



Comparison of Percutaneous Peripheral Intervention Performed in a Dedicated Hybrid Operating Theatre Vs. Cardiac Catheterization Laboratory

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Abstract

Objective: Percutaneous Peripheral Intervention (PPI) has emerged as the treatment-of-choice for patients with symptomatic peripheral vascular occlusive disease. The procedure may be performed in a variety of clinical settings including a standard operating theatre, interventional radiology suite, hybrid operating theatre (hybrid room), or cardiac Catheterization Laboratory (Cath Lab). The purpose of this retrospective clinical study was to test the hypothesis that PPI could be performed safely by vascular surgery specialists in a Cath lab at a reduced cost as compared to a hybrid theatre.

Methods: Consecutive PPI procedures performed by three dedicated vascular surgeons were retrospectively analyzed. The choice of venue was primarily related to facility availability although patients with high medical risk were preferentially treated in the hybrid suite. Demographic characteristics, peri-procedural outcomes and cost were tabulated and compared.

Results: A total of 146 PPI procedures performed either in the hybrid room (n=97) or the Cath lab (n=49) was reviewed. Patient indications and comorbidities including coronary artery disease, hypertension, dialysis-dependence, critical limb ischemia, in-patient status, diagnostic vs. therapeutic procedure, operative time and anatomic level of intervention were similar for the two groups. Patients undergoing PPI in the hybrid room had a higher incidence of prior peripheral revascularization (46% vs. 29%; p=0.049), were more likely to require general anesthesia (18% vs. 0%, p<0.05), were more likely to require open femoral access (9.3% vs. 0%; p=0.03), were accessed with larger sheaths (61% vs. 35%; p<0.01) and were imaged with less contrast dye (73±38 ml vs. 117±57 ml; p<0.01). Major complications including retroperitoneal hematoma (0% vs. 2%; p=0.34), acute limb ischemia (1% vs. 0%; p=1) and/or acute kidney injury (1% vs. 0%; p=1) were rare in both groups. Patients treated in the Cath lab were more likely to experience transient hypotension (10% vs. 22%; p=0.08) and/or transient post-procedure creatinine elevation (2.0±2.1 vs. 3.0±3.0; p=0.05). Surprisingly, both hospital charges and hospital costs were significantly less for patients treated in the hybrid room as compared to the Cath lab (total charges \$18714±9633 vs. \$26902±19753; p<0.01, total direct and indirect costs \$7174±3847 vs. \$9659±7064; p=0.01). Medical supplies indirect cost and room services total direct and indirect costs were also higher in the Cath lab (medical supplies indirect \$336±557 vs. \$836±1893; p=0.02; room services \$3183±2068 vs. \$5169±3314; p<0.01).

Conclusion: PPI can be safely performed in either a hybrid surgical suite or cardiac catheterization laboratory although treatment in a hybrid suite utilizes less hospital resources.

Keywords: Peripheral percutaneous intervention; Hybrid operating room; Cost; Perioperative complications

Introduction

Percutaneous Peripheral Intervention (PPI) has become the preferred therapeutic approach to patient with symptomatic peripheral arterial occlusive disease [1-3]. Endovascular interventions including balloon angioplasty, stenting, and/or percutaneous atherectomy can be performed in a variety of clinical settings (the operating room, radiology suite, and cardiac catheterization laboratory) and by a variety of clinical specialists (vascular surgeons, interventional cardiologists

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and radiologists)[4,5]. The newest clinical setting to be utilized for PPI, the hybrid operating theater (hybrid rooms), consists of an optimized theater incorporating advanced quality imaging technology with access to open surgical tools aimed at efficiently treating complex pathology[6,7].

Multiple named advantages of a hybrid room have included inclusion of sicker patients, improved patient and personal radiation safety, and procedural flexibility enabling the treatment of frequent multilevel disease[4,8,9]. However, with the exponential growth of the endovascular armamentarium, and as emergent conversion to open surgery becomes a rare occurrence; unencumbered access to a traditional operating room seems less useful [10].

The ideal procedure room is one that allows for efficient PPI at a competitive cost [11]. A conventional cardiac catheterization laboratory (Cath lab) could thus suffice to treat symptomatic atherosclerosis of the lower extremities using endovascular techniques.

