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Formation of Six Sigma Infrastructure for the Coronary Stenting Process

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ABSTRACT: The purpose of this study is to show how a tertiary care center in Turkey operating mainly in cardiology initiated Six Sigma principles to reduce the number of complications occuring during coronary stent insertion process. A Six Sigma's Define-Measure-Analyze-Improve-Control (DMAIC) model for coronary stent insertion is suggested. Data were collected for 24-months. Twenty-two Critical-to-Quality (CTQ) factors were identified for successful coronary stent insertion. The most frequent causes of complications in the process were found to be patients with previous bypass surgery or PCI, inexperience of staff members, highly damaged vessel structure, thin and/or long vessel diameter, inappropriate selection of stent type, inappropriate selection of balloon type and poor image quality.

Keywords: Six Sigma; cardiology; stent insertion; complications
JEL Classifications: I120; L15

1. Introduction

Coronary stent insertion is one of the revascularization techniques considered and integrated in heart failure management. The technique was initially described in 1977 (Howard-Alpe et al., 2007). In 1986, Jacques Puel and Ulrich Sigwart inserted the first stent into a human coronary artery. It was not until 1994 that the first Palmaz-Schatz stent was approved for use in United States.

Coronary stent insertion is often used in association with balloon angioplasty to treat narrowed or blocked coronary arteries. It is best reserved for unstable patients in the throes of a heart attack or those who suffer from persistent chest pain, despite maximum medical therapy. However, it may result in arrhythmia, blood clotting, restenosis, damaged heart or blood vessels, sudden cardiac death and allergic reactions (Kaufmann et al., 2010).

In the last two decades, there have been important developments in the field of Percutaneous Coronary Intervention (PCI), initially with balloon angioplasty alone and more recently in combination with coronary stent insertion (Smith et al., 2006). Being a treatment of acute or threatened artery closure following angioplasty, stent insertion optimizes the initial and longer term

revascularization by decreasing the perioperative and postoperative risk in selected patients (Al Suwaidi et al., 2000; Brikalis et al., 2007).

While the number of randomized clinical trials and other studies evaluating them are rapidly increasing, stents are now used in the overwhelming majority of percutaneous coronary revascularization procedures. Increased safety and efficacy of PCI has led to an exponential rise in the number of procedures being performed, with currently more than 9 percent of all PCIs involving the placement of at least one coronary stent (Howard-Alpe et al., 2007). However, the improved safety of PCI by stenting and thus significant reduction in the need for bailout bypass surgery do not decrease the procedural complication rate (Crawford et al., 2005).

According to the American Heart Association, over 70 percent of coronary angioplasty procedures include stenting. The annual number of PCIs has exceeded the annual number of coronary artery bypass surgeries, and the difference continues to grow (Brikalis et al., 2007).

The technical success rate of coronary stent insertion is around 95% (Seidensticker and Hoffman, 2008). However, high incidence of complications is still an increasing clinical problem. Therefore, this study proposes the use of Six Sigma Methodology to reduce the complications occurring during the coronary stent insertion process.

2. Coronary Stents

Coronary stents are fine tubes placed in the coronary arteries that supply the heart, to keep these arteries open in the treatment of coronary heart disease. They can be classified according to their basic design, their mode of delivery and their metallic composition. They are manufactured in various diameters (2.5mm-5mm) and various lengths (8mm-32mm). A desired stent should be flexible, trackable, biocompatible, radiopaque and thromboresistant with low unconstraint profile, high radial strength, low surface area, reliable expandability, hydrodynamic compatibility and circumferential coverage (Crawford et al., 2005).

Selection of a specific stent for a patient is based on the cardiology specialist's experience with that type and quality of stent, lesion characteristics for which it is being used (e.g. lesion length, ease of stent deliverability, need for side-branch access, size of the target vessel) and the stent delivery system (Al Suwaidi et al., 2000).

The main advantage of using stents is that the procedure to insert them is much less invasive than the surgery. In addition, stents reduce chest pain and have been shown to improve survivability in the event of an acute myocardial infarction. Thus by inserting a stent, the patient's chances of having a heart attack is decreased. Moreover, stents when compared with balloon angioplasty may reduce overall mortality in non-acute coronary artery disease and re-infarction rates in acute coronary artery disease (Nordmann et al., 2006).

