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RESEARCH ARTICLE

Mis-Alignment of Clinical Goals and Financial Incentives in Coronary Stent Revascularizations Adversely Affects Patient Outcomes

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ABSTRACT

The misalignment of clinical and financial incentives for coronary stent revascularizations (percutaneous coronary interventions, PCI) by the Medicare payor, CMS (Centers for Medicare and Medicaid Services), has adversely affected patient-beneficiaries. Financial incentives, remunerations, encourage performance of inappropriate and unnecessary PCIs. While Fractional Flow Reserve (FFR) can prevent unnecessary PCIs, nevertheless, FFR adoption has not occurred despite documented unequivocal benefits by: (1) identifying a lesion's ischemic potential, (2) determining need for stent revascularization, (3) replacing the inaccurate physician's visual estimate of vessel narrowing severity with the nonaligned FFR metric, and (4) replacing the inaccurate angiographic silhouette as the measure of success with post-PCI FFR, which, in addition, supplies critical substantive outcome data. CMS' payment schedules to physicians, hospitals, and, as a result, medical device vendors, unfortunately, incentivized maintenance of the status quo. If FFR were the requisite determinative that would disqualify ~1/3rd of PCIs, procedures which would become coronary angiograms (CA), then, with present reimbursement schedules, the resulting devastating fiscal headwinds would be problematic for all parties. In contradistinction, CMS savings, considering that 231,000 among the 700,000 potential PCI SVA (Single Vessel Angioplasty) patients, that converted to CA, whose hospital reimbursement is $3,108/case, would range from $1.2- $2.9 billion. However, positively altering the reimbursement schedule for physicians is central. If a PCI became a CA, physician reimbursement would decrease to $228-$394, in contradistinction, a $1,000 increase for FFR guidewire manipulation and data interpretation, plus the $228-$394 for CA performance would increase their payment to $1,200-$1,400/procedure, which is separate from hospital payments. Hospital payments should increase by $1,000-2,000 (i.e., solely profit) above the CA payment of $3,108, plus an added vendor FFR wire payment of $2,500. This total, $6,608-$7,608, is significantly less than hospital PCI+DES (Drug Eluting Stent) of $12,767-$20,127 revascularization payments, which would have been paid for a PCI. For vendors, stent payment losses, selling prices of $600-$1,600/stent, is overcome by (1) the FFR wires manufacturing costs ($200-$300) that approximates 10% of the $2,500 payment (gross profit of 90%), and (2) the significant FFR market expansion of >1 million PCIs and a similar sized CA market with a considerable percentage of undiagnosed coronary artery obliterative disease. This proposal financially incentivizes physicians to perform FFR, and hospitals, without a procedural profit loss, should be financial indifferent to the procedure performed. The mis-alignment of financial incentives is not illusory but can be restored with appropriate alignment that benefits all parties financially, prevents unnecessary PCIs, improves patient outcomes, and reduces Medicare/CMS expenditures by billions.

Introduction

Hodgson wrote (2012)[1], "For more than 10 years…the importance of routinely performing FFR has been emphasized in review articles and editorials. FFR guidance has been shown to be of value… the procedure is simple and reproducible, and the FFR strategy is highly cost-effective… So, … what part of the FFR link don't interventional cardiologists understand? …the cardiology community should not tolerate continuing to ignore it." In 2015, my commentary, *What was, What is, and What will be!*[2], Dohr[3] employed physiologic and structural tools to assess PCI appropriateness and procedural success, which improved clinical outcomes. While the cardiology community acknowledged FFR's benefits, enthusiastic adoption did not occur. Commentaries focused upon physician issues, rather than the mis-alignment of financial incentives applicable to stent revascularization, which prevented integration into an interventional care strategy. FFR has unequivocal benefits: (1) identifying a lesion's ischemic potential, (2) determining need for stent revascularization, (3) replacing the inaccurate physician's visual estimate of a vessel narrowing severity with the physiologic nonaligned FFR metric, and (4) post-PCI FFR replacing the inaccurate angiographic silhouette as the measure of success, while supplying critical substantive prognostic immediate and long-term outcomes data. CMS's payments to physicians, hospitals, and, as a result, medical device vendors, has favored maintaining stent revascularization, even if unnecessary.

