Lean Six Sigma Approach to Implement a Femur Fracture Care Pathway at "San Giovanni di Dio e Ruggi d'Aragona" University Hospital

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Abstract. Timeliness in the treatment of fracture of the femur, through surgery, is crucial in the elderly patient as it reduces the risk of mortality and disability. Here we propose a Lean Six Sigma (LSS) approach to reduce the preoperative length of stay for patients with femur fracture. Through the LSS, a tailored Diagnostic Therapeutic Assistance Path (DTAP) for these has been implemented and monitored over time. In particular, through the analysis, based on the application of the DMAIC cycle conducted on data extrapolated from the information system of the "San Giovanni di Dio e Ruggi d'Aragona" University Hospital of Salerno, the new DTAP was designed and implemented. After the introduction of the DTAP, a significant reduction in the average length of hospital stay was observed, with a preoperative length of stay within 48 h in 65% cases (compared to the previous 9%). In particular, the most significant reduction (over 55%) is obtained for patients aged over 65 years old. Such a result reflects not only the improvement in the care process but it is also compliant with the guidelines of the Italian Ministry of Health, as reported in the New Guarantee System for monitoring the quality of care.

Keywords: Lean Six Sigma · Care pathway · DMAIC · Femur fracture

1 Introduction

The fracture in the neck of the femur in people over 65 years old has to be considered a very serious event, given that scientific studies attest that a person's survival decreases drastically after such a trauma and that the mortality rate per year ranges from 10 to 36 percent according to the literature [1–5]. Furthermore, about half of these patients are unable to regain their ability to live independently: the increase in preoperative waiting times is correlated with the increase in the onset of complications and especially in the

medium-term mortality (180 days). In this direction, optimization of the preoperative phase would allow patients to be operated on quickly and therefore be discharged faster.

Among different approaches available in literature to improve the healthcare organizations [6–9], elaborate biomedical data [10–14] and optimize the care processes [15–17], the interest towards Lean Six Sigma (LSS) has grown since the methodological characteristics of both Lean and Six Sigma are set, aimed at guaranteeing a series of advantages and operational potentialities that are strengthened and increased when the two approaches are "integrated" [18–22]. While Lean focuses primarily on the problem of waste abatement "on the one hand", on the other, Six Sigma allows us to focus attention - tackling it in a rigorous and structured way - on the "variability" that very often characterizes the systems for producing goods or supplying services [23]. Combining the characteristics of Six Sigma and Lean in a single approach, this methodology focuses decisively on the needs and then proceeds to identify the key features defining the quality of the process analyzed [21, 24, 25].

Cost reduction plays an increasingly important role in the healthcare context and it is proven that the Lean Six Sigma approach allows, by implementing a new tailored Diagnostic Therapeutic Assistance Path (DTAP), economic savings [26].

Therefore, there are several applications in the literature of the Lean Six Sigma approach in healthcare. For example, the study of a DTAP to improve the efficiency and effectiveness of the treatment process for knee surgery [27] or previous studies relating to the intervention of the femur. The study conducted at the A.O.R.N. "A. Cardarelli" in Naples [26] can be a valid tool for inter-regional comparison. It is important to underline that the reference sample and the observation time are wider than those of the previous study and that the initial conditions are strongly different.

LSS proved to be a promising approach also for the improvement of femur fracture care pathway [28, 29]. In this study, we applied this methodology to implement a specific care pathway for patients with femur fracture in order to reduce their preoperative length of stay.

The results obtained made the "San Giovanni di Dio e Ruggi d'Aragona" University Hospital of Salerno, objects of this study, a regional and national excellence, according to AGENAS data. The "Femur: zero wait" project continues to improve the numbers presented here, recalling 6.3% of all femur fractures in the region to the hospital.

2 Methods

The study was conducted at the Complex Operative Unit (C.O.U.) of Orthopedic and Traumatology at the "San Giovanni di Dio e Ruggi d'Aragona" University Hospital of Salerno (Italy). The "Femur: zero wait" project was born in 2016. Two different groups of patients operated on due to a fracture to the femur were studied during 12 months before and 24 months after the adoption of the new DTAP. The first sample is made up of 559 patients while the second was made up of 1139 patients.

For the construction of the new DTAP, according to the LSS approach, the cycle "Define, measure, analyze, improve and control" (DMAIC) has been adopted to identify critical issues for quality and possible solutions to improve the care process.

2.1   Data Collection and Analysis

Data were collected both from the digital information system (QUANI SDO) of the hospital. For each patient included in the study, the following anamnestic, demographic and clinical variables were collected:

- gender (male/female);
- age (<60/60–75/>75);
- presence of complications, like cardiovascular diseases or diabetes, (yes/no);
- date of admission;
- date of surgery; and
- date of discharge.

The statistical data analysis was performed using IBM SPSS Statistics 20 software.

2.2   DMAIC Cycle

Each phase of the DMAIC cycle is discussed in the following.

