VALUE IN HEALTH ▮ (2016) ▮▮▮–▮▮▮

Available online at www.sciencedirect.com

ScienceDirect

journal homepage: www.elsevier.com/locate/jval

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

Julia Walter, MSc[1,*], *Matthias Vogl, PhD*[1,2], *Martin Holderried, MD, PhD*[3], *Christian Becker, PhD*[1,2], *Alina Brandes, PhD*[1], *Moritz F Sinner, MD, MPH*[4], *Wolf Rogowski, PhD*[1,5], *Jens Maschmann, MD*[6]

[1]*Institute of Health Economics and Health Care Management, Helmholtz Zentrum München, German Research Center for Environmental Health, Neuherberg, Germany;* [2]*Munich School of Management, Institute of Health Economics and Health Care Management & Munich Center of Health Sciences, Ludwig-Maximilians-Universität München, Munich, Germany;* [3]*University Hospital Tübingen, Tübingen, Germany;* [4]*Department of Medicine I, University Hospital Munich, Munich, Germany;* [5]*University of Bremen, Health Sciences, Institute of Public Health and Nursing Research, Department of Health Care Management, Bremen, Germany;* [6]*University Hospital Jena, Jena, Germany*

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.

Copyright © 2016, International Society for Pharmacoeconomics and Outcomes Research (ISPOR). Published by Elsevier Inc.

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

* *Address correspondence to:* Julia Walter, Helmholtz Zentrum Muenchen, German Research Center for Environmental Health, Institute of Health Economics and Health Care Management (IGM), P.O. Box 1129, 85758 Neuherberg, Germany.
E-mail: Julia.Walter@helmholtz-muenchen.de.

1098-3015$36.00 – see front matter Copyright © 2016, International Society for Pharmacoeconomics and Outcomes Research (ISPOR). Published by Elsevier Inc.

http://dx.doi.org/10.1016/j.jval.2016.05.004

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

inpatient costing scheme from the Institute for the Hospital Remuneration System. This costing scheme is used in about 13% (~250 out of 2000) of all German hospitals to calculate national reimbursement rates [18,19]. It is an activity-based microcosting system that allocates an activity-based cost driver to each combination of cost center and cost category to distribute costs at the patient level [20,21]. This allowed the assessment of cost and resource utilization differences between patients receiving VCD and MC.

The study controlled for confounders and comorbidities associated with increased risk for complications identified in the literature. Confounders included sex, age, obesity, hypertension, peripheral vascular disease, coronary artery disease, diabetes mellitus, renal dysfunction, antiplatelet medication, anticoagulant medication, CPR, number of catheterizations, year of the index procedure, and cardiogenic shock. In particular, men have been found to experience fewer complications after cardiac catheterization than do women [22]. Also, the risk of complications increases with age [22]. We included the year of index procedure to account for possible learning effects regarding the handling of VCDs. The analysis also adjusted for the following comorbidities associated with the risk of complications after cardiac catheterization: obesity [22], hypertension [23], peripheral vascular disease [22,24], coronary artery disease [23], diabetes mellitus [23], renal dysfunction, and potential bleeding from the intake of antiplatelet or anticoagulant medication before surgery [22]. The model also adjusted for the emergent complication of cardiogenic shock and CPR because these factors may greatly increase costs and LOS. Finally, the model adjusted for the total number of catheterizations during the hospital stay.