There are six type of stents, namely bare metal stents (made of stainless steel), bare metal stents (made of cobalt chromium), absorbable stents, bioactive stents, radioactive stents and drug-eluting stents. They are made of different materials; have different coatings and interact differently in the body.

The first generation and widely used stents are bare-metal stents. The major drawback with these stents is that they tend to trigger too severe a reaction within the body where too many cells are sent to heal the area around the stent. This severely increases the thickness of the vessel walls and reduces the diameter of the blood vessel. This process is called restenosis or re-narrowing of the blood vessel. Secondly, the presence of exposed metal struts in the coronary arteries is highly thrombogenic, and the early use of stents was associated with a high risk (16 to 24 percent) of stent thrombosis. This potentially devastating complication is associated with a 50 percent incidence of acute myocardial infarction (MI) and a 20 percent mortality rate (Howard-Alpe et al., 2007).

More recent stents are drug-eluting. In development are stents with biocompatible surface coatings which do not elute drugs, and also absorbable (metal or polymer) stents.

3. Methodology

Six Sigma, originally initiated by Motorola, Honeywell and General Electric (Mehrjerdi, 2011), is a powerful performance improvement tool that is changing the face of modern healthcare delivery today (Taner et al., 2007). Although it was initially designed for the manufacturing processes, Six Sigma has been adapted to the medical field for reducing surgical site infections (Pexton and

Young, 2004; Frankel et al., 2005) diagnostic imaging processes (Taner et al., 2012), emergency department (Miller et al., 2003), paramedic backup (Taner and Sezen, 2009), cataract surgery (Taner, 2013), radiology (Cherry and Seshadri, 2000).

In cardiology, very little research has been conducted on Six Sigma applications. LeBlanc et al. (2004) have used Six Sigma principles to increase productivity and capacity in a cardiac catheterization laboratory. Elberfeld et al. (2004) have improved the delivery and documentation of medication in patients with acute myocardial infraction and congestive heart failure by Six Sigma. Schoonhoven et al. (2010) have implemented lean Six Sigma to shorten the admission time for new patient and the throughput time of the cardiac consultation pathway, improve the efficiency of resource utilization and increase the number of patients treated and revenue earned in the cardiac outpatient clinic. Kelly et al. (2010) have successfully applied Six Sigma in a tertiary care center and reduced door-to-balloon time for PCI from 128 to 90 minutes. Gupta et al. (2012) developed more flexible and deliverable stents by implementing Six Sigma principles in combination with Finite Element Analysis.

4. DMAIC for Coronary Stent Insertion

As a method to eliminate variation, waste, errors and inefficiencies, Six Sigma uses a structured methodology called DMAIC to find the main causes behind problems and to reach near perfect processes. DMAIC is especially useful to analyze and modify complicated time-sensitive healthcare processes involving multiple specialists and treatment areas by identifying and removing root causes of defects (errors) and thus minimizing healthcare process variability (Kelly et al., 2010; Buck, 2001; Taner et al., 2007).

The DMAIC is a five-step improvement cycle that aims to continuously reduce errors:

1. *Define* the problems of the process, clarify its scope and define its goals;
2. *Measure* the current performance of the process, gather and compare data, refine its problems/goals;
3. *Analyze* the process by identifying sources, gaps and error root-causes and analyze best practices;
4. *Improve* the process by conducting trials to eliminate root causes, testing solutions, measuring results, standardizing solutions and implementing the improved processes by designing creative solutions to fix and prevent problems;
5. *Control* the new process by institutionalizing improvements and implementing mechanisms for ongoing monitoring in place (Park and Antony, 2008).

4.1. Define Phase

The cardiology unit staff decides that Six Sigma is the best way to achieve their goals. A project team is assembled and trained in the methodology. Committed and consistent leadership to overcome the complications is assured by this team.

The project team firstly generates a SIPOC (Supplier, Input, Process, Output and Customer) Table for coronary stent insertion process (Table 1). Cured and stable patient is considered to be the predictor of success in the coronary stent insertion process.