The FAME trials, the National Cardiovascular Data Registry (NCDR), and numerous randomized trials' peer reviewed publications , and the CMS (Center for Medicare and Medicaid Services) payment schedule, provide the information that details the mis-alignment of clinical goals and financial incentives. Presently, CMS' PCI payment to hospitals is 4-7x high than a coronary angiogram. FFR data indicate that PCI overuse is present in ~1/3rd of cases[13], results in worse patient-beneficiary outcomes, and seem contrary to CMS's mission to attain the "highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes". This misalignment of incentives to hospitals, vendors, and physicians can be changed through financial incentives that will encourage behavioral modification, and alteration of present PCI paradigms by replacing the coronary angiogram with FFR lesion assessment as the PCI determinative, add appropriate physician recompense for time, catheter and guidewire skills, and interpretation, provide significant payment for an uncompromised interventional FFR on-demand guidewire, and a hospital payment to avoid any revenue profit loss.

Physician inertia in FFR adoption and embracement, involve inconvenience, compensation, and unreliable FFR pressure wires, which has resulted in FFR utilization in <15% of PCIs. Physician criticisms of the FFR pressure wires included: (1) their unreliability and unpredictability of mechanical and tactile performance characteristics, (2) the inconvenience of multiple guidewire exchanges resulting in increased contrast volumes, (3) radiation exposure, and procedural time, inability to facilely record post-PCI FFR metrics because of having to recross newly deployed stents, and, (4) simply, unavailability. However, CMS' attitude towards FFR has changed with reimbursement for FFRCT (FFR computed tomography) of stable patients with intermediate coronary lesions. This position implicitly and overtly acknowledges that FFRCT was diagnostically accurate, superior to visual (angiographic) assessment, capable of discriminating between ischemic and nonischemic lesions, thereby, precluding unnecessary invasive coronary angiograms, and interventions. While noninvasive FFRCT provides (1) valuable physiological data, (2) FFRCT has constraints: limitation to stable patients, poor CT angiographic image quality preventing FFRCT calculations (~10% of CT angiograms), (3) low specificity, (4) double exposure to contrast, (5) turnaround time, and (6) limited availability (significant upfront costs). The ~$1,000 interpretation only reimbursement, is added to CT angiographic cost. FFRCT's purpose, in stable patients, is to limit unnecessary invasive procedures. In direct contrast, in the cath laboratory, 70% of PCI patients have the unstable acute coronary syndrome (ACS), and, similarly, invasive FFR differentiates ischemic and non-ischemic lesions, PCI necessity, which improves patient-beneficiary outcomes, and eliminates unnecessary Medicare expenditures.

The expectation is that patients admitted directly for PCI would have impeccable clinical indications for CA, as would physician visual lesion severity assessment, determinative for PCI, as well as angiographic documentation of procedural success. Each decisional choice made requires accurate and reliable information but the data being used is seriously flawed, and unreliable.

Clinical indications:

1. 500,154 PCI [CathPCI National Cardiovascular Data Registry (NCDR)] patients[4] were categorized

clinically: 71% (355,417) were acute of which 99% were appropriate, i.e., acute myocardial infarction, NSTEM, STEMI, cardiogenic shock, while 29% (144,737) had non-acute indications: 50% were appropriate, 38% uncertain, and 12% inappropriate (17,368 patients).

2. Analysis of 426,880 non-acute PCI patients (NCDR)[5], at 1199 sites, showed: 51% of patients had adequate data, but among the 49% with inadequate data: 50% were appropriate, 36% uncertain, and 12% inappropriate (25,101 patients).

3. Of 221,254 non-acute PCIs (NCDR)[5] 25,749 (12%) were classified as inappropriate, and after multivariable adjustment, white men with private insurance were more likely to undergo inappropriate PCIs than women, non-whites, or Medicare/public insurance/no insurance patients; patients in rural hospitals were less likely to undergo inappropriate PCIs than in suburban hospitals.