Statistical Analysis

We calculated sample characteristics as means and proportions with *P* values from *t* tests for continuous variables and from chi-square tests for binary variables. The low number of complications observed in the VCD group, three in the diagnostic group and seven in the interventional group, did not allow for a sound logistic regression analysis of this effect. Therefore, we calculated unadjusted relative risks and 95% CIs for having a complication with a VCD compared with an MC. Relative risks are a good measure of rare outcomes and therefore appropriate for analyzing complications in cardiac catheterization. However, because the relative risks were unadjusted, they have to be interpreted with caution, because differences could also result from differences in the group characteristics. We used regression analysis to adjust LOS and total costs of hospital stay for possible confounders. Thereby, we used generalized linear models with gamma distribution and log-link function because these allow the handling of right-skewed data and eliminate heteroscedasticity [25]. The null hypothesis underlying all models was that using a VCD did not have a significant influence on the outcomes: complications, LOS, and costs. We accounted for imbalances in basic characteristics between the groups and possible confounders by covariate adjustment using the propensity score [26]. This approach was preferred over propensity score matching because matching would have limited sample sizes even more, impeding comparison of complication rates. An individual's propensity score was estimated as the probability of receiving a VCD, given this individual's covariates, using a logistic model. In our study, we used the following covariates for the estimation: age, sex, year, all comorbidities (specified above), anticoagulant and antiplatelet medication, cardiogenic shock, and CPR. We used the recycled predictions method to estimate average costs and LOS, as well as adjusted differences [27]. Recycled predictions are used to understand the marginal effect of independent variables on a dependent variable. They are obtained from the gamma regression model by averaging predicted scores, after fixing the value of one independent variable (either VCD or MC) and using observed values on the remaining independent variables. The recycled predictions then provide adjusted means for both VCD and MC groups, where the difference is calculated. CIs and *P* values of the adjusted means and difference are based on nonparametric bootstrapping (1000 bootstrap repetitions, percentile method). In addition, in a secondary analysis we estimated costs and effects in subgroups of patients with high, medium, and low risk, with regard to age and sex, according to a definition provided by a similar study [14]. The low-risk group included men younger than 76 years, the medium-risk group included men older than 75 years and women younger than 76 years, and the high-risk group included women older than 75 years.

All analyses were performed using SAS 9.3 (SAS software of the SAS System for Microsoft, Version 9.3 copyright (c) 2002-2010 by SAS Institute Inc., Cary, NC, USA.); tables and figures were created in Microsoft Excel and PowerPoint.

Results

Univariate Analysis

In total, the study population comprised 8665 subjects, of which 2588 were in the diagnostic group and 6077 were in the interventional group. A total of 397 subjects received a VCD: 102 in the diagnostic group and 295 in the interventional group (Fig. 1).

In the diagnostic catheterization group, patients were on average 67 years of age and 61% of them were men in both the VCD group and the MC group. In the VCD group, the proportion of patients with public insurance compared with private insurance was significantly higher than in the MC group (95.1% vs. 86.5%, respectively). In all other characteristics, the diagnostic catheterization group was well balanced between VCD and MC (Table 1).

In the interventional catheterization group, age (68.1 years vs. 68.4 years) and sex distributions (75.3% vs. 73.8% for men) did not differ significantly between the VCD and MC groups. However, there was a significant difference in the prevalence of peripheral vascular disease and diabetes between subjects with a VCD and an MC, with the prevalence being lower in the VCD group (Table 1).

Table 2 compares absolute and relative frequencies of complications and displays the unadjusted relative risk of complications between VCD and MC in the diagnostic and interventional catheterization groups. In patients with diagnostic catheterization, compared with patients with MC, those who had a VCD had a relative risk of having a complication of 0.70 (95% confidence interval [CI] 0.22–2.16). For interventional catheterization, the relative risk was 0.44 (95% CI 0.21–0.93), indicating a significant reduction in risk when a VCD is used. A secondary analysis further dividing the groups into different risk groups did not result in differing risks with regard to VCD or MC. In total, the number of complications was low, especially in the VCD groups, with three and seven complications in the diagnostic group and the interventional group, respectively. Therefore, it was not possible to perform further multivariate statistical analysis on this effect.

Multivariate Analysis

Recycled predictions for the generalized linear model regression of costs for diagnostic and interventional catheterization are presented in Table 3, by the VCD group and the MC group. In both the interventional and the diagnostic catheterization groups, costs with VCD were significantly lower than with MC.