The coronary stent insertion is performed in a cardiac catheterization laboratory. Each group consists of a medical specialist/cardiology specialist, a nurse and a radiology technician. The process differs between emergent PCI and elective PCI (Table 1) since time is the most crucial parameter in urgent cases. On the other hand, prior to elective PCI, there is always an intricate balance between the experience and skill of the radiology technician, the opinion of the referring doctor, consultation with the medical practitioner and the preference of the patient (Crawford et al., 2005).

Radiology technicians have vital tasks in the process. They are responsible for the calibration, adjustment (angling, rotation and image quality) and regular maintenance of the angiography equipment. The procedure starts with the administration of a local anesthetic to the patient at the groin puncture site. Then, a cardiac catheterization procedure is performed in which a long, narrow catheter is passed through a sheath placed within a small incision in an artery in the groin, arm or wrist. Following this, a catheter with a small balloon at the tip is guided to the point of narrowing in the coronary artery under X-ray visualization to determine the location, the shape and the size of coronary arteries, and the type of blockage. Then, the contrast drug is injected through the catheter so the cardiology specialist can view the site where the coronary artery is narrowed. To view the area of

study from different angles, the patient is frequently asked to change positions, and subsequent contrast drug injections may be administered. During any injection, the imaging equipment may also move. As the balloon catheter is positioned at the location of the blockage in the coronary artery, it is slowly inflated to widen the artery, compress the blockage into the artery wall and stretch the artery out. Next, the stent is inserted into the coronary artery with the balloon-tip catheter. Fluoroscopic pictures are recorded and evaluated. Then, the cardiology specialist estimates the size of the occluded coronary artery and selects the type of balloon catheter and guide-wire that will be used. Then, the balloon is inflated by a mixture of saline and contrast drug. Either side of the balloon metallic markers that help the cardiology specialist to see the location of the stent. Inflation expands the stent against the walls of the diseased artery. Leaving the stent permanently in place to hold the artery open, the balloon catheter is deflated and removed together with the guide-wire, when the cardiology specialist is satisfied with the results. The patient is discharged usually the following morning.

Table 1. SIPOC for Coronary Stent Insertion

SUPPLIER	INPUT	PROCESS		OUTPUT	CUSTOMER
		Elective PCI	Emergent PCI		
General Practitioner	Patient	ECG		Cured Patient	Patient
Medical Specialist		First consultation for intake	Troponin	Stable Patient	
Cardiology resident		Additional testing (echo test, cycling test, biochemistry tests, holter monitoring, etc.)			
Cardiology specialist		Second consultation to review results	Check if heart attack		
Nurse		Decision to perform PCI or surgery			
Radiology technician		Procedure			
		Discharge			

The project team defines the performance objective as cured and stable patients after nearly perfect coronary stent insertion procedures; i.e., resulting in very few complications. They also define a complication as any unwanted outcome inhibiting the patient to be cured and stable. It compounds the illness and jeopardizes the patient's life or prolongs the planned hospital stay.

To achieve the performance objective, the project team first determines the Critical-to-Quality (CTQ) factors by examining the voice of the staff. The CTQ factors are those factors that may have an influence on the objective. These factors are presented in the fishbone diagram (Figure 1).