4. The procedural volumes of 8936 operators[6], having performed 723,644 PCIs (2009-2014) (42% Medicare), catalogued as low- (<50 PCIs/yr.) (39%), intermediate- (50-100 PCIs/yr.) (32%), or high-volume (>100 PCIs/yr.) (29%) operators, showed similar procedural indications for each group [elective (~45%), urgent (~41%), emergency (~15%), and salvage (<0.4%)], but only 80% of patients had appropriate PCI clinical indications.

5. Similarly, among 10,496 operators, having performed 3,747,866 PCIs (NCDR)[6], the median operator volume was 59 PCIs/yr. and 44% of operators performed <50 PCIs/yr., versus high-volume urban/teaching hospital operators (>100 PCIs annually), but only 81% had appropriate indications, i.e., 712,095 patients underwent a procedural without documented appropriate indications.

These data indicated that inappropriate indications were not isolated occurrence. Among the 25% of asymptomatic patients (308,083) within a 1,225,562 elective coronary angiogram (CA) cohort[7], two items were noteworthy: (1) while the incidence of asymptomatic CA patients in hospitals ranged from 1%-74%, and (2) hospitals with higher rates of asymptomatic CA patients had lower rates of appropriate PCIs, in contradistinction to lower volume PCI sites that had a higher proportion of appropriate PCIs What motivated physicians and hospitals to create an environment that accepted a high incidence of asymptomatic CA patients along with a significant PCI incidence of inappropriate, uncertain, indefinable, or inexplicable reasons? How can these patients be protected from inappropriate PCIs once in the interventional suite? Why across regional health care markets were lower PCI rates associated with higher appropriateness rates[8]. Publications produced behavioral changes, among 2,685,683 PCIs (NCDR) (2009-2014)[9], with a significant decrease occurred in non-acute PCIs (89,704 to 59,375), and inappropriate non-acute PCIs (26.2% to 13.3%). While admitting diagnoses defined the indications for a possible PCI, once in the cath lab, non-acute patient seems more likely than acute patients to need protection from unnecessary PCI's. Can the coronary angiogram provide the protection?

The severity of the coronary angiogram's vessel narrowing silhouette is the PCI determinative, the arbiter of revascularization and of procedural success. However, physician visual over estimation[10] of angiographic lesion severity is problematic, for example, all physician visually assessed PCI treated lesions as being ≥70% diameter stenosis (DS), although 25% were <70% DS by quantitative coronary angiography. A FAME[11] trial investigating the relationship between angiographic and functional severity detailed the inaccuracy of physician visual estimation of lesion severity in contradistinction to functional assessment (Table 1): 47% were intermediate lesions (665) of which 65% (432) were functionally normal; and 39% constituted severe lesions (551) of which 20% (110) were functionally normal. Thus, 550/ 1,414 (39%) of potential PCI lesions were functionally normal.

Table 1. Visual estimation of lesion severity vs. functional assessment

Visual % diameter stenosis*	**% of all lesions (1,414)**	**Functionally significant (FFR <0.80)**	**Functionally normal (FFR>0.80)**
50-70%	47%	35%	65%
71%-90%	39%	80%	20%
91%-99%	15%	96%	4%

* Among 509 patients with angiographically defined multivessel disease, only 235 (46%) had functional multivessel disease (>2 coronary arteries with an FFR <0.80).

Angiographic vs FFR PCI:

1. FAME[11,13] meticulously documented the benefit of FFR-guided PCI versus angiography-guided PCI: FFR functionally significant stenoses treated with PCI + optimal medical therapy (OMT) was superior to OMT alone, decreased the need for urgent revascularization, and resulted in significantly lower rates of the primary composite end point of death, myocardial infarction, or urgent revascularization at 2[14] and 5[15] years. Patients with Intermediate stenosis without evidence of ischemia were randomized[16]: if the (1) FFR >0.75 to a *Defer-PCI* or a *Perform-PCI groups*, and (2) with an FFR <0.75 to a planned PCI *Reference group;* at 5-years, event-free survival was not different between the Defer and Perform groups (80% and 73%; p=0.52), but was significantly worse in *the Reference group* (63%; p=0.03); and statistically lower composite rates of cardiac death and acute myocardial infarction were better in the *Defer, Perform*, than the *Reference* group (3.3%, 7.9%, and 15.7%; p<0.05). The outcome after deferral of PCI in a nonischemic intermediate coronary stenosis based on FFR ≥0.75 was excellent, with the risk of cardiac death or myocardial was not decreased by stenting. PCI did not benefit patients with non-ischemic lesions.