Comparative perioperative clinical and cost outcomes have been extensively reported across specialties in the same working environment, between a hybrid room and Cath lab, after endovascular aortic aneurysm repairs as well as trans-aortic valve replacements[12,13]. To date, limited evidence still exists on the minimally invasive treatment of peripheral vascular disease by vascular surgeons alone in a hybrid room vs. Cath lab.

The purpose of this study was to test the hypothesis that PPI could be performed by vascular surgeons in the Cath lab with similar postoperative complications and at a lower cost than PPI performed by the same group of specialists in a hybrid operating theater.

Methods

Study design and patient population

This study consisted of a retrospective clinical study of consecutive PPIs performed at a single institution by three vascular surgeons over two years in a hybrid operating room (dedicated to vascular surgical procedures) or cardiac catheterization laboratory. The first patient included corresponded to the first utilization of the hybrid room after construction. The cardiac catheterization laboratory was utilized by both vascular surgeons performed PPI and interventional cardiologists performed percutaneous coronary, and peripheral interventions. Reviewed interventions were performed by vascular surgeons. The choice of venue was primarily related to facility availability, although highest risk patients were preferentially booked for PPI in the hybrid room. Baseline patient characteristics, procedural details, and 30-day perioperative outcomes were recorded and compared in these two settings. Acute kidney injury was defined as creatinine elevation >0.6 mg/dL within 48 h of PPI. Patient anesthesia in the Cath lab consisted of surgeon-directed analgesia and modified conscious sedation with continuous cardiac monitoring. Image acquisition systems were similar between procedural rooms. CO₂ angiograms performed in both settings during the study period were excluded from analysis.

Financial data

Overall procedural costs, medical supplies, and room services expenses were obtained from cost accounting data associated with a specific current procedural terminology code on a given date. Financial data were subcategorized as, (1) total charges, (2) total direct costs (further divided into variable direct and fixed direct, and (3)

indirect costs. Total charges represent all billable items. Total direct costs related to patient care were subcategorized into variable direct costs (impacted by the specific nature of the procedure) and fixed direct costs (impacted by patient volume). Indirect costs are non-patient-related and include building, maintenance, security, and insurance. Total hospital costs and charges specifically for outpatient procedures were also analyzed. Professional fees derived from private physician practices were not included in this analysis.

Statistical analysis

Univariate comparison was performed between the hybrid room and the Cath lab for clinical and financial variables using chi-square for categorical and independent Student t-test for continuous variables. Results are presented as percentages and Mean ± Standard Deviation (SD). A p-value <0.05 was used for statistical significance. Analyses were performed using SPSS 23.0 (IBM SPSS Statistics for Windows, Version 23.0. Armonk, NY: IBM Corp.). This study was approved by the Institutional Review Board.

Results

Demographic characteristics and perioperative outcomes

One hundred and forty-six consecutive PPIs performed between July 2015 and 2017 were reviewed. Among these, 97 were performed in the hybrid room while 49 were done in the Cath lab. Baseline patient information did not significantly differ between groups (Table 1). However, patients undergoing PPI in the hybrid room had a significantly higher incidence of prior revascularization procedures (46% vs. 29%; p=0.049) without difference in Rutherford grade. Severe perioperative complications were rare and did not differ

Table 1: Baseline patient characteristics.

Variable	Hybrid room (n=97)	Cath lab (n=49)	p-value
Demographic characteristics			
Age, year ± SD	72 ± 10	74 ± 9	0.35
Male, No (%)	60 (62%)	33 (67%)	0.59
BMI, kg/m ² ± SD	27.6 ± 6.6	27.0 ± 4.9	0.55
Diabetes, No (%)	54 (56%)	33 (67%)	0.21
Hypertension, No (%)	91 (94%)	42 (86%)	0.13
Coronary artery disease, No (%)	49 (50%)	26 (53%)	0.86
End-stage renal disease on hemodialysis, No (%)	14 (14%)	11 (22%)	0.25
Chronic obstructive pulmonary disease, No (%)	11 (11%)	7 (14%)	0.6
Carotid artery stenosis, No (%)	11 (11%)	10 (20%)	0.21
Hyperlipidemia, No (%)	67 (69%)	36 (74%)	0.7
Rutherford categories			
Category 3	29 (30%)	10 (20%)	0.22
Category 4	8 (8.2%)	9 (18%)	
Category 5	14 (14%)	9 (18%)	
Category 6	46 (47%)	21 (43%)	
Intermittent claudication, No (%)	27 (28%)	19 (18%)	0.34
Chronic limb-threatening ischemia, No (%)	70 (72%)	40 (82%)	0.34
Prior limb revascularization, No (%)	45 (46%)	14 (29%)	0.049
Preoperative laboratory values			
Preoperative hemoglobin, g/dL ± SD	12.0 ± 2.6	11.4 ± 2.2	0.27
Preoperative creatinine, mg/dL ± SD	2.2 ± 2.4	2.4 ± 2.8	0.64