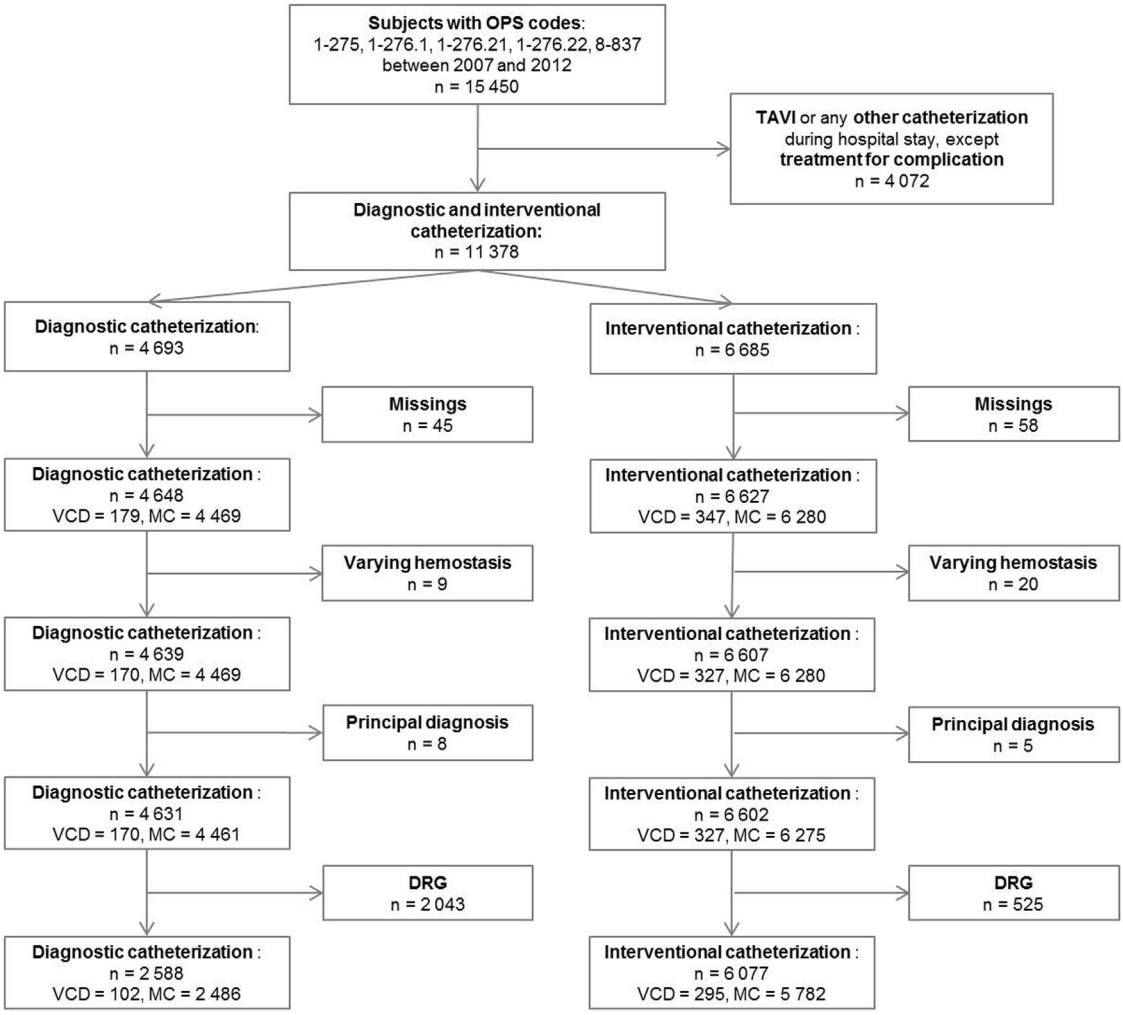

Fig. 1 – Patient flow diagram. Exclusion criteria: Missing data in basic characteristics or cost data, varying hemostasis, when two or more catheterizations were performed during hospital stay, complication as principal diagnosis, DRG not relating to left-heart catheterization or PCI. DRG, diagnosis related group; MC, manual compression; OPS, operations and procedure codes; PCI, percutaneous coronary intervention; TAVI, transaortic valve implantation; VCD, vascular closing device.

On average, costs were €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 secondary analysis of different risk groups showed significantly lower costs for VCD use in the group of low-risk patients with interventional catheterization. Costs were €317 (95% CI −€597.4 to −€4.4; $P = 0.042$) lower. Differences in other risk groups were not significant. However, notably, the sample size for subjects with a VCD in the high-risk group was small (N = 15, diagnostic catheterization; N = 29, interventional catheterization), so sound statistical interpretation might not be feasible. It is worth noting that there was a trend toward increasing costs with increasing risk in the VCD and MC groups.

Concerning costs per cost center, we found the highest predicted margins in the following cost centers: ward, intensive care unit, and cardiologic diagnostics and therapy. Costs were significantly lower in the VCD group on the ward. The adjusted difference was €166 (95% CI −291.5 to −€23.0; $P = 0.026$) for diagnostic catheterization and €208 (95% CI −€293.7 to −€109.9; $P < 0.0001$) in the interventional group. In the cost center cardiologic diagnostics and therapy, costs were significantly lower for VCD use in the interventional group with an adjusted difference of €247 (95% CI −€347.2 to −€143.3; $P < 0.0001$). Table 1 of the Appendix presents the predicted margins in the cost centers.