2. In the France PCI Registry[17] of 14,385 patients, 13,125 (91%) had angio-guided PCI and 1259 (9%) had FFR-guided PCI., the MACE rate was higher in the Angio-PCI (11.3%) versus the FFR-PCI (7.9%), and in mortality rates (3.9% vs. 1.4%, p<0.0001).

3. The Swedish Coronary Angiography and Angioplasty Registry[18] of 23,860 stable angina PCI patients (2005-2016) with FFR in 14% (3,367), showed, after a median 4.7-year follow-up, the FFR group had lower all-cause mortality.

4. In multivessel patients[19], before randomization, PCI lesions were identified by their angiographic appearance: 1005 patients were randomized to (1) *angiography-alone-PCI of only indicated lesions,* or (2) *assigned to FFR-guided-PCI, stenting only performed if FFR<0.80*. The mean number of indicated lesions/patient was 2.7+/-0.9 in the angiography group, and 2.8+/-1.0 in the FFR group, but the number of stents used/patient was dramatically reduced in the FFR arm, significantly decreasing from 2.7 (angiography) to 1.9 (FFR)(P<0.001). At 1-year, the FFR group's composite end points (death, nonfatal myocardial infarction, and repeat revascularizations) were significantly reduced (18.3% to 13.2%; p=0.02).

5. Similarly, the post-angiographic silhouette is not only a poor gauge of revascularization success[20-22], but also an inadequate predicter of clinical outcomes; post-PCI FFRs can convey significant prognostic information. Despite a normal angiogram, abnormal post-PCI FFRs predict significantly worse clinical outcomes than normal FFRs. The incidence (12%-37%[21, 23-26,]) of abnormal post-PCI FFRs with ischemic values (<0.81) is considerable; but adjunctive procedure(s) that normalize the FFR (0.78 to 0.87) resulted in significantly lower MACE. Even FFR refinements, e.g., post-PCI %-FFR-increase[27-29], were superior to angiography as a measure of success. A meta-analysis[27] of 5277 patients with 5869 vessels showed that, the 11.8% having post-PCIs 0f <0.80 demonstrated, at 2-years, significantly increased Target Vessel Failure (7.2%), and Cardiac Death or Target Vessel Myocardial Infarction (2.4%). A multivariate analysis of post-PCI FFR metrics[11], (Table 2) revealed it to be the most significant independent variable[31] of event rates.

Despite these data, in an interventionist survey[30], 57% of interventionists used FFR in <1/3rd of cases, 15%, never used FFR because of unavailability (47%), and problems with reimbursement (39%). If FFR ischemic lesion identification were superior to visual lesion assessment, then why is physician FFR usage underwhelming? FFR ischemic lesion stratification is not requisite for reimbursement prior to PCI, and, as such, the physician must judge benefits against the risks of unreliable FFR pressure wire usage. Physician consternation and worry is understandable, not only because of the FFR pressure wire's mechanical and tactile limitations, but also physician skills as related to PCI case volumes: 71% of interventionists perform <100 PCIs/yr., 44%, <50 PCIs/yr., and their patients primarily manifest with ACS and/or cardiogenic shock. Furthermore, despite the idealized interventional trainee's supervised experience (2023, recommended 12-month interventional cardiology fellowship volumes[31]: minimum of 250 interventional procedures, including > 200 PCIs, with at least 50 procedures a mix of coronary, peripheral vascular, and structural procedures, 25 related to physiologic assessment, and 25 related to intracoronary imaging.) Those numbers are fictional in the real world.

