



Continuous improvement process: ortho-geriatric co-management of proximal femoral fractures

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Abstract

Objective The objective of the current study was to evaluate the effect of a quality management system on treatment and care delivery of proximal femoral fractures. Specifically, our hypothesis was that the “plan–do–check–act (PDCA)” philosophy of the ISO 9001 quality management system results in a continuous improvement process.

Methods 1015 proximal femoral fractures were prospectively included into a hip fracture database over a 5-year period, after a restructuring process with implementation of clinical pathways and standard operation procedures. A close and structured ortho-geriatric co-management (certified ortho-geriatric center) was the basis for treatment. ISO 9001 certification was granted for the first time in 2012. Procedural and patient outcome parameters were analyzed by year and evaluated statistically using SPSS 25.0.

Results In both categories (procedural and outcome) significant changes could be detected during the 5-year period, e.g., significant reduction of time to surgery for the first 2 years, improvement in discharge management, and reduction of surgical complications. However, no significant changes could be demonstrated for mortality or internal complications such as pneumonia, urinary tract infections, or postoperative delirium. However, the incidence of the latter was already on a very low level at the onset of the quality improvement process.

Conclusion We could show a relevant and continuous improvement of several quality indicators during a 5-year period after implementation of a quality management system based on the PDCA philosophy for the treatment of proximal femoral fractures in elderly patients. However, other parameters (internal complications, cost-effectiveness, etc.) need our close attention in the future.

Keywords Proximal femoral fracture · Continuous improvement process · PDCA cycle · Quality management

Background

Hip fractures are among the most challenging injuries in elderly people. Even if epidemiological data vary between countries, it is estimated that hip fractures will affect around 18% of all women and 6% of all men globally. More than 400,000 women and 100,000 men will be affected within the European Union every year [1]. Although the age-standardized incidence has been gradually decreasing in many

countries, the overall number of hip fractures is expected to increase from 1.26 million in 1990 to 4.5 million by the year 2050 [2].

A high excess mortality is well described after hip fracture [3], which persists even 10 years after the fracture has occurred [4]. Moreover, patients with a proximal femur fracture experience a clinically important decline in functional status with considerable loss in quality of life [5]. Within 1 year after proximal femoral fracture (PFF), more than 20% of the patients will have to be institutionalized because of the fracture [6].

Organizing and standardizing the care process for these patients, with a focus on quality and efficiency, is one of the priorities for the next decade for health-care providers, health-care managers, and policymakers [7, 8].

One option to (re)organize the care process is the implementation of a quality management system (e.g., ISO 9001,

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Table 1 Key elements of the implementation of a quality management system (ISO 9001)

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1. Team building (foundation of a center for geriatric trauma)
 - (a) Steering committee (vision and mission)
 - (b) Quality circle
 - (c) Care team
 - (i) Interdisciplinary ward rounds
 - (ii) Case conferences and team meetings
 - (d) Geriatric trauma network
 - (e) Communication matrix
 2. Definition of key processes
 - (a) Inclusion criteria
 - (b) Clinical pathways
 - (i) Emergency management
 - (ii) Inpatient treatment
 1. Interdisciplinary and interprofessional treatment
 2. Early geriatric rehabilitation program
 - (iii) Discharge management
 - (iv) Standard operating procedures (SOPs)

(Evidence-based treatment: standardized surgical treatment, expert standards for nursing, anticoagulation, pain management, osteoporosis, fall prevention, malnutrition, standardized protocols, physical therapy)
 3. Internal audits
 - (a) Compliance with legal requirements and internal guidelines
 4. Document control
 - (a) Comprehensive manual
 5. Non-conformities
 - (a) Definition, collection and analysis of process and outcome parameters
 - (b) Mortality and morbidity conferences
 - (c) Critical incidence reporting system (CIRS)
 6. Planning and goals
-

Certification was granted for the first time in 2012; there were annual follow-up audits. Re-certification was issued in 2015

European Foundation for Quality Management (EFQM), Malcolm Baldrige National Quality Award [9–11].

