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UPOREDNA ANALIZA DUŽINE OPERACIJE I DUŽINE INTRAOPERATIVNE FLUOROSKOPIJE IZMEDJU INTRAMEDULARNE I EKSTRAMEDULARNE FIKSACIJE TROHANTERNIH PRELOMA

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Abstract
**Background/Aim.** There are cephalomedullary and extramedullary methods of trochanteric fractures internal fixation. Third generation Gamma Nail (GN) is a gold standard in these fractures surgery. Selfdynamisable Internal Fixator (SIF) is an extramedullary implant for trochanteric fractures treatment. The aim of this study was to compare these two methods regarding operation time and intraoperative fluoroscopy time.

**Methods.** Eighty-nine patients with surgical treatment of a trochanteric fracture were included in this study. There were two groups of patients – GN group (43 patients) and SIF group (46 patients). **Results.** Average operation times were 67.5 min (GN group) and 56.0 min (SIF group). Average intraoperative fluoroscopy times were 84.8 s (GN group) and 36.7 s (SIF group). The difference between the groups was statistically significant for both followed parameters (p<0,05). The correlation between operation time and intraoperative fluoroscopy time was confirmed in SIF group (p<0,05; r=0,405), while it wasn’t confirmed in GN group (p>0,05). **Conclusion.** The number of daily surgical interventions planed could depend on the type of trochanteric fracture internal fixation (intramedullary od extramedullary). Additional analysis including radiation dose assessment is desirable to clarify if shorter intraoperative fluoroscopy time in SIF method can have the influence in intraoperative x-ray protection clothing. There is higher variability in GN method than in SIF method regarding duration and type of repeated surgical maneuvers followed by x-ray checks. If there is the need to activate dynamization in long femoral axis after initially static fixation in that axis, the SIF method provides its spontaneous activation several weeks after surgery, without the need for additional surgery and for additional intraoperative fluoroscopy too.

**Keywords:**
operation time; intraoperative fluoroscopy time; Gamma Nail; Selfdynamisable Internal Fixator; trochanteric fracture.
Apstrakt

Uvod/Cilj. Postoje intramedularni i ekstramedularni oblici unutrašnje fiksacije trohanternih preloma. Primena gama klina treće generacije (GN) je danas široko zastupljena u ovoj vrsti lećenja. Samodinamizirajući unutrašnji fiksator (SIF) predstavlja ekstramedularni implantat koji se koristi u lećenju trohanternih preloma. Cilj ovog rada je poredjenje navedenih metoda fiksacije po pitanju dužine operacije i dužine intraoperativne fluoroskopije. Metode. U ovoj studiji je analizirano 89 bolesnika sa hirurški zbrinutim trohanternim prelomom. Ispitanici su podeljeni u 2 grupe – GN grupa (43 bolesnika) i SIF grupa (46 bolesnika). Rezultati. Prosečna dužina operacije je bila 67,5 min (GN grupa) i 56,0 min (SIF grupa). Prosečna dužina intraoperativne fluoroskopije je bila 84,8 s (GN grupa) i 36,7 s (SIF grupa). Izmedju grupa ispitanika je postojala značajna statistička razlika po pitanju oba navedena parametra (p<0,05). Povezanost izmedju dužine operacije i dužine intraoperativne fluoroskopije je bila potvrđena u SIF grupi (p<0,05; r=0,405), dok u GN grupi nije bila potvrđena (p>0,05). Zaključak. Broj planiranih dnevnih operacija može biti određen vrstom fiksacije trohanternih preloma (intramedularna ili ekstramedularna). Potrebna su dodatna ispitivajna koja uključuju i analizu doza zračenja kako bi se proverilo da li prosečno kraća intraoperativna fluoroskopija kod SIF-a može uticati na korišćenje opreme za zaštitu od rentgenskog zračenja od strane medicinskog osoblja. Zapaža se da GN metoda pokazuje veću varijabilnost u odnosu na SIF metodu po pitanju trajanja i u vrste repetitivnih hirurških manevara koji zahtevaju rentgensku proveru. Ukoliko je poželjno postoperativno aktivirati inicijalno blokiranu dinamizaciju u uzdužnoj osi butne kosti, SIF metoda omogućuje da to bude ostvareno bez potrebe za dodatnom hirurškom intervencijom i propratnom dodatnom intraoperativnom fluoroskopijom.