Table 2. Post-Stent FFR and Event Rate Incidence

Percent of 750 Patients	Post-Stent FFR	Event Rate
36%	>0.95	4.9%
32%	0.90-0.95	6.2%
32%	<0.90	20.3%
6%	<0.80	29,5%

Today, 71% if interventionists perform <2PCIs/wk., and 44%, <1PCI/wk[6], which account for 2/3[rds] of the annual ~1 million US PCI. While physicians would prefer FFR evidenced-based methodology, their unstable patients, volume of PCI procedures, skill levels, and procedural confidence might make them hesitant to deviate from their comfort level and use an unreliable FFR pressure wire that ultimately precludes FFR routine usage.

Paradoxically, despite FFR non-usage, physicians acknowledge FFR's evidentiary importance[32]; even after having decided an angiographic management strategy, plans changed once offered FFR data. In patients with ACS, reclassification by FFR was high and similar overall to that in non-ACS patients (38% versus 39%; *P*=NS), but the changes were different, fewer ACS reclassified from revascularization to OMT: (1) In the ACS cohort, 1-year outcome of patients reclassified based on FFR (FFR vs. angiography) was the same as non-reclassified patients, i.e., FFR was concordant with angiography, (2) FFR-based deferral to medical treatment was as safe with ACS and non-ACS patients, and, (3) when FFR data were disregarded (6%), worse outcomes occurred with increased MACE (19% vs. 9%), and angina recurrence (12% vs. 7%)). Similarly, FFR of intermediate lesions[33] reclassified 41% of patients from PCI to OMT. In 484 MVD patients with visual assessment of intermediate lesions, vessel management was reclassified by FFR in 30% (249/828) of vessels, patients were reclassified in 27% (130/484), and management changed in 46% (211/484) of patients. Physiologic information changed overall management strategy in 37% of 1- vessel; 45% of 2-vessels; and 67% of 3-vessel disease (p = 0.002)[34].

Physiologic lesion assessment is superior to angiography in determining revascularization necessity, and PCI success. But the interplay of FFR pressure wire characteristics, coupled with physician confidence and skill levels, procedural volumes, and patient stability meld which results in FFR non-usage. Physician acceptance of FFR's evidentiary magnitude is clear. Unfortunately, this dichotomy between evidentiary importance and procedural dilemmas has contributed to an inequity in interventional health care delivery. FFR is primarily performed on younger, stable patients within financially stable institutions, teaching centers with fellowship programs or wealthy urban medical centers with large PCI volumes, which can absorb the non-reimbursable pressure wire costs, while creating better outcomes, fewer complications, and lower mortality rates. Physician procedural hesitancy, especially in older patients, who have more comorbidities and higher rates of procedural complications, may be the reason its employed in <8% of Medicare aged (> 65 years) patients, as do FFR guidewire and procedural-cost economics influence decisions, strategies, and tactics in financially challenged institutions, inner-city and rural hospitals, whose constituents are the poor, people of color, immigrants, LGBTQ, and rural peoples.

The elderly are a rapidly enlarging proportion of the PCI population, with the age band width having shifted, with 25% >75 years: (1) while the mean age for PCI studies is 65 years, few studies focus upon septuagenarians, octogenarians, or nonagenarians, (2) elderly patient procedures are technically more challenging, with angiography making lesions appear worse, and vessels are more tortuous, calcified, and fragile, and (3) associated comorbidities (heart failure, renal dysfunction, and frailty) are more prevalent and severe, as are bleeding complication rates, all resulting in procedural related mortalities. While age has its benefits, aging's confounding anatomical and comorbid complexities, make PCI procedures more difficult, thereby, making interventionists, with limited experience, low PCI volumes, and developing skill-sets, more hesitant, thus FFR is avoided because of pressure wire vagaries, guidewire exchanges, prolonged procedures, increased contrast volumes and radiation exposure, despite the PCI benefits of better clinical outcomes, including imporved survival.

