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A Cost-Minimization Analysis of the Angioseal Vascular Closure Device following Percutaneous Coronary Intervention

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Abstract

The Angioseal vascular closure device has been shown to be safe and effective in reducing the time to hemostasis following percutaneous coronary intervention (PCI). The health economic implications of routinely using Angioseal after PCI have not been explored. We performed a cost-minimization analysis comparing routine Angioseal use after PCI to mechanical compression using a decision analytic model. The relative probabilities of 7 vascular access complications were derived from pooled analysis of published randomized trials. The incremental hospital cost of each vascular complication was estimated by a matched case control analysis of 3,943 patients who underwent PCI at our center between 1/02 and 12/04. Appropriate sensitivity and uncertainty analyses were performed. After accounting for differences in expected rates of specific complications between the two strategies, as well as the incremental costs of each vascular event, the routine use of Angioseal was associated with a reduced cost per PCI procedure of \$44. Probabilistic sensitivity analysis of all model assumptions using second order Monte Carlo simulation confirmed the economic advantage of Angioseal in 74% of model replications. In conclusion, following PCI, the routine use of Angioseal for femoral vascular access management was associated with net cost savings as compared with mechanical compression. This cost savings was in addition to the previously demonstrated advantages of Angioseal in terms of patient comfort and preference.

Keywords

Vascular complication; Angioplasty; Vascular Closure Devices; Cost-Effectiveness

BACKGROUND

Over the past 10 years, there has been widespread adoption of VCDs following coronary angiography and intervention in the United States,^{1,2} however, the cost implications of this practice have not been carefully assessed. While the cost of a VCD in the U.S. is approximately

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\$200, the costs of specific vascular complications following PCI have been poorly characterized. Given the uncertainty over the costs of vascular access complications following PCI and whether VCDs truly reduce the frequency of these complications,^{2–4} it is unclear whether the previously demonstrated advantages of VCDs in terms of patient comfort and preference are financially attractive. We sought to study the economic impact of routine arterial closure after PCI using the Angioseal device by synthesizing published and locally collected data in a decision analytic model.

METHODS

A decision analytic model was constructed to evaluate the routine use of Angioseal following percutaneous intervention (PCI) from the perspective of total hospital costs. This model was designed to incorporate the probability of seven potential vascular complications, as well as the incremental hospital costs associated with each complication. The vascular complications studied included: access site bleeding (associated with need for transfusion or decrease in hemoglobin by 3g/dl or greater), large hematoma formation (>5cm in maximal diameter), pseudoaneurysm (confirmed by vascular ultrasound), arterio-venous fistula (confirmed by vascular ultrasound), retroperitoneal hemorrhage (confirmed by radiologic evaluation), acute limb ischemia (necessitating vascular evaluation) and access site infection (confirmed by culture). The model assumed that vascular events were mutually exclusive, and that the costs of minor complications occurring simultaneously with major complications would be dominated by the costs of the major complication.

The rates of each vascular complication following PCI were estimated from a pooled analysis of all randomized studies of the use of Angioseal published between 1996 and 2005, based on a MedLine search.^{5–11} Technical aspects of the PCI procedures, such as anticoagulation practices and sheath sizes, varied considerably among these studies, and were not consistently reported. Given their rare occurrence in randomized studies, the expected probabilities of acute limb ischemia and access site infection were estimated by pooling rates from the largest published registries and case series.^{4,12–15}

The cost attributable to each vascular complication was derived from an evaluation of the direct costs incurred by patients suffering that complication at Brigham and Women's Hospital between 1/02 and 12/04 through a case-control analysis. This was accomplished for each specific complication as follows.

Encounter-level costs for each PCI admission were derived from the hospital's cost accounting system (TSI System, Eclipsys Corp., Delray Beach, FL). Costs included all dispensed medication, disposable inventory, nursing time, non-professional labor, procedural costs, as well as allocated proportions of hospital fixed and operating costs. Professional fees and costs potentially incurred beyond the index hospitalization were therefore not measured.