Ključne reči:
dužina operacije; dužina intraoperativne fluoroskopije; gama klin; samodinamizirajući unutrašnji fiksator; trohanterni prelom.
Introduction

Trochanteric fractures are osteoporotic fractures, mainly occurred in elderly\(^1,2\). These fractures are an important social-economic factor influencing quality of life\(^3\). Relation between trochanteric and femoral neck fractures, as a type of osteoporotic hip fractures too, is variable in different parts of the world, confirming the influence of genetic and environmental factors in their incidence. Femoral neck fractures are more present in Northern Europe, while trochanteric fractures are more occurred in Central and Southern Europe\(^4\). Horii et al found the trochanteric fractures incidence rapidly grows in relation to femoral neck fractures after eighth decade of life\(^5\).

Internal fixation is the most common type of trochanteric fractures treatment. Analysis of operation time can be useful both in daily planning of operative program (number of operations) and in anesthesia administration. Intraoperative fluoroscopy time is important to be analyzed, primarily regarding adequate protection of medical staff who are at daily X-ray exposure. There are different data in the literature about comparative analysis of intramedullary and extramedullary trochanteric fractures fixation regarding operation time and intraoperative fluoroscopy time. These data are mainly referred to comparison between cephalomedullary methods and Dynamic Hip Screw (DHS).

Gold standard in trochanteric fractures internal fixation is third generation of Gamma Nail, as an intramedullary method with a cannulated lag screw\(^6,7,8,9\). Trochanteric fractures with pertrochanteric component (fracture line extending in lower-medial direction from the greater trochanter) require the use of lag screws\(^6,9\). Selfdynamisable Internal Fixator (SIF) is an extramedullary implant being in routine use at many centers, predominantly for femoral fractures fixation. There are different types of SIF implants. The type having a “trochanteric unit” includes the use of lag screws for femoral neck and head\(^10,11,12,13\). The “trochanteric unit” is available in two modes – the mode with multiple thinner non-cannulated lag screws and the mode with one wider cannulated lag screw.

The aim of this study was to compare an intramedullary and an extramedullary method of pertrochanteric fractures internal fixation – third generation Gamma Nail and Selfdynamisable Internal Fixator with two non-cannulated lag screws, regarding operation time and intraoperative fluoroscopy time.
Methods

Two groups of patients with a unilateral trochanteric fracture having a pertrochanteric component were analyzed in this study – 43 patients treated by third generation Gamma Nail (GN group) and 46 patients treated by Selfdynamisable Internal Fixator with two lag screws (SIF group). Regarding AO/OTA classification, based on preoperative and intraoperative X-rays analysis by the authors, all cases included 31-A1 and 31-A2 fractures, but also 31-A3 fractures accompanied by a pertrochanteric fracture line. Both groups included consecutive cases treated at Clinic for Orthopaedics and Traumatology in Clinical Center Niš (Niš, Serbia) by all working surgeons from the clinic, after 1st January 2012. Average age was 73.4 years in GN group and 76.2 in SIF group. There were 67% female and 33% male patients. The fixation method used (intramedullary or extramedullary) depended on the surgeon’s choice to the method he was more familiar.