In diagnostic catheterization, there were significantly lower costs for VCD usage in the cost categories physician, nursing and technical staff, pharmaceuticals, and infrastructure. In interventional catheterization, differences were significant only in the cost categories drugs and material (see Table 2 of the Appendix).

Table 3 displays the estimated margins for LOS according to type of catheterization and use of a VCD. We did not find any significant difference between using a VCD or an MC, neither in the primary nor in the secondary analysis. However, in the risk groups, there was a trend for longer stays in the MC group. Also, LOS increased with increasing risk.

Discussion

This study investigated whether the use of a VCD significantly influences safety, costs, and LOS. The results showed that, in both catheterization procedures—diagnostic and interventional—costs were lower when a VCD was used. Overall and in the low-risk group, these cost differences were significant. The unadjusted relative risk of a complication was significantly different

ARTICLE IN PRESS

Table 1 – Sample characteristics according to type of catheter.

Means and proportions	All catheters			Diagnostic catheters			Interventional catheters		
	VCD	MC	Significance	VCD	MC	Significance	VCD	MC	Significance
n (%)	397 (4.9)	8268 (95.4)		102 (3.9)	2 486 (96.1)		295 (4.9)	5782 (95.1)	
Sex: male, %	71.8	70.2		61.8	61.8		75.2	73.8	
Age (y), mean ± SD	67.7 ± 11.3	67.8 ± 11.5		66.7 ± 11.82	67.3 ± 12.1		68.1 ± 11.11	68.4 ± 11.22	*
Public health insurance	89.9	89.7		95.1	86.5	*	88.1	91.1	
Peripheral vascular disease, %	3.0	7.6	†	3.9	7.5		2.7	7.6	‡
Diabetes, %	24.4	29.8	*	20.6	23.8		25.8	32.3	*
Renal disease, %	15.1	19.6	*	11.8	17.1		16.3	20.7	
Hypertension, %	76.6	80.8	*	31.4	23.1		79.3	82.5	
Obesity, %	12.6	14.5		10.8	15.7		13.2	14.0	
Coronary artery disease, %	95.7	95.1		84.3	84.9		99.3	99.6	

Notes. Means and proportions of sample characteristics for the different types of catheters and both VCD and MC. P value of significant difference between the groups by t test for age and χ^2 or, where applicable, Fisher exact test for all other variables.

MC, manual compression; VCD, vascular closing device.

* < 0.05

† < 0.001.

‡ < 0.01.

only in the overall group of interventional catheterization. Because the relative risk was unadjusted, a causal inference cannot be made. However, when a VCD was used, there was a trend toward lower complication rates and shorter LOS in all risk groups. The lack of significant results concerning the risk of complications could have been due to the overall low number of complications and limited power. From analyzing costs in the different cost categories, we could deduce which factors mostly influence these cost savings. In diagnostic catheterization especially, costs for physicians, nurses, and infrastructure were significantly reduced when a VCD was used. A reason for this was the big influence of LOS on these three cost categories. Because these categories constitute a large proportion of total costs, a reduction in LOS greatly affected total costs. In addition, lower complication rates, as well as the use of a VCD itself, allowed for earlier ambulation. Costs centers with the highest costs were cardiologic diagnostics/therapy and ward. In both diagnostic and interventional procedures, significant cost savings could be achieved with the use of a VCD by shortening the stay on the ward. This can result from not only a shorter stay but also reduced labor costs. It can take one or more people to perform MC, reducing the overall productivity, because these people cannot do other tasks. It is possible that this effect was more pronounced on the ward than, for example, in the intensive care unit, because of a higher nurse patient ratio. In diagnostic catheterization, this effect could also be found in significantly reduced labor costs for physicians and nurses in the corresponding cost categories. In interventional catheterization, significant cost savings, by on average €272 when using a VCD, were also achieved in cardiologic diagnostics/therapy. Overall, from a hospital's perspective, the use of a VCD appears to be favorable compared with the use of MC.