In a report of 491 ACS elderly (83+/-6 years) patients (without exclusion of STEMI or cardiogenic shock), PCI (285) patients had better short and long-term survival with all-cause mortality being 7%, 13%, and 22% at 30 days, 1 and 3 years, compared with 20%, 39%, and 57%, in non-PCI (206) patients (all p < 0.001)[35]. FAME[36] compared

1-year outcomes between FFR-guided PCI and angiography-guided PCI of <65 (512) and ≥ 65 (493) years patients with angiographic-PCI versus FFR-PCI, and degrees of visually estimated stenoses versus functionally significant lesions (FFR ≤ 0.80): older patients had significantly higher FFRs in 50%-70%, and 71%-90% stenoses, and, in 71%-90% stenoses, the proportion of functionally severe lesions was *significantly lower* in the elderly, despite a severe angiographic appearance, which deceived interventionists into performing unnecessary PCIs. Octogenarians undergoing PCI do well, despite having in-hospital significantly (2-4x) higher complication rates (4% vs.1%), nevertheless, can substantially benefit: 7,472 octogenarians[37] compared to 102,236 younger patients (62 years) had higher complication rates: death (3.8% vs. 1.1%), Q-wave myocardial infarction, stroke, renal failure, bleeding, and vascular complications; and coronary lesion characteristics[38] make PCI technically more challenging with more ostial lesions, calcified vessels, tortuous vessels, and left main lesions.

The Japanese Percutaneous Coronary Intervention Registry collected data, between 2014-2016, from 1,018 hospitals of 562,640 elderly PCI patients[39] (≥60 years), who had either ACS (209,928) [ST-segment–elevation myocardial infarction (STEMI), non-STEMI, and unstable angina] or non-ACS CAD (352,712) [stable angina, old myocardial infarction, and/or silent ischemia]. The two cohorts stratified by decade; older sub-cohort patients had more heart failure, kidney disease, and ACS patients were more likely presenting with cardiogenic shock. The various cohorts had similar success and complication rates, however, mortality and bleeding were lower in stable sub-groups. But bleeding was significantly higher among ACS patients (0.53% vs 0.20%), as was mortality, rising by decade from 1.2% to 5.2%, in nonagenarians. Increasing age had the comorbidity confounder frailty (i.e., physical functional decline, cognitive impairment, malnourishment, and reduced physical capacity), and was independently associated with major bleedings, and increased morbidity and mortality. Frailty was present in 19% of ≥75 years (469,390) patients (mean: 82 years) admitted with acute myocardial infarction; frail patients were less likely to receive PCI than non-frail patients (15% vs. 33%, p<0.001), but when performed, PCI lowered the in-hospital mortality[40], and 1- and 3-year survival improved[41]. Clinical judgment, adroit technical skill, good data, and uncompromised devices are critical and necessary for physicians to perform such successful procedures; and physician hesitancy because of patient age should not be the exclusionary determinative for PCI[42]. These data are remarkable considering the patient numbers, and their ages. However, if the physiologic assessment of lesions were applicable, a considerable number of PCIs might have been avoided. Furthermore, the issue of bleeding, especially at the femoral puncture site may be mitigated by the radial approach.

Dr Nanette Wenger (1992)[42] wrote, "'Not only is cardiovascular disease the major cause of death and disability in aged patients, but also the profile of cardiovascular illness in the United States has shifted to encompass predominantly elderly populations.… Yet it is precisely in this population that the traditional exclusion, or at best underrepresentation, of elderly persons in clinical trials has generated an information void." The only thing that has changed is a higher percentage of the aging population. Aging's complexities, anatomies, and comorbidities are related to procedural complications, and outcomes, as such, this population cohort demands from the interventionist perfected PCI skills. In this active, vibrant, and aging population, when PCI is effective, and less traumatic, the results are shorter recovery times, better outcomes, and quicker return to functional independence, while avoiding debilitation and dependency. Requisite invasive FFR can improve care in the aging.