Gamma Nail used in this study was third generation short Gamma Nail. The type of Selfdynamisable Internal Fixator used had “trochanteric unit” with three holes for non-cannulated lag screws. In all cases with this implant, proximal fracture fragment was fixed by two lag screws. Three lag screws can be used in patients with very wide femoral neck and there was no such case in this study. When using just two lag screws, triangular configuration of these holes gives an opportunity for surgeon to have the choice for more adequate between two possible positions for the lower lag screw after application of the first (upper) lag screw. Fixation of the distal fracture fragment included one screw passing the hole of the clamp and another screw (antirotation screw) passing the oblong hole in the implant body. The main role of the clamp is expressed when the lateral cortex is fractured distal to the lag screws and if the dynamisation in long femoral axis is desirable. Fully screwed screw for the clamp initially blocks that dynamisation, while local biomechanical forces can spontaneously unlock the clamp several weeks after surgery, thus spontaneously activating the dynamisation in long femoral axis (Figure 1). Locking of the Gamma Nail can be performed initially in dynamic or in static mode (the surgeon can sometimes assess that initially dynamic mode can’t provide sufficient initial fracture stability). If there is the need to transform postoperatively the Gamma Nail fixation from initially rigid (static) to a dynamic mode in the long femoral axis, there has to be performed additional surgery (locking screw removal).
Operation time (minutes) and intraoperative fluoroscopy time (seconds) were analyzed in the patient groups. Operation time was measured as the time between initial surgical incision and final suture. Intraoperative fluoroscopy had been read on the screen of the C-arm used.

Statistics for average values comparing included T-Test and Mann-Whitney U test. Bivariate correlation, by Spearman’s correlation coefficient, was analyzed between followed parameters.

**Results**

In relation to SIF group, average operation time and intraoperative fluoroscopy time were significantly higher in GN group (p<0,05) (Table 1). The highest values of operation time and intraoperative fluoroscopy time (115 min; 176 s) were in GN group, while the lowest values (20 min; 16 s) were in SIF group.

The correlation between operation time and intraoperative fluoroscopy time was confirmed in SIF group (p<0,05) and this correlation was low positive (0,3<r<0,5). The correlation was not confirmed in GN group (p>0,05) (Table 2).

**Discussion**

Longer average operation time in GN group could be explained by a more frequent need for intraoperative fluoroscopy in an intramedullary method than in an extramedullary method, due to the reduced visual exposure of the implant position. Also, fixation by Gamma Nail includes more guiding instruments than in the fixation by Selfdynamisable Internal Fixator. Every guiding instrument involves additional manual maneuvers of the surgeon, thus prolonging the operation time. Rimming of the medullary canal is a maneuver specific to intramedullary fixation, being a factor for longer operation time too.

Shorter average intraoperative fluoroscopy time in SIF group could be explained by a more frequent need for intraoperative fluoroscopy in intramedullary methods than in extramedullary methods of fixation, as in explaining for longer operation time too. Operative technique of Selfdynamisable Internal Fixator in trochanteric fractures treatment is followed by fluoroscopy in three phases of the surgery – checking the position of the K-
wire for femoral neck and head, checking the first lag screw position and final check of the fixation (Figure 2). The technique of Gamma Nail is followed by intraoperative fluoroscopy checks in all above mentioned phases, but also in additional phases – checking the elastic guide-wire position and checking the vertical level of implant body before the K-wire admission to the femoral neck and head.

Correlation between operation time and intraoperative fluoroscopy time was confirmed in SIF group. The correlation was low positive $^{14}$, i.e. longer intraoperative fluoroscopy is expected to be followed by longer operation time and vice versa, but this relation is not high proportional. Otherwise, the correlation was not confirmed in GN group. This could be explained by the assumption that, in cephalomedullary fixation, the need for repetitive x-ray checks is variable regarding phases of the surgery. This means that repetitive x-rays are in some cases more needed during, e.g. K-wire setting, while in other cases are more needed in elastic guiding wire admission, etc. Different phases of the surgery are followed by different duration of appropriate surgical maneuvers and hence by different time required for its repetitive performing. Furthermore, that additional time is sometimes not significant regarding total operation time (very short duration of the maneuver). Surgical procedure of the SIF method in the trochanteric fractures treatment is followed by the need for repetitive x-ray checks mostly in the first phase (checking the position of the K-wire for femoral neck and head), while second and third phase are mostly not followed by the need for repetitive fluoroscopy (second phase can be followed mostly by one additional x-ray check due to the eventual need for the first lag screw correction). The variation in the need for repetitive x-ray checks regarding phases of the surgery thus could be considered as lower in SIF than in Gamma Nail method, explaining the difference in correlations of operation time and intraoperative fluoroscopy time between the groups.