Define. In this phase, the problem is identified, that is "reduction of the preoperative duration of the hospital stay for patients undergoing surgery for fracture of the femur". Having taken note of all the complications that the delay in the operative response may entail, the project that uses the number of days of hospitalization as a quality criterion is approved. A project plan is also developed together with a Gantt chart representing the cycle implementation dateline (see Fig. 1).
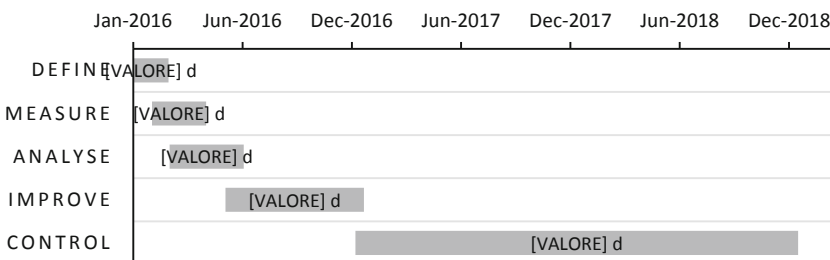

Fig. 1. Gantt diagram.

Measure. After defining the project and its objective, we proceed to the observation of the process. The execution diagram in Fig. 2 shows the retrospective measurement of the preoperative length of stay in the period from 01/01/2015 to 31/12/2015 on a sample of 559 patients with fractures of the femur.
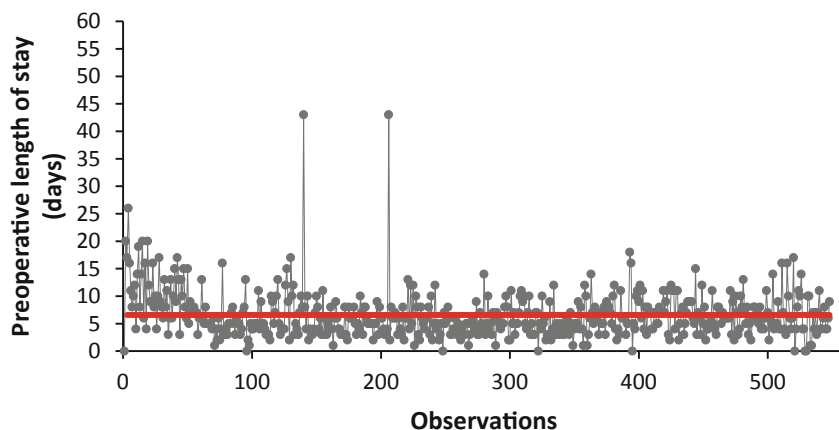
Fig. 2. Run chart of preoperative length of stay for patients undergoing femur fracture surgery before improvement. Average value of 6.57 is reported as a red line.

In the initial state, a patient waits an average of 6.57 days (red line) with a standard deviation of 4.33, before being operated on. The result therefore justifies the intervention on DTAP, subject of this study, to reach the optimal value of 2 days.

Through the Table (Table 1) the results obtained on the different sub-classes of the sample are shown in detail.

Table 1. Results of initial observation.

Variable		Preoperative length of stay before improvement (Days: mean $\pm$ SD)
All patients		6.57 ± 4.33
Gender	M	6.94 ± 5.47
	F	6.39 ± 3.68
Age	≥ 65	6.60 ± 4.30
	<65	6.23 ± 4.56
Complications	YES	5.06 ± 2.63
	NO	6.69 ± 4.42

Analyze. After the measure phase, the causes that lead a high result compared to the protocol have been identified. Main causes for prolonged preoperative length of stay have been identified through interviews with healthcare staff and then brainstorming activities have been carried out to identify possible solutions. Among others, higher risk of nosocomial infections and not standardized procedures to send the patients to surgery and then start the rehabilitation have been recognized as main causes of the problem.

Improve. Corrective actions have been implemented through the development of a specific Diagnostic and Care Pathways (DTAP) for patients with femur fracture. The DTAP aims to operate patients within 24–48 h from admission in order to start the rehabilitation faster, avoid risk of infections related to prolonged preoperative length of stay and begin the discharge procedures promptly.

The new DTAP consists of the following phases:

1. Pre-operative phase:

   – Assignment of the yellow code in the triage phase in the emergency room to make the patient lead quickly in the ward;
   – Timely multi-professional classification;
   – Adequate drug therapy: such as thrombosis prophylaxis and electrolyte balance;
   – Prevention of pressure injuries.

2. Surgical intervention:

   – Maximum 48 h of waiting;
   – Technique aimed at rapid mobilization.

3. Post-operative phase

   – Early mobilization in the first post-operative day by the support staff;
   – Multidisciplinary evaluation and start of the rehabilitation continuity protocol within 48 h after the intervention;
   – Health education and secondary fracture therapy: fall prevention and osteoporosis therapy.