Figure 1. Fishbone diagram

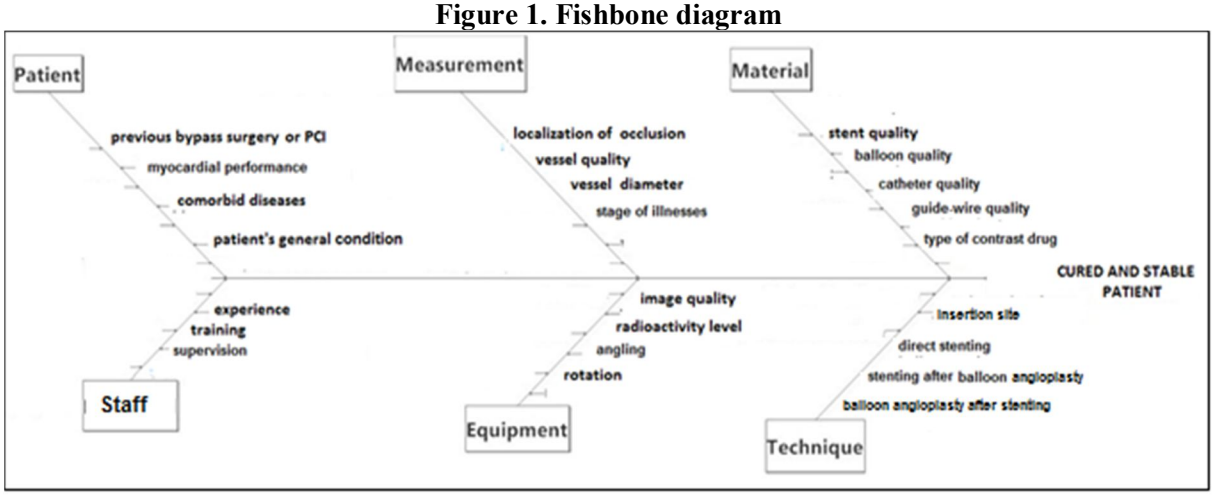

Table 2. Monthly distribution of the patients

	Jan 2011	Feb 2011	Mar 2011	Apr 2011	May 2011	Jun 2011	Jul 2011	Aug 2011	Sep 2011	Oct 2011	Nov 2011	Dec 2011	Total 2011
Coronary angiography	692	672	788	680	608	614	392	376	454	442	485	592	6795
Emergent PCI	36	31	31	39	39	30	18	27	30	33	35	48	397
Elective PCI	113	120	117	105	123	96	100	84	127	145	151	138	1419
Total PCI	149	151	148	144	162	126	118	111	157	178	186	186	1816
	Jan 2012	**Feb 2012**	**Mar 2012**	**Apr 2012**	**May 2012**	**Jun 2012**	**Jul 2012**	**Aug 2012**	**Sep 2012**	**Oct 2012**	**Nov 2012**	**Dec 2012**	**Total 2012**
Coronary angiography	729	680	689	651	636	532	439	385	514	290	661	680	6736
Emergent PCI	70	46	77	66	59	55	46	53	52	65	86	89	764
Elective PCI	131	118	140	133	94	107	110	97	94	132	115	100	1395
Total PCI	201	164	217	199	153	162	156	150	146	197	201	189	2159

4.2. Measure

The project team determines the metrics to measure existing process. The metrics to be chosen for a Six Sigma study are:

1. Total number of coronary stent insertions performed in the unit
2. Number of complications

Data were collected daily by the project team for a period of 24-months. In this period, a total of 3975 coronary stent insertions were performed. Average number of insertions performed per day and month in 2011 were calculated to be 5.04 and 151.33, respectively. Likewise, for 2012 they were found to be 5.99 and 179.92, respectively. Overall, they were determined to be 5.52 and 165.63, respectively. Complications were noted as they occurred. The project team identified thirteen types of occurring complications and classified them as how soon they occur, namely acute, sub-acute or chronic (Table 3). Factors and root causes of these complications are tabulated by type (Table 4). Cumulative number and frequency of each complication for 24-months is given in Table 5.

Table 3. Complication types

	Complication	Acute	Sub-acute	Chronic
Type I	Skin injury from radiation	X		
Type II	A high lifetime risk from X-ray exposure.			X
Type III	Stroke which can cause paralysis and long-term disability.	X	X	
Type IV	Emergent surgery to reopen the coronary artery.	X		
Type V	Heart attack by tear or perforation of coronary artery or bleeding.	X		
Type VI	Heart attack by adverse reaction to contrast drug.	X		
Type VII	Arrhythmia	X	X	
Type VIII	Minor allergic reactions to dye.	X	X	
Type IX	Loss of kidney function due to dye.		X	
Type X	Damage to blood vessels at groin puncture site.	X	X	
Type XI	Sudden closing of stent within the first month due to blood-thinning tablets.		X	
Type XII	Major bruising or swelling at groin puncture site.	X	X	
Type XIII	Restenosis		X	X

4.3. Analyse Phase

The project team analysed the occurrence probability of each complication (Table 5) and related them with the factors on Table 4. The data reveal that Type VIII, XII, XIII and XI were the four most frequently complications occurring in emergent PCIs, whereas Type VIII and XIII were determined to be frequently experienced in elective PCIs. In either case, Type I and II were rarely observed (Table 5).