The PCI treatment paradigm involves a mis-alignment of clinical, and financial needs and incentives to hospitals, medical device vendors, and physicians, which directly adversely affects patients because the economics of PCI are not consonant with appropriate treatment management. While the benefits of the multiplicity of novel interventional cardiology methodologies are excellent when indicated, but lost in these attainments is the issue of procedural necessity. PCI begins with clinical indication, accuracy of angiographic assessment, revascularization success, and resulting patient care management. However, the remunerative incentive for hospitals, and vendors is in maintaining the status quo. (Table 3), and CMS' byzantine payment schedule provides substantiation. Theoretical analysis of the previously defined 231,000 potential non-ischemic lesions undergoing SVA PCI could result in no PCI, which reverts the procedure to become a CA. CMS' PCI+DES reimbursement of $12,767-$20,127, depending upon medical complications and comorbidities, would revert to that of a CA, $3,108. Medicare expenditure for those 231,000 patients, falls from a PCI expenditure of $2.95-$4.65 billion to $718 million. Similarly, hospitals would be affected, and for a lab with 100 PCIs annually, a 30% change in procedural mix, PCI to CA, changes the revenue

range $383,010-$603,810 to $93,240. For DES vendors, $600-$1,000/DES, and 1.4 stents/case vendor revenue decrease would be $25,000-$42,000. FFR pressure wires are not reimbursed. Thus, why change the status quo, with the patients undergoing unnecessary PCIs being simply collateral damage.

Table 3 (effective, October 1, 2023) Medicare (CMS) Remuneration

CPT Code	Description	Physician ($)	Ambulatory	Hospital Outpatient	Hospital Inpatient[1]
93454	Coronary Angiography (CA)	$228-394	$1,633	$3,108	
92920	PTCA w/o STENT	$506	$3,413	$5,452	$11,111-$16,459
C9600	CA W/Drug Eluting Stent (DES)	$563	$6,706	$10,493	$12,767-$20,127
93571	FFR+/- additional vessel[5]	$69+/-50	-	-	$12,767-$20,127[2]
C1761	Coronary lithotripsy w/stent***	$140	-	-	$20,785-$28,987[3]
92972	Coronary lithotripsy w/o stent *	$140	-	-	$18,514
	FFRCT[4]	$80-$109	$950.50[4]		

1. Depends upon associated medical complications and comorbidities.
2. Payment packaged into primary procedure, no separate payment.
3. No requirement for assessing the extent of vessel wall calcification, and IVL catheter costs $4,707-$10,500, and generator (825DX!) costs $29,999.
4. The CMS provides $950.50 for the Outpatient Computerized Tomographic FFR (FFRCT) analysis payment is $950.50, plus the added CT angiogram charge of $400-$1,000.
5. The ASP (average selling price) of coronary FFR guidewire is ~$675, disposable IVUS catheters $600-$1,000 with $2,550 for Boston Scientific Comet Pressure guidewire, and multifunction data interpretative equipment $100,000-$200,000

All patients deserve and expect their physicians to provide care and treatments, authenticated by an evidenced-based rationale, published guidelines, randomized trials, registries, and relevant literature reviews. Physicians are obligated to provide the best care to the patient, but physicians can be influenced by local and regional practices, past experiences, especially unfavorable occurrences, and external pressures which can lure, ensnare, or entangle physician, because of personal needs, into flawed and often unsustainable financial situations, e.g., compensation, wages, work environs, employers, industry marketing, and industry direct physician payments. These situations can influence physician decision-making, therein, shaping pivotal judgments and determinations that can be inconsistent with their obligations. Now, after decades of stent revascularization, the vexing conundrum of vessel wall calcification and non-elasticity has been effectively dispatched with the adjunctive coronary lithotripsy, enabling facile stent expansion (Table 3). However, neither PCI necessity as indicated by physiologic lesion assessment, nor IVUS determination of vessel wall calcification is required to gauge the need for these expensive adjunctive procedures. My focus is FFR, and I will deviate no further. The rectification of the mis-alignment of financial incentives can be achieved by realignment of clinical goals, patient needs, physician responsibilities, and hospitals and vendors aspirations. The vendor's responsibility is paramount in providing a primary uncompromised solid core interventional FFR on-demand guidewire that can remain in place, once positioned, throughout the procedure, enabling ischemic lesion stratification, stent placement and deployment, determination of PCI success, and possible need for adjunctive procedure. Such a wire exists with present technology. Payment incentives must be adjusted to allow physicians and hospitals to be agnostic towards income source, PCI or CA. Physicians, the determinative provider, require adequate compensation for their knowledge, competences, and skills. Similarly, hospitals and medical centers, the physician workplace, must be compensated such that no allegiance remains for a particular procedure. Vendors must be compensated for the development of this unique guidewire, stent revenue losses, while made aware of the considerably larger FFR and CA markets. Payors' expenditures will be drastically reduced, and that should be satisfying.

