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Manual Compression versus Vascular Closing Device for Closing Access Puncture Site in Femoral Left-Heart Catheterization and Percutaneous Coronary Interventions: A Retrospective Cross-Sectional Comparison of Costs and Effects in Inpatient Care

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ABSTRACT

Objectives: To compare complication rates, length of hospital stay, and resulting costs between the use of manual compression and a vascular closing device (VCD) in both diagnostic and interventional catheterization in a German university hospital setting. **Methods:** A stratified analysis according to risk profiles was used to compare the risk of complications in a retrospective cross-sectional single-center study. Differences in costs and length of hospital stay were calculated using the recycled predictions method, based on regression coefficients from generalized linear models with gamma distribution. All models were adjusted for propensity score and possible confounders, such as age, sex, and comorbidities. The analysis was performed separately for diagnostic and interventional catheterization. **Results:** The unadjusted relative risk (RR) of complications was not significantly different in diagnostic catheterization when a VCD was used (RR = 0.70; 95% confidence interval [CI] 0.22–2.16) but significantly lower in interventional catheterization (RR = 0.44; 95% CI 0.21–0.93). Costs were on average €275 lower in the diagnostic group (95% CI −€478.0 to −€64.9; P = 0.006) and around €373 lower in the interventional group (95% CI −€630.0 to −€104.2; P = 0.014) when a VCD was used. The adjusted estimated average length of stay did not differ significantly between the use of a VCD and manual compression in both types of catheterization. **Conclusions:** In interventional catheterization, VCDs significantly reduced unadjusted complication rates, as well as costs. A significant reduction in costs also supports their usage in diagnostic catheterization on a larger scale.

Key words: cost comparison, length of stay, manual compression, risk of complication, vascular closing device.

Key points

i. **What is already known about the topic**
Vascular closing devices (VCDs) significantly reduce time to hemostasis and ambulation, and enhance patient comfort. However, studies show conflicting results concerning complication rates: some show a significant reduction in complications, whereas others report an equal risk of complications or even a higher risk of specific complications. Previous cost comparisons have indicated that the use of VCD was associated with lower costs. However, these were mostly based on randomized controlled trials with a narrow population, small single-center studies, or analytical models usually referring to US settings.

ii. **What does the article add to existing knowledge**
To our knowledge, this study is the first to compare costs between the use of VCD and manual compression in a German context and to differentiate between diagnostic and interventional catheterization. A large sample comprising a wide variety of patients with differing comorbidity levels was analyzed on

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the basis of data from a German hospital setting.

Introduction

Cardiovascular diseases are still the most common cause of death in Germany. In 2013, around 354,000 people died of cardiovascular diseases. This accounts for approximately 39.6% of all deaths in 2013 [1]. The standard diagnostic and treatment modality for cardiovascular diseases is femoral catheterization. In this procedure, a catheter is inserted in the femoral artery and pushed forward into the coronary arteries or the left ventricle of the heart; then, a diagnostic or therapeutic procedure can be performed. In 2008, around 845,000 diagnostic and 304,000 therapeutic catheterizations were performed in Germany [2]. Among the Organization for Economic Co-operation and Development countries, the number of percutaneous coronary interventions (PCIs) performed in 2008 was the highest in Germany, where 624 of these procedures were performed per 100,000 inhabitants, as compared with the rest of the Organization for Economic Co-operation and Development countries whose average was 177 per 100,000 [3].