All cases in which a vascular event occurred underwent detailed chart review to identify potential confounders of total hospital cost. Outliers in hospitalization cost (>2 standard deviation from mean) were excluded from the analysis as non-representative. The remaining cases of vascular complications were considered representative of the complication following the PCI procedure, and summary measures of direct hospital costs were generated for each complication.

A matched case-control analysis was used to identify control patients, from the procedures in which the patient did not suffer a vascular complication, in a four to one ratio. Matching was based on age (within 5 years), gender, history of peripheral vascular disease, diabetic status, acute myocardial infarction on presentation, use of drug eluting stents, use of glycoprotein IIb/IIIa inhibitors, and Charlson Comorbidity index score¹⁶ (within 2 points). The median control

cost was calculated in a manner identical to that used for the cases. Cases that did not have PCI on the day of admission or had a length of stay > 2d following PCI (in the absence of acute MI) were excluded.

The incremental cost for each adverse vascular outcome was calculated as the difference between the median cost of hospitalization for the patients suffering a particular vascular complication and the median of the matched controls who had not suffered a vascular complication. The inter-quartile range for each complication cost was calculated by subtracting the median cost of admissions without the complication from the 25th and 75th percentile costs for admissions with the complication.

The expected values for the costs of mechanical compression and the costs of Angioseal VCD were calculated using the decision tree shown in Figure 1.¹⁷ The model was constructed and all related analyses performed using DATA 4.0 decision analytic software (TreeAge Incorporated, Williamstown, MA). For our base case analysis, the tree was calculated using the point estimates for each event probability and cost, derived as described above. The hospital equipment costs assumed were those for our center: \$190 for the Angioseal STS device and \$110 for the FemStop mechanical compression device (RADI Medical Systems, Wilmington, MA), which is used routinely at our center for patients not receiving a vascular closure device following PCI. The base case was conservatively modified by reducing the assumed rate of access site bleeding to be 50% of the rate derived from the pooled randomized trial data, since this rate was significantly higher than an internal review of the rates of bleeding following mechanical compression at our center.

One-way sensitivity analyses were performed on all model inputs.¹⁸ The upper and lower bounds for event probabilities were taken from the 95% confidence intervals of observed binomial event rates in randomized trials whenever possible (see Table 1). For event costs, upper and lower bounds were taken from the interquartile range for event costs, derived as described above (see Table 2). Overall model uncertainty was also explored using probabilistic sensitivity analysis. Second-order Monte Carlo simulation^{19,20} was performed by replacing each model input with a probability distribution. Beta distributions were used for event probabilities, and log-normal distributions were used for costs. The expected values for each limb of the decision tree were calculated by drawing once at random from each of those distributions, and this process was repeated for 10,000 iterations. The costs of Angioseal closure and mechanical compression were not varied in this analysis.

RESULTS

The probability and 95% confidence interval of each of the vascular outcomes for both Angioseal and mechanical compression, derived from the pooled analysis of available randomized control trial data, are shown in Table 1. For each outcome, the pooled analysis included between 1 and 6 studies, representing prospective evaluation of between 612 and 10,113 study patients (studies did not all assess the same outcomes, or use consistent outcome definitions). As shown, the rates of access site bleeding, large hematoma and arterio-venous fistula were significantly higher in the mechanical compression group as compared with the Angioseal group, while the rates of the other complications were similar between groups.

Between January 2003 and December 2004, 4,672 patients undergoing PCI at our facility were followed prospectively for vascular complications through time of discharge and had complete cost accounting and hospital admission records available. The estimated attributable cost for each outcome is summarized in Table 2, and ranged from \$1,399 for a hematoma to \$6,698 for a retroperitoneal hemorrhage.

The base-case decision analytic model yielded a net cost savings of \$44 per case for those patients treated with the Angioseal vascular closure device, as compared to those patients treated with mechanical compression (see Figure 2).