Then, they classified these factors as "vital few" and "trivial many" according to how frequent they caused the complications. The "vital few" factors, i.e. the factors that had the most impact on the success of stent insertion were determined to be:

1. Presence of previous bypass surgery or PCI
2. Experience of the staff members (i.e. cardiology specialist and radiology technician)
3. Vessel quality
4. Vessel diameter
5. Image quality
6. Stent quality
7. Balloon quality

Table 4. Factors and Root Causes of Complications

Factors	Root causes	Complication Type											
		I	II	III	IV	V	VI	VII	VIII	IX	X	XI	XII	XIII
Measurement	Stage of illnesses				X	X		X						
	Vessel quality			X	X	X		X			X		X	X
	Vessel diameter					X					X		X	
	Localization/type/site of occlusion				X	X		X						X
Material	Stent quality				X	X								
	Balloon quality				X	X								
	Catheter quality			X		X					X		X	
	Guide-wire quality			X		X								
	Type of contrast drug						X		X	X				
Staff	Supervision			X		X							X	
	Experience			X		X					X	X	X	
	Training										X	X	X	X
Patient	Presence of comorbid diseases			X		X		X		X				
	Myocardial performance							X		X				
	Patient's health condition			X	X	X	X	X		X	X		X	X
	Presence of previous bypass surgery or PCI				X			X						X
Equipment	Radioactivity level	X	X											
	Rotation of angiography machine's table					X	X							
	Angling of angiography machine's table					X	X							
	Image quality					X	X							
Technique	Insertion site (arm, groin or wrist)										X		X	
	Direct stenting or stenting after balloon angioplasty or balloon angioplasty after stenting				X	X		X						X

The analysis also showed that the "trivial many" factors were training of the staff members, supervision, comorbid diseases, patient's general health condition, stage of the illness, catheter quality, guide-wire quality, type of contrast drug, rotation, angling, radioactivity level, insertion site (arm, groin or wrist), direct insertion of stent, stenting after balloon angioplasty and balloon angiography

after stenting. These factors had lower impact on the success of coronary stent insertion. Therefore, the project team focused on the "vital few" factors to manage the process.

The project team calculated from the formula in the Appendix the current Defects per One Million Opportunities (DPMO) and sigma levels for each complication type occurring in Elective PCI and Emergent PCI separately (Table 5).

The highest sigma levels were obtained for Type I for both PCI conditions. The lowest sigma levels were found to be of Type VIII for both PCI conditions. Having sigma levels lower than 4.00, the alerting complications for Elective PCI were Type XIII, XII, XI, X, IX, VIII, VII, VI and V. Likewise, they were found to be Type Type XIII, XII, XI, X, IX, VIII, VII, VI, V, IV and III for Emergent PCI. These are the complications whose rates need to be significantly reduced.

Table 5. Cumulative frequency, DPMO and Sigma Levels per Type

Complication Type	Emergent PCI	DPMO (Emergent PCI)	Sigma Level (Emergent PCI)	Elective PCI	DPMO (Elective PCI)	Sigma Level (Elective PCI)
Type I	1(0.086%)	860	4.63	1(0.035%)	350	4.89
Type II	2(0.17%)	1,700	4.43	3(0.10%)	1,000	4.59
Type III	13(1.11%)	11,110	3.79	9(0.31%)	3,100	4.24
Type IV	15(1.29%)	12,900	3.73	5(0.17%)	1,700	4.43
Type V	11(0.94%)	9,400	3.85	22(0.63%)	6,300	3.99
Type VI	2(0.17%)	1,700	4.43	22(0.77%)	7,700	3.92
Type VII	58(4.99%)	49,900	3.15	108(3.82%)	38,200	3.27
Type VIII	350(30.14%)	301,400	2.02	801(28.36%)	28,360	2,07
Type IX	22(1.89%)	18,900	3.58	28(0.99%)	9,900	3.83
Type X	20((%23.22)	232,200	2.23	125(4.42%)	44,200	3.20
Type XI	110(9.47%)	94,700	2.81	170(6.01%)	60,100	3,05
Type XII	205(17.65%)	176,500	2.43	144(5.09%)	50,900	3,14
Type XIII	347(29.8%)	298,000	2.03	544(19.26%)	192,600	2.37

4.4. Improve Phase

This phase assesses failure modes, traces root causes, generates solutions and implements best solutions.

