a mean DOS and/or HLOS were compared in a non-parametric analysis, neither was significantly different.

Conclusion: This meta-analysis favours ACD regarding the number of wound complications compared with SCD in endovascular aneurysm repair, thoracic endovascular aneurysm repair, and transcatheter aortic valve repair. Treatment duration (DOS and HLOS) was not reduced in ACD. The differences are of limited clinical significance and with this equivocal quality of evidence, the ACD may be considered safe for CFA access in suitable patients.

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INTRODUCTION

Initially, access for endovascular aneurysm repair (EVAR), thoracic endovascular aneurysm repair (TEVAR), and transcatheter aortic valve repair (TAVR) was achieved by surgical cut down (SCD) of one or both groins, then arteriotomy closure devices (ACD) emerged as an alternative to SCD in

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all of these procedures. ACDs have the potential to reduce the length of the incision, the duration of surgery (DOS), the risk of wound complications, and the hospital length of stay (HLOS), and thereby improve patient satisfaction.[1–5] Early studies mentioned a long learning curve and many exclusion criteria,[6–8] such as calcified arteries and morbid obesity. SCD equally remains a challenge in these patients. A meta-analysis comparing ACD and SCD, published in 2011, only described the relationship between sheath size and the necessity for conversion but did not evaluate the complication rate or duration of treatment.[9] Therefore, the available literature on patients treated for an aneurysm of the abdominal or thoracic aorta or percutaneous aortic valve implantation with either the use of an ACD or SCD was investigated. A comparison between ACD and SCD was made in terms of effectiveness and applicability, complications, and duration of treatment in patients selected for an endovascular procedure. A systematic review was performed and a meta-analysis of the available data is presented.

MATERIALS AND METHODS

This study was carried out following the recommendations of the Cochrane Collaboration and according to the "Preferred Reporting Items for Systematic reviews and Meta-Analysis" (PRISMA) guidelines to ensure the quality and completeness for both systematic review and meta-analysis.[10–12]

The search included the period January 2000—August 2016. Articles that specifically examined the differences between ACD and SCD of femoral arterial access measuring 12 French (Fr.) or more were searched for.

Information sources

A systematic literature search with a combination of medical subject heading (MeSH) terms and free text words was entered in MEDLINE. The terms "percutaneous closure" or "percutaneous repair" or "percutaneous access" were combined with "aortic aneurysm*[MeSH] or aortic valve* [MeSH] or abdominal aortic aneurysm* or thoracic aneurysm* or vascular*". The Cochrane Library and Embase databases were searched with the terms "percutaneous access", "percutaneous closure", and "percutaneous repair", combined with "aortic aneurysm", "thoracic aneurysm", "aortic valve", and "surgical cut down". In addition, a manual cross-reference search was performed of the identified literature.

Literature search

Two independent reviewers (B.P.V., R.A.P.) performed the literature search and assessed the relevance of each source for inclusion in the review. Disagreements were resolved by discussion and adjudicated by a third reviewer (C.J.Z.). Types of studies considered for a pooled analysis included randomised controlled trials (RCTs), and cohort studies that met the following criteria: (i) were published as full articles; (2) compared access related complications with ACD and SCD applied during EVAR, TAVR, and TEVAR; and (3) were published in English.

Types of intervention

ACD was developed for remote arterial closure of arterial punctures measuring 12 Fr. or more. It was defined as a small incision of 1—2 cm and remote closure of the arterial puncture. SCD was defined as a longitudinal, transverse, or oblique incision, visual access and puncture of the common femoral artery (CFA), followed by arterial suture or fascia closure technique.

Study selection

To ascertain validity of the included articles regarding their selection process, design, analyses, and outcome measures, the Newcastle—Ottawa Quality Assessment Scale (NOS) for cohort studies was used.[13] Two investigators independently performed this assessment and disagreements were resolved by discussion and consensus (B.P.V., R.A.P.). The methodological quality and risk of bias were assessed following instructions of the *Cochrane Handbook for Systematic Reviews of Interventions*.[14] The included studies were evaluated on various domains. Attention was paid to random sequence generation, allocation concealment, blinding of participants, personnel and outcome assessment, incomplete outcome data, selective outcome reporting, and other bias.

Based on the aforementioned components, calculations were performed on all included studies. A separate analysis of the RCTs was performed.

Data collection process

A standard data extraction form was completed for each article and converted to a predefined template with demographics, procedural data, and rate of complications.

Emphasis was given to the exclusion criteria for ACD use in the included studies and the size of the sheath used for implantation. The exclusion criteria were registered and reviewed. Possible relations between ACD sheath size and the conversion rate were explored.

Statistical analysis

The primary outcome measure was the effect of the different interventions (ACD vs. SCD) on the occurrence of complications: haematoma, seroma, femoral neuropathy, wound dehiscence, surgical site infection (SSI), pseudoaneurysm formation, iliac rupture, and dissection/rupture/stenosis/fistula of the CFA. Odds ratios (OR) and 95% confidence intervals (95% CI) for each complication were calculated. The secondary outcomes were DOS (minutes) and HLOS (days). For these continuous outcomes, the difference in means (and 95% CI) was the effect measure.

A meta-analysis was performed for each endpoint if at least two studies could be combined. The random effects model was used for computing a summary statistic in the meta-analyses using the package metaphor in R,[15] because of the expected high heterogeneity between studies. The