Comparison with Literature

Our findings aligned with those of a recent Belgian study [14] and confirmed that VCD is the safer option in interventional catheterization: Kerré et al. found a significant reduction in vascular complications when using a VCD (1.5%) compared with MC (3%), although their rates are lower than the 2.7% (VCD) versus 5.5% (MC) reported here. Kerré et al. also calculated lower costs for VCD (−€498) and they found a significant reduction in LOS. However, the Belgian study only looked at patients undergoing a PCI and did not differentiate between diagnostic and interventional procedures. A review by Dauerman et al. [28] compared the occurrence of vascular complications in different studies. Complication rates ranged from 1.7% to 5.5% in MC and from 1.1% to 3.2% in VCD use in patients undergoing PCI [28]. Although these results are similar to our findings, they differ in that they only assess interventional catheterization. Results from a meta-analysis by Biancari et al. [4] showed the rates and risks of the specific complications such as hematoma and pseudoaneurysm in interventional catheterization, as well as in diagnostic procedures. In comparison with their results, we found marginally lower complication rates.

The transferability of the results for the economic effects to other countries is limited because accounting systems and costs differ. However, to our knowledge, there were no published studies relating to costs in Germany and we therefore used a study from Switzerland for comparison. Schoenenberger et al. [13] compared the costs of 43 patients undergoing elective PCI with MC or Angio-Seal (a frequently used VCD). They found significant differences in total costs, costs for physicians, costs for nurses, and costs on the ward as well. Compared with our study, costs were lower, with €425 for VCD and €934 for MC, but the inclusion criteria were vastly different from those in our study.

Table 2 – Absolute and relative frequencies of complications and unadjusted relative risks according to VCD usage and type of catheterization by different risk groups.

Complications	Diagnostic catheterization				Interventional catheterization			
	VCD	MC	RR	CI	VCD	MC	RR	CI
All observations, n (%)	3 (2.9)	105 (4.2)	0.70	0.22–2.16	7 (2.4)	309 (5.3)	0.44	0.21–0.93
Low risk, n (%)	1 (1.7)	44 (3.6)	0.55	0.08–3.92	4 (2.3)	118 (3.7)	0.63	0.24–1.69
Medium risk, n (%)	2 (5.6)	46 (4.8)	1.16	0.29–4.60	2 (2.2)	120 (6.3)	0.34	0.09–1.37
High risk, n (%)	0 (0.0)	15 (5.2)	0.58	0.04–9.34	1 (3.4)	71 (10.7)	0.31	0.05–2.19

Notes. Absolute and relative number of complications and relative risks with CIs. *Low risk* is defined as men with age < 76 y, *medium risk* as men with age > 75 y or women with age < 76 y, and *high risk* as women with age > 75 y.
CI, confidence interval; MC, manual compression; VCD, vascular closing device.

A study by Dauerman et al. [28] reported mean time to ambulation in both diagnostic and interventional catheterizations. It was significantly lower in patients with VCD (162 minutes) than in those undergoing MC (270 minutes) in the diagnostic study arm, but not significantly different in interventional catheterization (411 minutes vs. 466 minutes). These results and also the results from a Belgian study [14] differ from ours with regard to average LOS. The average LOS in our study was around 5 to 7 days in each study arm and group, whereas other studies report around 2 to 3 days [14]. This is partly because average LOS stay is biased in our study by patients who were readmitted. However, readmission might indicate complications occurring after discharge, which is important to account for in comparisons.

Table 3 – Comparison of adjusted costs and length of stay according to VCD usage and type of catheter by different risk groups.

Adjusted costs	All risk groups	Low risk	Medium risk	High risk
Diagnostic catheters				
Adjusted costs (€)				
VCD	2006	1847	2086	2494
MC	2281	2071	2397	2797
Adjusted difference (€)	−275	−224	−310	−304
CI of adjusted difference	−478.0 to −64.9	−478.0 to 24.6	−644.0 to 48.5	−911.8 to 329.5
P value	0.006	0.072	0.094	0.348
Interventional catheters				
Adjusted costs (€)				
VCD	3830	3583	4135	4420
MC	4202	3900	4432	5019
Adjusted difference (€)	−373	−317	−297	−599
CI of adjusted difference	−630.0 to −104.2	−597.4 to −4.4	−789.6 to 296.4	−1679.2 to 813.2
P value	0.014	0.042	0.286	0.346
Adjusted length of stay	**All risk groups**	**Low risk**	**Medium risk**	**High risk**
Diagnostic catheters				
Adjusted length of stay (d, days)				
VCD	4.81	4.27	4.81	6.98
MC	5.03	4.84	5.31	6.38
Adjusted difference	−0.22	−0.21	−0.50	0.59
CI of adjusted difference	−0.72 to 0.29	−0.87 to 0.46	−1.30 to 0.34	−1.08 to 2.44
P value	0.374	0.524	0.238	0.548
Interventional catheters				
Adjusted length of stay				
VCD	5.17	4.43	6.13	6.92
MC	5.25	4.59	5.74	7.06
Adjusted difference	−0.07	−0.16	0.38	−0.14
CI of adjusted difference	−0.48 to 0.37	−0.59 to 0.29	−0.43 to 1.33	−1.86 to 1.81
P value	0.698	0.494	0.378	0.864