In a recent study, we showed that the implementation of clinical pathways as part of a quality management system leads to a relevant quality improvement [3]. In a prospective clinical trial using a pre-during-post design, we demonstrated that quality indicators improved significantly: processes improved [e.g., time to surgery, number of patients included in an early geriatric rehabilitation program (EGRP)], general complications decreased, and less patients had to be institutionalized. At the same time, the recorded number of postoperative delirium and acquired decubiti increased due to a better awareness and improved documentation [12].

These efforts were expanded to meet the criteria of the ISO 9001:2008 system. Table 1 summarizes the key elements leading to the certification of the geriatric trauma center in 2012. The ISO 9000 family of quality management standards is designed to help organizations ensure that they meet the needs of customers and other stakeholders while meeting statutory and regulatory requirements related to a product or service [13].

One core element is the PDCA (plan–do–check–act) or Deming cycle, an iterative four-step management method used for the control and continuous improvement of processes (CIP), service and care delivery [14]. These efforts can seek “incremental” improvement over time or “break-through” improvement all at once. Delivery (customer valued) processes are constantly evaluated and improved in the light of their efficiency, effectiveness and flexibility.

The quality management system ISO 9001 has been shown to improve care delivery in several studies [1, 2]. However, no clinical trials have been published to analyze the effect of this complex and costly intervention in hip fracture management. Therefore, the overall goal of this study was to evaluate the outcome of the implementation of a quality management system, namely the ISO 9001, with particular focus on the continuous improvement process in hip fracture management.

Patients and methods

The present study was designed as a single-center cohort study and conducted in a charitable 1031 bed, academic teaching hospital with approximately 44,000 admissions annually and roughly 250 proximal femoral fractures.

With the decision to implement a quality management system for the treatment of elderly patients with proximal femoral fractures, it was decided to evaluate its effects prospectively.

Routine data were collected along the clinical pathways and recorded in a clinical database.

Approval by the institutional review board (IRB) was obtained prior to the study and informed consent was obtained from all individual participants included in the study.

Inclusion–exclusion criteria

All patients consecutively admitted for PFF were considered for inclusion based on the following criteria: (1) closed fracture of the proximal femur: femoral neck fracture, per- and intertrochanteric fractures (according to the AO-classification 31 A1–3 and B); (2) age above 80 years, or age above 65 years with relevant co-morbidities¹ (3) eligible for surgical intervention.

Exclusion criteria were: pathological fracture (except osteoporotic), peri-prosthetic fracture, isolated fractures of the greater trochanter and multiply injured patients.

Intervention

Implementation of a quality management system and certification according to the ISO 9001 system. Key elements of this complex intervention are summarized in Table 1.

One core element of the quality management system is the PDCA cycle:

P (Plan): clinical pathways were developed using a multidisciplinary approach during several workshops (quality circles) and consented by a steering committee.

The following sub-processes were defined and standardized: (1) emergency treatment, (2) surgical treatment, (3) intensive care, (4) postoperative care, (5) early geriatric rehabilitation [15].²

Standard Operating Procedures (SOPs) were established for: activating care, bridging of anticoagulants, decubitus, delirium, nutrition management, osteoporosis, pain management.

D (Do): care pathways and SOPs were implemented during the first year (2012) and ISO 9001:2008 certification was granted.

C (Check): clinical care pathways were controlled using checklists, and quality indicators were collected (Table 2) and assessed by the steering committee.

A (Act): based on the results of the quality indicators/outcome parameters, quality circles were engaged with improving the care pathways, structural and staff issues.

Major interventions during the 5-year period included: implementation of an interdisciplinary ward, increase of

¹ Diabetes mellitus with end-organ damage, liver disease, moderate to severe, malignancy, moderate to severe chronic kidney disease, chronic heart failure, myocardial infarction, COPD, dementia, hemiplegia. Corresponding to a Charleston Comorbidity Index of 4 and above and an estimated 10-year survival of less than 50%, the geriatrician responsible decided upon inclusion and exclusion.

² Early geriatric rehabilitation program: geriatric and social assessment, weekly team meeting, activating care of specially trained nursing staff, 20 units of physical and occupational therapy during a 14-day period.