After catheterization, there are two possible ways to achieve hemostasis of the access puncture site: manual compression (MC) or insertion of a vascular closing device (VCD). MC has been used from the beginning of catheterization and consists of applying manual pressure to the puncture site for around 20 to 30 minutes by a physician or trained staff. The other possibility is to use a VCD. These devices result in a shorter time to hemostasis, as well as earlier ambulation and more comfort for the patient [4]. In 2008, more than 100,000 VCDs were used in the German hospital setting [5]. Although VCDs and MC are both associated with complications, it is not clear whether VCDs produce better treatment and cost outcomes compared with MC. Typical complications associated with VCDs and MC include hematoma and bleeding, arteriovenous fistula, pseudoaneurysm , retroperitoneal hemorrhage, thrombosis, infection, and others [6]. Recent studies have questioned whether there were in fact fewer complications when using a VCD for access site closure [4,7,8]. For example, Biancari et al. [4] showed a significant increase in groin infections after the deployment of a VCD. Complications normally prolong length of hospital stay and also have an influence on costs. Several cost-effectiveness studies comparing the use of VCD with MC pointed toward VCDs being more cost-effective [9–13]. A recent study from Belgium found differences in costs, complications, and length of stay (LOS) in consecutive patients with PCI [14]. However, most of these studies were based on small sample sizes or decision-analytic models only and cannot easily be transferred to routine care. Also, to our knowledge, studies have not yet been conducted from the perspective of a German hospital setting. Furthermore, most studies look only at interventional catheterization rather than also including diagnostic procedures.

Therefore, the purpose of this study was to compare complication rates, length of hospital stay, and resulting costs between the use of MC and a VCD in both diagnostic and interventional catheterization based on data from one German university hospital.

Methods

Study Population

We used data extracted from the medical record database of the University Hospital "Universitätsklinikum Tübingen" for all patients who had a coronary or peripheral catheterization between 2007 and 2012. The study included all patients identified by the operations and procedure codes (OPS, the German Version of the International Classification of Procedures in Medicine) as having a left-heart catheterization of a PCI. Exclusion criteria for procedures included 1) transaortic valve implantation during the same hospital stay, because this is associated with a comparably large puncture site requiring a vascular suture, rather than MC, and 2) any other catheterization during the same hospital stay, except treatments for complications, because VCDs cannot be allocated to specific catheterization sessions, and any complications occurring might thus result from either the coronary catheterization or the other procedure. Leaving out the treatments would have biased the results toward fewer complications overall. Other exclusion criteria included 3) missing values in routine or cost data; 4) the use of different methods of hemostasis during one hospital stay, because complications cannot be allocated to either VCD or MC (identified by the number of catheterizations on different days and the number of VCDs used); and 5) having one of the complications as the principal diagnosis because in that case, the complication would be unlikely to result from the use of VCD or MC. Finally, 6) we excluded all subjects with a diagnosis related group coding not related to cardiac catheterization to keep the emphasis on coronary catheterizations.

For the analysis, we divided the study group into diagnostic and interventional catheterizations because patients undergoing these two procedures differ markedly in their profiles. The diagnostic catheterization group included patients with an OPS coding for only diagnostic catheterizations during the hospital stay, whereas the interventional catheterization group included those with an OPS coding of both an interventional and a diagnostic procedure.

Study Design

We conducted a retrospective cross-sectional analysis of a cohort of patients with a coronary catheterization. The exposure of interest was receiving either a VCD or an MC to achieve hemostasis. Data on sociodemographic characteristics, diagnoses, and procedures came from hospital medical records and on inpatient costs from the hospital's cost accounting systems. We identified complications, comorbidities, as well as medication use, cardiopulmonary resuscitation (CPR), and cardiogenic shock by considering all *International Classification of Disease* (*ICD*) and OPS codes noted during the hospital stay for the analyzed procedure. Data from time periods before and after these hospital stays were not available. The outcomes of interest were 1) presence of complication, 2) LOS, and 3) costs per hospital stay.

1. We used the following known complications arising from cardiac catheterization and the use of VCDs: hematoma and bleeding [7], arteriovenous fistula [15], pseudoaneurysm [15], retroperitoneal hemorrhage [15], thrombosis [15], infection of access puncture site [15], and other complications.
2. The following formula defined LOS: day of discharge – day of admission + 1. Thereby, an LOS of 1 represented same-day discharge.
3. Data on inpatient costs and resource utilization at patient level came from the hospital's cost accounting and reporting system. We used a full-cost approach for measuring costs, meaning that all costs that occurred during the hospital stay were summed up to total costs per individual. This included labor (physicians, nursing, and technical staff), pharmaceutical, material, and infrastructure costs [16]. Investment costs were not calculated [17]. We determined cost-center and cost-category groups on the basis of standardized German