Table 2: Procedural details.

Variable	Hybrid room (n=97)	Cath lab (n=49)	p-value
Inpatient status, No (%)	37 (38%)	17 (35%)	0.68
General anesthesia, No (%)	18 (19%)	0 (0%)	<0.05
Operative findings			
Therapeutic angiogram, No (%)	65 (67%)	28 (57%)	0.28
Diagnostic angiogram, No (%)	32 (33%)	21 (44%)	0.24
Therapeutic interventions spectrum			
Level of intervention			
Iliac, No (%)	16 (26%)	7 (25%)	0.938
Femoropopliteal, No (%)	45 (69%)	23 (82%)	
Tibial, No (%)	20 (31%)	9 (32%)	
Multilevel, No (%)	16 (26%)	11 (39%)	0.153
Atherectomy, No (%)	39 (40%)	15 (31%)	0.28
Balloon angioplasty, No (%)	67 (69%)	26 (53%)	0.2
Stenting, No (%)	28 (29%)	8 (16%)	0.11
Drug-coated devices, No (%)	0 (0%)	2 (4.1%)	0.11
Associated open operation, No (%)	3 (3.1%)	0 (0%)	0.55
Technical components			
Operative time, minutes ± SD	97 ± 63	83 ± 46	0.17
Heparin, units ± SD	5000 ± 1647	4796 ± 2354	0.55
Retrograde femoral access, No (%)	81 (84%)	46 (94%)	0.12
Cut-down, No (%)	9 (9.3%)	0 (0%)	0.03
Largest sheath size ≥ 7 FR, No (%)	59 (61%)	17 (35%)	<0.01
Access managed by manual compression, No (%)	86 (89%)	46 (94%)	0.39
In-room sheath removal, No (%)	18 (19%)	20 (41%)	<0.01
Fluoroscopy time, minutes ± SD	22 ± 13	20 ± 16	0.61
Contrast dye administration, mL ± SD	73 ± 38	117 ± 57	<0.01
Estimated blood loss, mL ± SD	16 ± 45	8 ± 6	0.21

significantly between groups (Table 3). Patient undergoing PPI in the Cath lab were more likely to demonstrate transient hypotension (10% vs. 22%; p=0.08), and a higher postoperative creatinine level (2.0±2.1 vs. 3.0±3.0; p=0.05) without a significant difference in the occurrence of acute kidney injury (1% vs. 0%; p=1.0). 42 patients underwent reoperation within 30 days. 35 of these 42 reoperations were related to peripheral arterial occlusive disease and included 15 bypasses, 5 common femoral endarterectomies with patch angioplasty, 3 ipsilateral repeat PPI, 4 contralateral PPI, 5 above-the-ankle, and 4 below-the-ankle limb amputations. One patient underwent urgent re-exploration for retroperitoneal hematoma within 24 h of PPI.

Intraoperative performance and cost

Procedural details are presented in Table 2. Patients undergoing PPI in the hybrid room were more likely to require general anesthesia (19% vs. 0%; p<0.05), access with larger sheaths (61% vs. 35%; p<0.01) or with cut-down (9.3% vs. 0%; p=0.03) without any difference in successful revascularization (67% vs. 57%; p=0.28). Contrast dye volume utilization was significantly higher in the Cath lab (73 ml ± 38 ml vs. 117 ml ± 57 ml; p<0.01). Sheaths were most often removed in-room immediately post-procedural in the Cath lab rather than after dissipation of heparin in the hybrid room (19% vs. 41%; p<0.01). Of

Table 3: 30-day Peri-procedural outcomes.