Failure Mode and Effect Analysis

Risk assessment of the coronary stent insertion process was done by the failure mode and effect analysis (FMEA). The project team utilised FMEA to break down the process into individual steps: potential failure modes (i.e. complications), severity score, probability score, hazard score, criticality and detection, so that the staff members could look at key drivers in the process based on the past experience.

Complication trends and their consequences over a 24-month period were monitored and recorded. Complications were prioritized according to how serious their consequences were (i.e. severity score), how frequently they occurred (probability score) and how easily they could be detected. Hazard analysis was employed in order to identify failure modes and their causes and effects. The project team determined the severity of each complication and assigned scores for them. The severity of each complication was scored from 1 to 4 (Table 6).

Table 6. Severity Scores

Severity Score	**4**	**3**	**2**	**1**
Severity of Complication	Death or permanent harm	Temporary harm	Bias	No harm

For each complication type, the hazard score was calculated by multiplying the severity score with the probability score. Consequently, an FMEA table was drawn (Table 7). Among the complications, Type XIII yielded the highest hazard scores for both conditions. Type V, VI and XI were almost equally hazardous complications of Elective PCI. Type II and IV yielded the same hazard score for Emergent PCI. According to FMEA, Type I was the least hazardous complication for both conditions.

Table 7. FMEA Table

Complication Type	**Hazard Analysis**					**Decision Tree Analysis**		**Treatment**
	Severity Score	**Probability Score**		**Hazard Score**		**Critical?**	**Detectable?**	
		Emergent PCI	**Elective PCI**	**Emergent PCI**	**Elective PCI**			
Type I	2	0.00086	0.00035	0.00172	0.0007	Yes	Yes	Dressing
Type II	3	0.0017	0.0010	0.0051	0.003	Yes	Yes	Drug treatment
Type III	4	0.0111	0.0031	0.0444	0.0124	Yes	Yes	Neurological treatment and/or rehabilitation by physiotherapy
Type IV	4	0.0129	0.0017	0.0516	0.0068	Yes	Yes	Surgery
Type V	4	0.0094	0.0063	0.0376	0.0252	Yes	Yes	Surgery
Type VI	3	0.0017	0.0077	0.0051	0.0231	Yes	Yes	Drug treatment
Type VII	2	0.0499	0.0382	0.0998	0.0764	Yes	Yes	Drug treatment
Type VIII	1	0.3014	0.2836	0.3014	0.2836	No	Yes	Drug treatment
Type IX	3	0.0189	0.0099	0.0567	0.0297	Yes	Yes	Dialysis (Temporary)
Type X	3	0.2322	0.0442	0.6966	0.1326	Yes	Yes	Surgery or conservative treatment
Type XI	4	0.0947	0.0601	0.3788	0.2404	Yes	Yes	Treatment with another angioplasty, or at worse, with surgery.
Type XII	3	0.1765	0.0509	0.5295	0.1527	Yes	Yes	Surgery or conservative treatment
Type XIII	3	0.298	0.1926	0.894	0.5778	Yes	Yes	Treatment with another angioplasty, or at worse, with surgery. Use drug eluting stents to stop the artery from narrowing again.

Improvements

The project team developed preventive measures for each type of complication in order to bring the overall process under control. They implemented a corrective action plan (Table 8) to reduce and/or eliminate complications.