Notes. Adjusted prediction of costs and length of stay and adjusted difference with CI and *P* value, from gamma regression with 1000 bootstraps. Adjusted by propensity score, age, sex (age and sex not in risk groups), year of catheterization, intake of antiplatelet or anticoagulant medication during hospital stay, the comorbidities hypertension, coronary artery disease, peripheral artery disease, renal failure, diabetes, and obesity, as well resuscitation, cardiogenic shock, and number of catheterizations. *Low risk* is defined as men with age < 76 y, *medium risk* as men with age > 75 y or women with age < 76 y, and *high risk* as women with age > 75 y.
CI, confidence interval; DRG, diagnosis related group; MC, manual compression; VCD, vascular closing device.

An unexpected result was LOS being on average higher in subjects undergoing a diagnostic procedure than an interventional one, although interventional catheterization is generally a more invasive procedure. Possibly, this results from the stability or acuity of the patient. For patients presenting with chest pain diagnostic workup, subsequent hospitalization and treatment plan for the chief presenting complaint may take longer than for a stable patient who returns to the hospital for a scheduled interventional catheterization.

Study Limitations

First, the quality of hospital accounting data is limited. Complications can only be derived from *ICD*s coded during the hospital stay, where coding errors can occur. According to O'Malley et al. [29], most errors occur as a result of different descriptions of the diagnosis (sometimes 5–10 synonyms for the same clinical entity) and transcription of the diagnosis from clinicians' notes into *ICD* codes by the coder. Studies have reported error rates ranging from 17.1% to 76.9% [30] in this process.

Second, *ICD* codes are not assigned to a specific date and time. We can allocate a complication to the hospital stay but not to the VCD or MC procedure. However, a large number of *ICD* codes used for the analyses were so-called T codes implicitly stating to be a complication arising from a procedure.

Furthermore, results from the secondary analysis in the risk groups have to be interpreted with care, because the sample size was small, especially in the high-risk group.

Another limitation was that data did not distinguish between catheterizations that were performed through the femoral or the radial artery. Compared with the femoral approach, the radial approach is associated with a significantly decreased risk of bleeding complications [31,32]. The method of achieving hemostasis with the radial approach is MC or a compression device [33]. In our analysis, patients with a radial access would appear in the MC group and could bias the result toward fewer complications in this group. However, in a study by Dehmer et al. [34] on US registry data from 2010 and 2011, the femoral approach was used in more than 90% of cases. Therefore, we expect our results not to be biased, because a large proportion of subjects in our analysis underwent their procedure in the year 2008, when the radial approach was not yet widely used.

Because we derived data from only one university hospital, selection bias could have been a problem. Nevertheless, because a similar analysis currently conducted with representative health insurance data did not differ widely in the patient population characteristics, the authors expect that the results from this study are generalizable to a broader population [35].

Finally, as in any observational study, we could control for only those potential confounders that are known and could be measured in the data. Because this study was not a randomized trial, we cannot exclude the possibility that VCDs were administered to a biased sample of patients. We performed propensity score regression adjustment to control for this and mimic the properties of randomized controlled trials. However, there is still a possibility of bias through unmeasured confounding. Therefore, further work is necessary to validate these results.

To our knowledge, this is the first study to compare costs concerning VCDs from the perspective of a German hospital. Also, it is the first study to estimate costs for diagnostic procedures. Interestingly, in an as yet unpublished similar work done by our team, we compared costs from the perspective of a public insurance company and found no significant cost differences between the use of VCD and MC. Comparing the results from this study to the unpublished work could lead to an overall conclusion that in fact using a VCD saves money from the perspective of a hospital. However, public insurance companies do not benefit from these savings yet because the diagnosis related group for catheterization with VCD or MC is the same. Another strength of our analysis is the separation of diagnostic and interventional procedures. Often, only interventional procedures are taken into account. However, VCD use in diagnostic procedures decreases complication rates, costs, and LOS as well. Future research should analyze different VCDs individually and also compare safety and costs from a German perspective. A multicenter study with different hospitals and long-term health insurance data can generalize our results and make possible long-term complications of VCD use versus MC available. An implication for decision makers would be to put more effort into encouraging the use of VCDs when they are applicable.