Table 2 Quality indicators

Perioperative mortality
Local infection
Hematoma
Seroma
Pneumonia
Leucocyturia (urinary tract infection)
Elevation in creatinine
Decubitus
Postoperative delirium
Early geriatric rehabilitation program
Start of early geriatric rehabilitation program
Discharge
Length of stay
Time to surgery
Time to first contact to geriatrician
Active mobilization during the first 24 h
Time to physical therapy

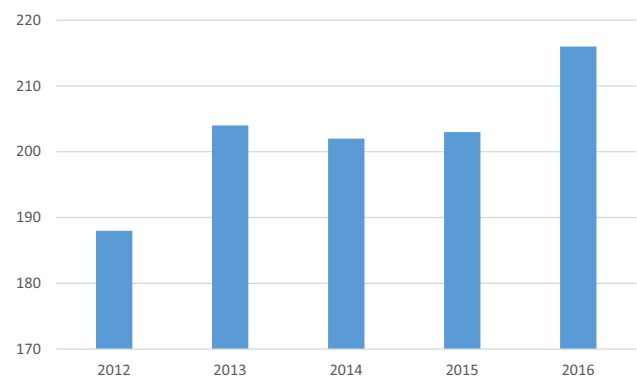


Fig. 1 Patients included into the study between 2012 and 2016. A significantly increasing number of patients were included every year considering the complete period (Kruskal–Wallis test, $p < 0.001$)

geriatric nursing competence in the care team, and increase in the capacity for early geriatric rehabilitation (physical therapy, occupational therapy). Expansion of cooperation (endocrinology/osteology; nutrition specialists, dentist).

Patients were included after radiological confirmation of the diagnosis of a proximal femoral fracture. Data were collected during acute hospital treatment (17 ± 8 days), and a follow-up of 30 ± 9 days (mean \pm SD). Quality indicators (Table 2) were recorded using checklists and documented in a hip fracture database.

A total of 1015 patients were included in the study during the 5-year period. Analysis was performed by year. Figure 1 shows the distribution of the patients. Demographic data are displayed in Table 3.

Table 3 Demographic data and quality indicators during the 5-year period

	2012	2013	2014	2015	2016	Significance (<i>p</i> value)
<i>n</i>	188	204	202	203	216	
Female (%)	78.2	69.6	73.3	75.1	69.4	0.23**
Age (mean)	83.7	82.8	83.9	82.8	83.7	0.462**
Full weight bearing (%)	90.4	95.1	97.5	99.0		<0.001*
Mortality (%)	5.9	3.9	5.9	4.4	7.0	0.632*
Revisions (%)	3.7	2.9	0.5	1.5	0.9	0.104
Failure of fixation (%)	3.7	1.5	1.0	0.0		<0.001*
Wound site infection (%)	1.1	1.0	2.0	1.5	0.9	0.868
Pneumonia (%)	8.0	10.8	12.9	10.7	9.7	0.616
UTIs* ^a (%)	11.2	25.5	15.3			0.033* ^b
Increase in creatinine	16.0	20.1	16.3			0.353**
Decubitus (acq.)	1.1	3.4	1.5			0.201**
Delirium (%)	10.1	14.2	5.0	8.8	22.7	<0.001* ^c
Time to surgery (h)	18.8	17.25	21.55	22.47	25.14	0.004 ^d
Time to geriatric consultation (h)	81	74	63	41	64	<0.001*
Time to physical therapy (h)	59	51	57	54	57	0.186
Mobilization <24 h (%)	64	60	66	74	71	0.026*
Length of stay (days)	16.1	16.7	16.6	16.9	18.0	0.228
Full weight bearing	90.4	95.1	97.5	99.0		<0.001*
EGRP ^e	52	68	66	66	75	<0.001* ^f
Start EGRP (h)	33	34.6	33.0	28.8	25.1	<0.001* ^g
Discharge to home	9.6	3.9	11.4	10.2	14.8	<0.001*
Discharge to nursing home (as before)	5.3	15.7	17.3	20.5	15.3	0.646*
Discharge to nursing home (new, permanent)	0.5	1.5	0.0	0.0	1.4	0.173*
Discharge to short-term care	2.7	5.4	6.9	4.4	7.4	0.644*
Discharge to geriatric rehabilitation	42.6	56.9	44.6	48.3	42.1	0.017
Discharge to orthopedic rehabilitation	5.3	7.4	3.5	3.9	3.2	0.355
In-hospital transfer	6.9	5.9	10.4	8.3	8.3	0.542