Variable	Hybrid room (n=97)	Cath lab (n=49)	p-value
Vital signs			
Transient systolic blood pressure <90 mmHg, No (%)	10 (10%)	11 (22%)	0.08
Tachycardia, No (%)	14 (14%)	8 (16%)	0.81
Postoperative laboratory values			
Postoperative hemoglobin, g/dL ± SD	11.1 ± 2.2	10.3 ± 2.1	0.09
Postoperative creatinine, mg/dL ± SD	2.0 ± 2.1	3.0 ± 3.0	0.05
Postoperative creatinine change, mg/dL ± SD	0.13 ± 0.54	-0.20 ± 0.63	<0.01
Transfusions, No (%)	5 (5.2%)	3 (6.1%)	1
Complications			
Groin hematoma not requiring reintervention, No (%)	18 (19%)	10 (20%)	0.83
Retroperitoneal hematoma, No	0	1	0.34
Acute limb ischemia, No.	1	0	1
Arteriovenous fistula, No	0	0	1
Acute kidney injury, No	1	0	1
Embolization, No.	0	0	1
Pseudoaneurysm, No	0	0	1
Mortality, No.	0	0	1
Hospitalization			
Length of hospital stay, day ± SD	5 ± 7	4 ± 6	0.62
Readmission, No (%)	26 (27%)	15 (31%)	0.7
Reoperation, No (%)	27 (28%)	15 (31%)	0.85

*8 FR sheath used in 1 patient in hybrid room

note, the incidence of groin hematoma without need for additional intervention was not significantly different between both settings (19% vs. 20%; p=0.83).

Procedural charges were significantly higher in the Cath lab (\$18714±9633 vs. \$26902±19753; p<0.01). This was reflected by an increase in total, direct, and indirect procedural costs associated with the Cath lab (Table 4). The higher cost of PPI performed in the Cath lab was reflected in room services charges, indirect, and total cost. Medical supplies indirect cost related to overhead including security, insurance, electricity, and heating was also significantly higher in the Cath lab (\$336±557 vs. \$836±1893; p=0.021). Total costs (11315±4656 vs. 11106±8103; p=0.88) and charges (30169±12374 vs. 33075±25470; p=0.88) associated with outpatient PPI did not significantly differ in the hybrid room vs. Cath lab.

Discussion

In this study, patients undergoing PPI in the hybrid room vs. Cath lab were comparable at baseline and exhibited similarly low rates of periprocedural 30-day complications. Minor technical differences included the more common use of a larger sheath and arterial cut-down for access. PPI performed in the Cath lab incurred higher detailed and overall costs and charges.

The higher use of general anesthesia facilitated by an integrated operating suite was a confirmed advantage of the hybrid room in this cohort [9]. Similarly, the combination of open-endovascular revascularization techniques was observed only in the hybrid room, albeit infrequent [4]. However, no other significant difference in

Table 4: Charges and costs.

Variable, US\$ ± SD	Hybrid room (n=92)	Cath lab (n=45)	p-value
Total charges	18714 ± 9633	26902 ± 19753	0.001
Procedure breakdown			
Variable direct cost	4990 ± 3339	4353 ± 3963	0.33
Fixed direct cost	784 ± 677	1509 ± 988	<0.01
Total direct cost	5774 ± 3407	5862 ± 4767	0.9
Indirect cost	1400 ± 876	3796 ± 2569	<0.01
Total cost	7174 ± 3847	9659 ± 7064	0.009
Medical supplies breakdown*			
Total charges	8696 ± 6978	8773 ± 8450	0.96
Direct cost	3606 ± 3151	3866 ± 3835	0.68
Indirect cost	336 ± 557	836 ± 1893	0.021
Total cost	3942 ± 3209	4702 ± 5143	0.3
Room services costs and charges**			
Total room services charges	9873 ± 6258	18429 ± 13619	<0.001
Room services direct cost	2112 ± 1303	2187 ± 1397	0.76
Room services indirect cost	1070 ± 1048	2982 ± 2130	<0.001
Room services total cost	3183 ± 2068	5169 ± 3314	<0.001

*Hybrid room n=93, Cath Lab n=42

**Hybrid room n=93, Cath Lab n=45

percutaneous revascularization strategy was noted. Notably, no significant difference in costly drug-coated device utilization was encountered. This homogeneity differed from previous reports on transfemoral transcatheter aortic valve replacements occurring in distinct procedural settings. Indeed, Babaliar et al. describe minimal morbidity and mortality between a minimalist Cath lab and a standard hybrid operating room with lower hospital costs conveyed in the Cath lab, partially attributed to limited concomitant percutaneous coronary intervention in addition to reduced invasive monitoring[14].