In conclusion, this study is the first to compare costs for VCD use in a German context from the perspective of a hospital. We found that the usage of VCDs appears to be a cheaper alternative than MC, especially in diagnostic catheterization in which VCDs are not so commonly used. Cost savings could be realized by using this method more often. In interventional catheterization, it also seems to be the safer option; however, the results could only be presented as unadjusted relative risks. Because a similar analysis currently conducted with representative health insurance data did not differ widely in the patient population characteristics, we expect our results to be generalizable [35].

Source of financial support: This research was carried out on behalf of the Helmholtz Zentrum München. The Helmholtz Zentrum München is an independent organization funded by the German and Bavarian governments. It was supported by a grant from the German Federal Ministry of Education and Research (grant no. 01KQ0902V). The authors do not have a conflict of interest with regard to this project.

Supplementary materials

Supplemental material accompanying this article can be found in the online version as a hyperlink at http://dx.doi.org/10.1016/j.jval.2016.05.004 or, if a hard copy of article, at www.valueinhealthjournal.com/issues (select volume, issue, and article).

REFERENCES

[1] Todesursachen in Deutschland. Gesundheit Todesursachen in Deutschland. Wiesbaden: Statistisches Bundesamt, 2013.
[2] van Buuren F. 25. Bericht über die Leistungszahlen der Herzkatheterlabore in der Bundesrepublik Deutschland. Kardiologe 2010;4:502–8.
[3] Organization for Economic Co-operation and Development. Managing Hospital Volumes, Germany and Experiences from OECD Countries. Organization for Economic Co-operation and Development, 2013: Available from: http://www.oecd.org/els/health-systems/ManagingHospitalVolumes_GermanyandExperiencesfromOECDCountries.pdf. [Accessed June 17, 2015].
[4] Biancari F, D'Andrea V, Di Marco C, et al. Meta-analysis of randomized trials on the efficacy of vascular closure devices after diagnostic angiography and angioplasty. Am Heart J 2010;159:518–31.
[5] Gesundheitsberichterstattung des Bundes. Robert Koch-Institut, Statistisches Bundesamt, Bundesministerium für Bildung und Forschung, 2010.
[6] Lochow P, Silber S. Emergencies in the doctor's office: bleeding from the puncture site after coronary angiography [in German]. MMW Fortschr Med 2003;145:40–2.
[7] Koreny M, Riedmuller E, Nikfardjam M, et al. Arterial puncture closing devices compared with standard manual compression after cardiac catheterization: systematic review and meta-analysis. JAMA 2004;291:350–7.
[8] Nikolsky E, Mehran R, Halkin A, et al. Vascular complications associated with arteriotomy closure devices in patients undergoing