*Welch test, Levene > 0.05

**Kuskal–Wallis

^aUrinary tract infection (leucocyturia)^bPost hoc Games–Howell 2012 vs. 1214, *p* = 0.033^cPost hoc Games–Howell 12 vs. 16, *p* = 0.004; 13 vs. 14, *p* = 0.013, 14 vs. 16, *p* < 0.001; 15 vs. 16 *p* < 0.001^dPost hoc Bonferroni 12 vs. 16, *p* = 0.051; 13 vs. 16, *p* = 0.004^eEarly geriatric rehabilitation program^fPost hoc Games–Howell 12 vs. 13, 14, 15, 16, *p* < 0.05^gPost hoc Games–Howell 12 vs. 16, *p* < 0.001; 13 vs. 16 *p* < 0.001

Statistical analysis

Statistical analysis was performed using SPSS 25.0. The different groups (years) were tested for homogeneity with respect to age, age distribution and sex using Pearson's Chi-squared test and Kruskal–Wallis test. Missing values were replaced using the SPSS algorithm.

Parametric and nonparametric statistical tests were used to analyze the test variables. First, they were tested for homoscedasticity using Levene's statistics. If homoscedasticity could be assumed throughout the groups, analysis of variance (ANOVA) was used to test for significant

differences between the groups. In case of heteroscedasticity, a robust test (Welch test) was used. Where necessary, Bonferroni or Games–Howell post hoc tests were used. Statistical significance was assumed with *p* < 0.05.

Results

The mean age of the patients was 83.3 (± 7.7) years. As expected, more female (73%) than male (27%) patients were included. The five cohorts (2012–2016) were homogeneous

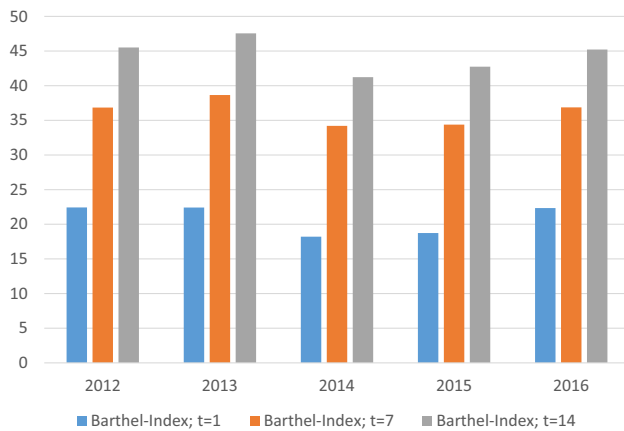


Fig. 2 Barthel Activities of Daily Living (ADL) Index improved significantly between the 1st and 14th postoperative day. However, no change was detected over the 5-year period on comparing the 1st, 7th and 14th day

in terms of age, age distribution (Kruskal–Wallis test, $p=0.462$) and sex (Pearson’s Chi square test $p=0.23$).

Outcome parameters were divided into procedural parameters and patient outcome parameters.

In both categories, significant changes could be detected during the 5-year period.

Concerning the procedural parameters, a significant decrease of the “time to surgery” could be achieved for the first 2 years, followed by a sudden significant increase in the year 2016 (Table 3). In this respect, it is important to mention that OR capacity was reduced by 10% in 2016 due to lack of staff. While time to the “first contact with a geriatrician” decreased continuously between 2012 and 2016 (Welch test, $p < 0.001$), time to the “first contact with a physiotherapist” was relatively stable (ANOVA, $p=0.186$). However, it was possible to mobilize significantly more patients during the first 24 h (Welch test, $p=0.026$). The number of patients included in an “early geriatric rehabilitation program (EGRP)” increased significantly from 52 to 75% (Welch test, $p < 0.001$). An increasing number of patients could be discharged home (Welch test, $p < 0.001$) or to a geriatric rehabilitation program (ANOVA, $p=0.014$) over the 5-year period. No significant changes in length of stay were detected ($p=0.228$). The results are summarized in Table 3.