Table 8. Corrective Action Plan

Complication Type	Preventive Measures
Type I	-Calibrate the angiography equipment periodically. -Provide regular maintenance to the angiography equipment.
Type II	-Calibrate the angiography equipment periodically. -Provide regular maintenance to the angiography equipment. -Monitor the angiography equipment's radioactivity level (by dose measurement).
Type III	-Analyse the patients with neurological risks. -Regulate the blood-diluting drugs. -Analyse the high risk patients for stroke.
Type IV	-Use appropriate and correct stent in coronary angioplasty and PCI.
Type V	-Use appropriate and correct stent in coronary angioplasty and PCI.
Type VI	-Determine the allergic patients by diagnostic tests and give treatment with preventive drugs before the procedure.
Type VII	-Use appropriate materials. -Analyse and treat patients with rhythm disorders before the procedure.
Type VIII	-Determine allergic patients by diagnostic tests and treatment with preventive drugs before the procedure.
Type IX	-Administer the contrast drug specific to the patient. -Determine those who have kidney problems and well-hydrate them with appropriate fluids before the procedure.
Type X	-Use of appropriate and adequate materials. -Apply compress appropriately and within sufficient time on the groin.
Type XI	-Use correct, proper and adequate materials. -Provide drug treatment before procedure.
Type XII	-Use appropriate and adequate materials. -Apply compress appropriately and within sufficient time on the groin.
Type XIII	-Determine the stent type correctly. -Use a stent with appropriate diameter and length to the lesion.

During the angiography procedure, some patients develop an allergic reaction to the contrast drug used. In addition, since angiography involves exposure to radiation through the X-rays used in the procedure, some patients experience skin allergies. To monitor exposure to radiation and minimize the harm, the staff members and the patients start wearing radiation dosimeters that detect exposure and lead aprons that shield the body, respectively.

Patients with chronic renal disease suffer further damage to their kidneys from the contrast drug used in a renal angiogram. The improvements such as carefully taking patient history, performing diagnostic tests before surgery, and well-hydrating the patients with this disease before the procedure, are implemented.

Patients who have blood-clotting problems, have a known allergy to contrast drug, or are allergic to iodine are tested and identified as unsuitable candidates for an angiogram.

From the data, the project team determined that the ionic contrast drug being used had a strong impact in causing complications. They advise the use of a non-ionic contrast drug although it is more expensive but less toxic than the ionic one.

The stent selection bias of cardiology specialists and low image quality are overcome by purchasing equipment with higher technology. The new equipment automatically assigns the stent type and number with respect to the diameter of the diseased vessel under study.

The team also determined that inexperienced radiology technicians had caused longer PCI times and more exposure to radiation. They are technically trained on the angiography equipment. The equipment are properly calibrated prior to and during usage to ensure proper calibration levels and image quality, and scheduled for regular maintenance.

4.5. Control Phase

This phase begins once the improvements in the overall workflow have been established and appeared to be working. It is ensured that the standardised changes are institutionalised and that the staff members establish a clear understanding of improvements and focus on CTQ factors. The staff members continue to collect data and monitor the process. For this purpose, they use Minitab to calculate the mean number of daily and monthly complications, and instant sigma level of the process. They daily plot Control Charts to detect the variability in the process and check if the process is under control.

This phase is the most critical one for establishing a long-term continuation of improvement and a differentiating element for the implemented Six Sigma strategies. Finally, the benefits of the improved system and the new safety culture are institutionalized in the cardiology unit.

5. Conclusion

This study demonstrates how Six Sigma principles can be applied to coronary stent insertion process. It supports the need to apply the DMAIC improvement cycle into cardiology units. The proposed application involves measuring, recording, comparing and reporting data on daily basis. This enables the staff members to continuously monitor and rethink about the process for continuous improvement. Improvements have positive impacts on surgical safety, cost and patients' quality of life.

The most common and difficult three complications that will be least improved by implementing Six Sigma are determined by the team to be:

1. The occurrence of major adverse cardiac/coronary events during the procedure,
2. The occurrence of restenosis at six months,
3. The treatment of long lesions in thin vessels.

As a limitation, these are thought to negatively affect the sigma level and lower the acceptance of Six Sigma in cardiology units.

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Appendix

A Six Sigma process produces 3.4 defective parts per million opportunities (DPMO). Normal distribution underlies Six Sigma's statistical assumptions. An empirically-based 1.5 sigma shift is introduced into the calculation. To calculate the DPMO, two distinct datasets are required:

A = Total number of coronary stent insertions performed.

B = Total number of complications occurred.

The DPMO formula is:

DPMO = B x 1,000,000/A

The higher level of sigma after the initiation of Six Sigma indicates a lower rate of complications and a more efficient process.