percutaneous coronary procedures: a meta-analysis. J Am Coll Cardiol 2004;44:1200–9.
[9] Resnic FS, Arora N, Matheny M, et al. A cost-minimization analysis of the angio-seal vascular closure device following percutaneous coronary intervention. Am J Cardiol 2007;99:766–70.
[10] Juergens CP, Leung DY, Crozier JA, et al. Patient tolerance and resource utilization associated with an arterial closure versus an external compression device after percutaneous coronary intervention. Catheter Cardiovasc Interv 2004;63:166–70.
[11] Rickli H, Unterweger M, Sutsch G, et al. Comparison of costs and safety of a suture-mediated closure device with conventional manual compression after coronary artery interventions. Cathet Cardiovasc Intervent 2002;57:297–302.
[12] Carere RG, Webb JG, Buller CE, et al. Suture closure of femoral arterial puncture sites after coronary angioplasty followed by same-day discharge. Am Heart J 2000;139:52–8.
[13] Schoenenberger U, Ammann P, Maeder M, et al. Angio-Seal vascular closure device: an evaluation of cost effectiveness. Cardiovascular Medicine 2006;9:257–64.
[14] Kerre S, Kustermans L, Vandendriessche T, et al. Cost-effectiveness of contemporary vascular closure devices for the prevention of vascular complications after percutaneous coronary interventions in an all-comers PCI population. EuroIntervention 2014;10:191–7.
[15] Chevalier B, Lancelin B, Koning R, et al. Effect of a closure device on complication rates in high-local-risk patients: results of a randomized multicenter trial. Catheter Cardiovasc Interv 2003;58:285–91.
[16] Vogl M. Improving patient-level costing in the English and the German 'DRG' system. Health Policy (Amsterdam, Netherlands) 2013;109:290–300.
[17] Vogl M. Hospital financing: calculating inpatient capital costs in Germany with a comparative view on operating costs and the English costing scheme. Health Policy (Amsterdam, Netherlands) 2014;115:141–51.
[18] InEK - Institut für das Entgeltsystem im Krankenhaus. Krankenhäuser mit einer Kalkulationsvereinbarung für DRG/PEPP oder Investitionskosten (Stand July 22, 2014). Siegburg 2014: Available from: http://www.g-drg.de/cms/Kalkulation2. [Accessed June 25, 2015]..
[19] Destatis, Statistisches Bundesamt. Grunddaten der Krankenhäuser 2013. Wiesbaden 2015. Available from: https://www.destatis.de/DE/Publikationen/Thematisch/Gesundheit/Krankenhaeuser/GrunddatenKrankenhaeuser.html. [Accessed: June 17, 2015].nhäuser 2013. 2015.
[20] Porter ME. What is value in health care? N Engl J Med 2010;363:2477–81.
[21] Vogl M. Assessing DRG cost accounting with respect to resource allocation and tariff calculation: the case of Germany. Health Econ Rev 2012;2:15.
[22] Hamm CW, Albrecht A, Bonzel T, et al. Diagnostic heart catheterization [in German]. Clin Res Cardiol 2008;97:475–512.
[23] Ates M, Sahin S, Konuralp C, et al. Evaluation of risk factors associated with femoral pseudoaneurysms after cardiac catheterization. J Vasc Surg 2006;43:520–4.
[24] Byrne RA, Cassese S, Linhardt M, et al. Vascular access and closure in coronary angiography and percutaneous intervention. Nat Rev Cardiol 2013;10:27–40.
[25] Kilian R, Matschinger H, Loeffler W, et al. A comparison of methods to handle skew distributed cost variables in the analysis of the resource consumption in schizophrenia treatment. J Ment Health Policy Econ 2002;5:21–31.
[26] Austin PC. An introduction to propensity score methods for reducing the effects of confounding in observational studies. Multivariate Behav Res 2011;46:399–424.
[27] Graubard BI, Korn EL. Predictive margins with survey data. Biometrics 1999;55:652–9.
[28] Dauerman HL, Applegate RJ, Cohen DJ. Vascular closure devices: the second decade. J Am Coll Cardiol 2007;50:1617–26.
[29] O'Malley KJ, Cook KF, Price MD, et al. Measuring diagnoses: ICD code accuracy. Health Serv Res 2005;40:1620–39.
[30] Hsia DC, Krushat WM, Fagan AB, et al. Accuracy of diagnostic coding for Medicare patients under the prospective-payment system. N Engl J Med 1988;318:352–5.
[31] Rao SV, Ou FS, Wang TY, et al. Trends in the prevalence and outcomes of radial and femoral approaches to percutaneous coronary intervention: a report from the National Cardiovascular Data Registry. JACC Cardiovasc Interv 2008;1:379–86.
[32] Jolly SS, Amlani S, Hamon M, et al. Radial versus femoral access for coronary angiography or intervention and the impact on major bleeding and ischemic events: a systematic review and meta-analysis of randomized trials. Am Heart J 2009;157:132–40.
[33] Balaji NR, Shah PB. Cardiology patient page: radial artery catheterization. Circulation 2011;124:e407–8.
[34] Dehmer GJ, Weaver D, Roe MT, et al. A contemporary view of diagnostic cardiac catheterization and percutaneous coronary intervention in the United States: a report from the CathPCI Registry of the National Cardiovascular Data Registry, 2010 through June 2011. J Am Coll Cardiol 2012;60:2017–31.
[35] Jaunzeme J, Eberhard S, Geyer S. How "representative" are SHI (statutory health insurance) data? Demographic and social differences and similarities between an SHI-insured population, the population of Lower Saxony, and that of the Federal Republic of Germany using the example of the AOK in Lower Saxony [in German]. Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz 2013;56:447–54.