Control. This phase consists of monitoring the optimized process by measuring performance up to two years after the implementation of the DTAP for fracture of the femur. The preoperative length of stay of 1139 patients were analyzed, demonstrating the effectiveness of the new DTAP, reducing the number of days to on average 2.93 with a standard deviation of 3.31. All results are show in the Table below (Table 2):

Table 2. Results after the implementation of the DTAP.

Variable		Preoperative length of stay before improvement (Days: mean ± SD)
All patients		2.93 ± 3.31
Gender	M	3.40 ± 3.37
	F	2.77 ± 3.27
Age	≥ 65	2.87 ± 3.30
	<65	4.01 ± 3.31
Complications	YES	2.71 ± 2.82
	NO	2.98 ± 3.41

3   Results and Discussion

As control of the process performances, a run chart of preoperative length of stay over two years after the implementation of the DTAP has been carried out (see Fig. 3).
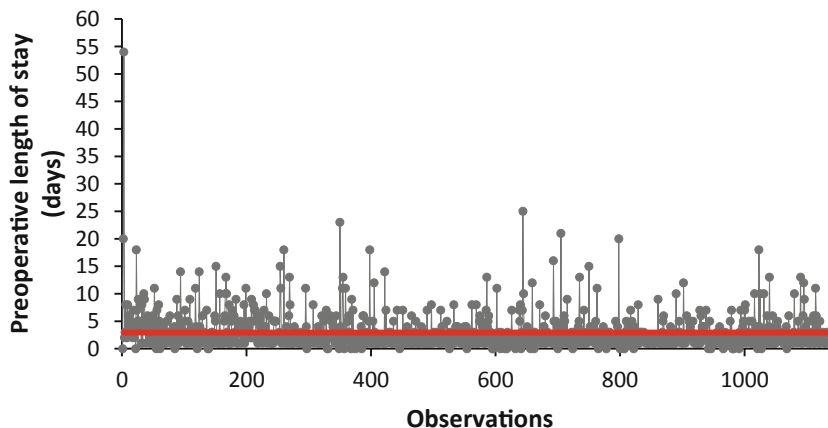

Fig. 3. Run chart of preoperative length of stay for patients undergoing femur fracture surgery after improvement. Average value of 2.93 is reported as a red line.

By comparing Fig. 2 and Fig. 3 a reduction in the average preoperative length of stay is showed (red line). The results of statistical comparison of the performances before and after the improvement are reported in the following Table 3.

Table 3. Results of statistical comparison on the length of stay related to variables.

Variable		p-value
All patients		<0.001
Gender	M	<0.001
	F	<0.001
Age	≥ 65	<0.001
	<65	0.005
Complications	YES	<0.001
	NO	<0.001

Considerable improvements have been achieved thanks to the implementation of the DTAP for femur fracture. The benefits of the Lean Six Sigma approach is demonstrable and visible in all sub-classes. The average number of days of preoperative length of stay of patients underwent a reduction of over 55% and the most significant reduction (over 56%) is obtained precisely for the class of patients of

interest, with aged >65 years. The statistically significant difference is confirmed by the obtained p-value in the groups, which are all below 0.005 (95% confidence interval used). The following Table 4 summarizes the percentage of over 65 patients with femur fracture operated on within 48 h.

Table 4. Percentage of over 65 patients undergoing femur fracture surgery within 48 h from admission.

Before improvement	After improvement	Recommended percentage
9% (49 out of 559)	64% (734 out of 1139)	>60% (from national guidelines)

The Italian Ministry of Health is introducing a new system, the so called New Guarantee System (NSG) [30], which includes a set of indicators to assess the quality and timeliness of care processes. The NSG also analyzes the ability of healthcare facilities to intervene surgically within 48 h from arrival in the hospital with femur fracture for patients over the age of 65, and set the threshold to >60% patients undergoing surgery within 48 h. Our results demonstrate that the implemented care pathway ensure the compliance to this new guarantee system with a 64% of patients operated on within 48 h from admission.

4   Conclusion

In conclusion, in this work it has been demonstrated, through the applications on real case studies, how the adoption of an LSS approach can be of great benefit for the efficiency of the care and management of patients with femur fracture. This approach would in fact make it possible to considerably reduce patients' preoperative length of stay and improve the quality of the care process. Early mobilization is also a key aspect and a delay could nullify the benefits of an intervention in less than 48 h. The implementation of the DTAP for femur fracture allows the provision of higher quality services by the hospital structure, guaranteeing a better and leaner path for the patients undergoing surgery of the femur.

Limitations of the study is that the work is focused on the optimization of the only preoperative phase without assessing the impact on the postoperative phase, which is important in the overall care process. Indeed, it also affects the overall hospitalization time and impact on the management costs of the sick quality of life. These aspects are still under evaluations and will be subject to further improvements.

Moreover, future perspectives will include a further innovative model: the orthogeriatrics, where elderly patients with femur fracture will also be followed by an internist doctor, the orthologist, who will help to consolidate the quality levels of care with a further improvement in outcomes.

Conflict of Interest Statement. The authors have no conflict of interest to declare.

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