CMS has accepted and established a framework to reduce unnecessary PCIs with FFRCT's $1,000 interpretative payment, in addition to CT's CA payment. Similarly, for invasive FFR, the physician's guidewire maneuvering and skills, and data interpretation payment should be $1,000, complemented by the physician's CA's $228-$394 payment, depending upon PCI's complexity. The physician's compensation would be $1,200-$1,400

when a PCI reverts to a CA. Hospital payment, for PCI to CA, of $1,000-2,000 (solely profit, and requires substantive investigation) would be added to CA payment of $3,108, plus the vendor's FFR wire payment of $2,500, totaling $6,608-$7,608. This $6,608-$7,608 is less than PCI+DES of $12,767-$20,127 stent revascularization payments. For the vendors, stent payment losses, $600-$1,600/stent, is overcome by the $2,500 FFR guidewire payment less manufacturing costs ($200-$300), and the increased FFR market expansion to the 1 million PCIs and CA market. Elective CA[43] has an estimated 1 million procedures annually, in which FFR is not performed, but 38% of patients without known CAD were found to have visually obstructive coronary disease, and ~ 30% went go on to revascularization (PCI or CABG); FFR could prevent unnecessary procedures, like FFRCT. CMS savings, coming from the 231,000 potential PCI SVA patients converted to CA, ranges from $1.2- $2.9 billion, with a 63% saving at high-end PCI+DES reimbursement. This is without addressing the multivessel PCI patients, statistically ~9% would need no PCI. This proposal provides considerable financially incentivizes for physicians to preferentially perform FFR, hospitals being indifferent to the procedure performed, while simultaneously benefiting payors and vendors.

CMS should create a task force to investigate why FFR is not the determinative for PCI, FFR's effects upon clinical outcomes, validating post-PCI FFRs which can improve clinical endpoints improvements, and the mis-alignment of financial incentives regarding procedures and their excess usage, determine appropriate hospital compensation, disabuse the absence of FFR guidewire compensation, and recognize physician importance and obligation for adequate compensation. All parties should be involved in such a Health Care Economics study, which can affirm the need for independent physiologic lesion interrogation metrics. This would show empathy and provide compassionate assurance to the coronary disease patient-beneficiary that whenever or wherever a PCI was performed, with whatever devices or adjunctive procedures necessary, that PCI indications were valid, PCI was warranted, appropriate, and successfully performed.

Conclusions:

All patients deserve and expect their physicians to provide medical and/or surgical care, authenticated by an evidenced-based rationale, published guidelines, randomized trials, registries, and relevant literature reviews. Patient evaluations, PCI clinical indications, coronary angiography as PCI determinative and of successful revascularization are severely flawed, which adversely affects patient clinical outcomes. The independent diagnostic FFR physiologic methodology can dramatically improve patient outcomes: by ischemic lesion stratification, enable appropriate PCI revascularization and success determination. The vendor's responsibility is providing an uncompromised primary interventional FFR on-demand guidewire. Restoration of the mis-alignment of financial incentives can be achieved by realignment of clinical goals, patient needs, physician responsibilities, and hospitals and vendors want. FFR utilization would require an alteration in financial incentives, considerable recognition of physician importance, and behavioral modifications by all parties with increasing physician payments for skill and technical expertise, preventing loss of hospital revenue profits, and significantly increasing vendor FFR guidewire payment. Physicians should take the position that unnecessary and inappropriate PCI procedures should cease, that all involved parties should have compassion and empathy for patients whose cardiovascular pathology may be solved with methodologies when appropriately applied and fittingly utilized. Finally, the patient-beneficiary should be confident knowing that, whenever or wherever a PCI was performed, the clinical indications warranted the PCI procedure, which was solely performed in the patient-beneficiary's best interest.

Conflict of interest

Disclosure: I was an investor and director of an FFR-IVUS R&D company, Phyzhon Inc., which became defunct in 2022.

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