One-way sensitivity analyses demonstrated that the model was insensitive to all estimated event probabilities except the rates of access site bleeding and pseudoaneurysm. The model is also sensitive to the relative cost of compression, compared with the Angioseal device. Threshold values of these parameters representing the point at which the model result changes from favoring Angioseal to favoring compression are shown in Table 3. Holding all else equal, Angioseal is cost-saving compared with compression as long as the cost of performing compression exceeds \$66.

To further explore the robustness of the base case results, probabilistic sensitivity analysis was performed, based on random re-sampling of all model inputs (Monte Carlo simulation). The Angioseal closure strategy was found to be cost saving compared with mechanical compression in 74% of model iterations. The distribution of expected cost savings with Angioseal from the Monte Carlo simulation is shown in Figure 3.

DISCUSSION

In this analysis, the routine use of the Angioseal vascular closure device following PCI was associated with a savings in direct hospital costs of \$44 per patient as compared with routine mechanical compression. Net cost savings were preserved unless the rate of access site bleeding or rate of pseudoaneurysm formation varied significantly from the estimates from the pooled analysis. In addition, the estimated cost savings associated with the use of Angioseal was preserved for all analyses of cost estimates, unless the cost of bleeding following mechanical compression was significantly below the estimated 25th percentile cost. Finally, the strategy of routine use of Angioseal in appropriate candidates post-PCI was associated with a net cost savings unless the cost of mechanical compression could be reduced below \$66 per case.

Although estimates of the incremental cost of each of the specific complications we report have not been published, our estimates appear consistent with recent data regarding the cost of vascular complications in general after PCI (~\$4800) based on Medicare claims data.²¹ The attributable cost methodology used for this analysis provides a quantitative basis for estimating the costs of specific inpatient hospitalization costs incurred by patients suffering these events compared to matched control patients who did not suffer the event. While the median cost differences appeared reasonable, several findings were unexpected. The relatively high cost of “minor” vascular complications such as significant access site bleeding (\$5,440) and hematoma formation (\$1,400) likely represent the increased length of hospitalization associated with transfusion and the routine evaluation of such patients with vascular ultrasound at our institution. It is the relative high cost of the “minor” complications, which occur with greater frequency than major vascular complications, which drives the net cost savings result of the use of Angioseal found in this analysis. Supporting this hypothesis are the findings from the REPLACE 2 trial, in which minor bleeding without transfusion was estimated to cost approximately \$400 per event and reductions in this event accounted for one third of the cost offset with the use of bivalirudin.²²

The generalizability of this analysis may be affected by several important study limitations. Probabilities of vascular complications for both the Angioseal and mechanical compression strategies were derived from a pooled analysis of a heterogeneous group of small randomized trials of the devices, which may not accurately represent the observed differences in practice at a particular center. Secondly, the costs of vascular complications were derived from a limited number of cases with detailed cost accounting data from a single high volume tertiary care

medical center. In addition, the evidence that the use of the Angioseal vascular closure device may be associated with a reduced risk of femoral vascular access complications as compared to compression may not easily be extended to other types of vascular closure devices. Finally, there was limited information on rare events such as access site infection or acute limb ischemia and the estimates of both event rate probability and cost, based on few observed cases, may be inaccurate. However, the model was not sensitive to varied estimates of these low-frequency events.

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Figure 1. Decision Analytic Tree structure. The diamond shape denotes the decision node. For each main limb of the tree, patients can have either no complication, or one of 7 distinct complications, based on chance.

Figure 2.

Final cost estimates from base case analysis. Results indicate a relative cost savings of \$44 per patient receiving the AngioSeal device following PCI as compared with mechanical compression.

Figure 3.

Monte Carlo Simulation Results. Histogram represents the relative frequency of cost savings estimates from routine use of Angioseal as compared with mechanical compression following PCI. The simulation was run for 10,000 iterations.

Table 1
Vascular complications by vascular access management strategy: A pooled analysis of published data.