Patient outcome parameters showed a significant decrease of implant failure during the 5-year period (Welch test, $p < 0.001$) and a trend toward a lower revisions rate (mean 1.9%), ANOVA, $p=0.104$.

Interestingly, a continuous increase of detected postoperative delirium was documented (Welch test, $p < 0.001$).

No significant differences were detected for mortality (during the observation period of 30 days), local

complications (infection) and internal complications (e.g., renal failure, pneumonia or decubitus acquired during therapy).

Mean Barthel’s Activities of Daily Living (ADL) Index increased significantly during the first 14 days postoperatively (Fig. 2), However, no significant change of the levels achieved was detected over the 5-year period.

Table 3 shows the results of the outcome parameters, including statistical analysis.

Discussion

With implementation of a quality management system in 2012, quality indicators (Table 2) were recorded between 2012 and 2016. The data presented show that procedural parameters and outcome parameters improved over the 5-year period in small, but significant steps according to the ISO philosophy “continuous improvement process”. This was achieved by implementing the PDCA cycle [16].

“Time to surgery”, an important quality indicator [17, 18], improved during the first 2 years, but deteriorated during the following 3 years. A likely explanation might be the reduction of OR capacity in 2015/2016, and the overall increasing number of anticoagulated patients [19]. Especially the increasing prevalence of new oral anticoagulants (NOACs), where no clear recommendation on waiting time before surgery is available, is an important issue. Time to surgery has been shown to be an important predictor for 30 days postoperative mortality in several studies [17, 18]. Although the exact cutoff is still unknown, a recent large population-based study in Canada (retrospective cohort study with 72 hospitals and 42,230 patients) suggested that a wait time of 24 h may represent a threshold defining higher risk [18]. Another study showed that coordinated, region-wide efforts to improve timeliness of hip fracture surgery successfully reduced time to surgery and appeared to reduce the length of stay and adjusted mortality in hospital and at 1 year [20]. A reduction of time to surgery with a coordinated quality management system was described by Saez-Lopez et al. for the Spanish system [21, 22], Lau et al. in Hong-Kong [23], and Kalmet et al. for the Dutch system [24]. This negative development during the latter 3 years was addressed by several quality circles with OR-management to prioritize PFF treatment. Together with the Department of Anesthesiology, the SOP for the management of anticoagulated patients was revised. This led again to a significant decrease in time to surgery in 2017 (-2 h, t test; $p < 0.001^3$).

In our cohort, “length of stay” was constant over the 5-year period (ANOVA, $p=228$). This is in contrast to the

³ Data not presented.

results reported by Burgers et al. [25], Fliweert et al. [26] and Kalmet et al. (Dutch system), or Koval et al. [27, 28] (US system), as well as Soong et al. [29] (Canadian System), who documented a significant decrease of “length of stay” with the implementation of clinical pathways for hip fracture management. However, reduction of length of stay was not our primary intention. Moreover, these studies are difficult to compare, since the national health systems differ substantially.

Our result show that an increasing number of patients were included in an “early geriatric rehabilitation program” (52% in 2012 up to 75% in 2016, Welch test, $p < 0.001$), providing more access to physical and occupational therapy.

Other parameters that improved similarly were: start of EGRP (Welch test, $p < 0.001$), mobilization within 24 h of surgery (Welch test, $p = 0.026$), and time to geriatric consultation (< 0.001).