Surprisingly, the results of this study suggest that PPI can be performed more cheaply in the hospital's hybrid room compared to its Cath lab. Even more so, traditional factors contributing to increased cost were not significantly different between the hybrid room and the Cath lab [15]. The hypothesis that a high-quality imaging system in a novel hybrid environment would lead to a decrease in fluoroscopy time did not hold[4,11]. Furthermore, unlike Varuet et al. in their analysis of endovascular treatment of aortic disease in a hybrid room, no difference in operative time was found between peripheral interventions performed in the Cath lab vs. hybrid room[16].

So far, the reasons for these cost differences remain speculative. At its core is likely the financial system for cost accounting deployed in the study institution; its Cath lab has been recently renovated at considerable expense and this capital cost is likely being amortized in the accounting ledger. Other possible drivers include the additional monitoring personnel routinely deployed in the Cath lab and the fact that anesthesia costs were not captured for cases performed in the hybrid room. Of course, these practices and parameters are institution-specific and may not be generalizable to other sites[4].

Several additional differences in the conduct of PPI in the hybrid room vs. Cath lab are notable. The statistically significantly higher volume of contrast dye utilized in the Cath is likely a result of the differences in technique between the two procedural venues. In

the hybrid suite, dye boluses are typically administered by vascular surgeons more accustomed to delivering small aliquots by hand injection. In contrast, dye administered in the Cath lab is more frequently delivered by technicians using automatic power injectors intended to opacify coronary arteries in motion. A second finding, that transient hypotension was more frequently documented in the Cath lab, likely reflects a higher level of continuous hemodynamic vigilance by the anesthesiologists attending patients in the hybrid suite.

Nevertheless, this study provides clinical and financial insight to support a hybrid operating suite and brings some resolve to cost concerns associated with its utilization[12]. In the absence of recommendations from clinical societies and given the lack of differences in patient comorbidities in this cohort, decision on operative environment would be best based on operator comfort, and hospital-reported lower cost. At this stage, no direct cost benefit could be linked to a potential increase in comfort in a larger and often more functional space than the alternative Cath lab[6,13,17,18].

Patients living with peripheral arterial disease have twice the annual expenditures of those without and one of the highest drivers of these costs is invasive procedure[18]. In this study, readmission rates were higher than the 17% 30-day unplanned readmission rate reported in the National Readmissions Database[19]. This was likely due to a high proportion of critical limb ischemia, and emphasizes the societal burden of treating this severe disease[20].

This study was a retrospective single center review. Its other limitations include the absence of randomization associated with a risk of selection bias for each operating venue. Although patient and physician preferences were not specifically controlled, no significant differences were encountered in diagnostic procedures, inpatient status, operative time, fluoroscopy time or length of stay. Additionally, no data on learning curve, its impact on procedural costs, utilization of the hybrid room vs. the Cath lab over time, or comparison with PPI performed by interventional cardiologists in the Cath lab over time, or comparison with PPI performed by interventional cardiologists in the Cath lab are reported herein. Finally, this study focused on procedural cost differences only; other in-hospital and outpatient costs were not captured. For example, professional fees derived from a separate cost account system were not available for review and analysis. Limited details on the nature of indirect costs were also available[4].

In summary, periprocedural clinical outcomes were not significantly different between PPI performed in the hybrid room vs. Cath lab. Overall, complications were rare. Using direct and indirect cost accounting, PPI performed in the Cath lab utilized more hospital resources than PPI performed in the hybrid suite.

Conclusion

In conclusion, PPI performed in a dedicated hybrid operating theater by vascular surgeons is safe and cost-effective.

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