Complication	Patients	AngioSeal Treated Patients			Patients	Mechanical Compression Treated Patients			Sources
		Events (%)	Lower	Upper		Events (%)	Lower	Upper	
Bleeding	480	8 (1.67%)	0.52%	2.81%	561	43 (3.00%)*	2.00%	5.46%	7,9,10
Hematoma	463	22 (4.75%)	2.81%	6.69%	549	31 (5.65%)	3.72%	7.58%	8,9,10
Arterio-venous fistula	1,471	3 (0.20%)	0.00%	0.43%	8,642	72 (0.83%)	0.64%	1.02%	3,4,14,15
Pseudoaneurysm	627	6 (0.96%)	0.19%	1.72%	699	12 (1.72%)	0.75%	2.68%	6-11
Retroperitoneal hemorrhage	627	2 (0.32%)	0.00%	0.76%	699	1 (0.14%)	0.00%	0.42%	6-11
Acute limb ischemia	1,471	2 (0.14%)	0.00%	0.32%	8,642	8 (0.09%)	0.03%	0.16%	3,4,14,15
Access site infection	306	1 (0.33%)	0.01%	0.97%	306	0 (0.05%) [†]	0.01%	0.29%	9

*The bleeding rate in compression treated patients was assumed to be only 1/2 the rate obtained from the pooled result of randomized trial data. This conservative assumption was made after comparison of pooled results with contemporary registry data as well as local bleeding rates at our institution.

[†]Though there were no observed access site infections in the compression treated patients in the one randomized trial reporting this outcome, the rate for compression treated patients was assumed to be non-zero for the purposes of this analysis, though substantially lower than the rate in the Angioseal treated patients

Table 2

Costs of vascular complications at Brigham and Women's Hospital.

Complication	Total Events	Representative Cases	Median Cost (case)	Median Cost (control)	Attributable Cost	95% CI	
						Lower	Upper
Bleeding	71	6	\$17,167	\$11,727	\$5,440	\$2,250	10,226
Hematoma	35	24	\$14,347	\$12,948	\$1,399	\$700	6,959
Arterio-venous fistula	5	2	\$15,521	\$14,106	\$1,415	\$700	4,409
Pseudoaneurysm	5	5	\$19,602	\$13,245	\$6,357	\$4,900	10,408
Retroperitoneal hemorrhage	25	20	\$18,688	\$11,990	\$6,698	\$3,038	12,751
Acute limb ischemia*	3	2	\$23,238	\$17,704	\$5,534	\$5,200	14,000
Access site Infection	1	1	n/a	n/a	\$5,127		
Compression					\$2,400	\$1,500	3,300
Angioseal					\$4,200	\$3,000	6,000

* There were limited cost data for access site infections. The costs of access site infection were estimated from the cost of admission for similar surgical site infections, and were assumed to be lower (by 50%) for the mechanical compression treated patients as compared with the Angioseal treated patients, in order to account for the likelihood of a more complex peri-vascular infection in the presence of the device.

Table 3

One-way sensitivity analysis: summary of model inputs to which overall model result was sensitive. Note that no other base case assumptions affected model results through the ranges of values analyzed.

Model Input	Base Case Value	Sensitivity Analysis		Threshold value [*]
		Lower bound	Upper bound	
Complication Rates				
Access site bleeding				
Angioseal	1.67%	0.52%	2.81%	>2.49%
Compression	3.00%	2.00%	5.46%	<2.19%
Pseudoaneurysm				
Angioseal	0.96%	0.19%	1.72%	>1.66%
Compression	1.72%	0.75%	2.68%	<1.02%
Cost inputs				
Access site bleeding	\$5,440	\$2,250	\$10,226	(<\$2,105) [†]
Compression cost	\$110	0	\$150	<\$66
Angioseal cost	\$190	\$100	\$300	>\$234

* Base case results indicated cost savings for routine use of Angioseal. Changes in the direction indicated in the threshold value column would change the result toward favoring routine compression.

[†] Value outside of estimated range.