However, these quality indicators did not improve continuously, but showed “stepwise” improvement from 2012 to 2013 and again in 2016 (Table 3). Increase in the number of patients included in the EGRP, a personnel-intensive intervention, was only possible with an increase in the staff resources. This has to be taken into account, when considering the overall costs. In our setting, the following costs were incurred for the expansion of the EGRP in 2016 (mainly personnel costs): Par-time positions for: geriatric trainee, physical and occupational therapist, and case manager; comprising a total of approximately 110.000 €. These costs are refinanced by an additional receipt of approximately 4.600 € per case. Currently, the ProFinD2 study evaluates the cost-effectiveness of this program [30]. To date, this program is relatively inflexible and reimbursement is a major concern. Several criteria have to be fulfilled and a fixed number of treatments are required for reimbursement purposes (at least 20 sessions of (physical) therapy within 14 days). One consequence is an extended length of stay in comparison to hospitals/units not providing this program. In our own cohort, changes in length of stay increased from 16 to 18 days ($p = 0.228$) during the 5-year period.

Despite the above-mentioned improvements, postoperative 30-day-mortality did not change significantly. It remained stable at a low level (5.4%, Welch test, $p = 0.632$). This is in contrast to other works. Koval et al. [27, 28] (US system) and Forni et al. [31] (Italian system) showed significant changes in postoperative mortality with implementation of clinical pathways for hip fracture management. On the other hand, our result corresponds to the findings of Beaupre et al. [32] (Canadian system) and Kalmet et al. (Dutch system) [24]. They found a reduction of postoperative morbidity, but not in-hospital mortality.

During the observation period, we could not accomplish a decrease in the incidence of acquired pneumonia, urinary

tract infection or kidney failure, despite more promising results in the early phase of our study (2011/2012) [12].

The increasing number of postoperatively detected delirium persisted throughout the observation period (Table 3). This was reported earlier by others in the early phase after implementation of the clinical pathways. Generally, this increase is followed by a decrease of postoperative delirium with the interventions later [33, 34]. This reduction was not yet detected in our cohort. More efforts (e.g., teaching, sufficiently well-trained staff) are necessary to improve the outcome in this respect. However, the number of delirium recorded is not only confounded by an increase in detection, but also by a possible decrease in incidence with the multidisciplinary approach. Overall, the rate of hip fracture patients that suffer a delirium is relatively low and comparable to those reported in other intervention studies [35, 36].

Other parameters improved significantly, e.g., failure of fixation ($p < 0.001$) or fixations with full weight-bearing postoperatively ($p < 0.001$). Possible explanations are: surgical SOPs, teaching efforts, morbidity and mortality conferences, etc.

Among the limitations of this study is the lack of patient-reported outcome measures (PROMs), e.g., quality of life. Griffin et al. criticized the lack of patient-reported outcomes in the British national database and conducted a cohort study showing that quality of life does not improve significantly during recovery from hip fracture (120 days) in patients over 80 years of age [5]. Since 2017, we have been reporting our data to a national geriatric hip fracture database. This includes patient-related outcome; however, results are not yet available.

The established quality management system is a learning system. We showed the improvement of several parameters over a 5-year period. However, others have not improved yet. According to the PDCA philosophy, we will have to work on interventions decreasing postoperative pneumonia, urinary tract infections, and prevention and treatment of postoperative delirium, among others. Moreover, we have to enhance the knowledge of the medical and nursing staff regarding the geriatric trauma patient (additional geriatric qualification is required), evaluate new concepts of nursing (e.g., primary care nursing) [37], and further optimize room concepts for disabled elderly patients.

Further studies must show whether the implementation of multifactorial interventions has an impact on mid- or long-term outcome in terms of: mortality, morbidity, mobility and independence. Due to limited funding, we had to restrict our follow-up to 30 days. With the implementation of a national geriatric hip fracture database, follow-up will be extended to 120 days.

Last but not least, the cost-effectiveness of the obviously time and resource-consuming implementation of quality

management systems for hip fracture management has to be analyzed.

Conclusion

We showed significant and relevant improvements in hip fracture care in elderly patients with the implementation of a quality management system based on the PDCA philosophy (continuous improvement process). The basis for a successful treatment is a close ortho-geriatric co-management. However, many questions remain open. More long-term observational studies are needed to judge the effect of our current efforts toward a better management of this patient collective.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval Approval by the internal review board (IRB) was obtained.

Informed consent Informed consent was obtained from all individual participants included in the study.

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