Alonso et al. analysed scatter radiation around the C-arm and they found that the lead protection is a must within 2 m of the C-arm unit $^{15,16}$. Operative technique of trochanteric fractures fixation by Selfdynamisable Internal Fixator allows the surgeon to stay at the distance of 2 meters and more from the C-arm while performing intraoperative fluoroscopy in all phases of the surgery. Otherwise, some phases of the Gamma Nail technique, as in other cephalomedullary methods, require the surgeon to be next to the operating table and C-arm (entry point positioning, elastic guiding wire admission or phases with very short repetitive maneuvers) $^{17}$. Based on the point of view above (Alonso
et al.), there could be assumed that x-ray protective clothes (protective apron, thyroid shield) are not strictly to be used in trochanteric fractures fixation by SIF implant, while it is strictly recommended during Gamma Nail fixation.

Kelly et al. found that trochanteric fractures internal fixation (including both intramedullary and extramedullary methods) is followed by significantly higher dose of radiation if cumulative intraoperative fluoroscopy time exceeds 50 seconds and if operation lasted longer than 1 hour. Given to our results of average operation time and average intraoperative fluoroscopy time, there could be assumed that average dose of radiation could be expected to be significantly higher in GN group than in SIF group. This statement, if it is accepted as true, could contribute to the above assumptions in x-ray protective clothing. However, additional studies including dose of radiation analysis are being desirable in checking of this statement.

Dynamisation in the femoral neck axis is important in trochanteric fractures with a pertrochanteric component, providing significant interfragmentary transfer of the load. This dynamisation doesn’t have to be blocked at the first postoperative time due to a lot of cancellous bone in the fracture area. In other trochanteric fractures there can be desirable to provide dynamization in the long femoral axis. When the implant with a lag screw is used, the dynamization in long femoral axis can be realized if the fracture has the line extending laterally bellow the entry point of a lag screw. Furthermore, this line can sometimes be overlooked using standard x-rays and a comminutive trochanteric fracture can be misconsidered as a just pertrochanteric fracture (31-A1 or 31-A2). In some cases with a trochanteric fracture fixation which is primarily rigid in the long femoral axis (as in static locking of a short Gamma Nail) the need to transform the fixation into longitudinally dynamic mode can be manifested in the weeks after surgery. Transforming of Gamma Nail fixation into longitudinally dynamic mode requires additional surgery regarding intervention with the locking screw, including additional fluoroscopy too. When a Selfdynamisable Internal Fixator used, initially blocked longitudinal dynamisation can be activated by spontaneous partial unlocking of the clamps, as the result of local biomechanical forces, thus excluding the need for additional surgery and for additional intraoperative fluoroscopy. The amount of biomechanical forces energy passing throw the clamp is higher if the fracture healing is prolonged, i.e. if the fracture fragments contact is insufficient longer. The clamp can be unlocked if this energy exceeds its certain amount,
thus Selfdynamisable Internal Fixator can be considered as an “intelligent implant” that “recognize” the need for dynamization in the long femoral axis, providing its activation “by ownself”, being the only implant with this feature today \(^{10,11,12,13,24}\).

Regarding the literature data about third generation Gamma Nail, Sim et al. \(^{25}\) found the average operation time was 85 min, while Kelly et al. \(^{18}\) found the average intraoperative fluoroscopy time was 116 s. Furthermore, Wu et al. \(^{26}\), Unger et al. \(^{27}\) and Arirachakaran et al. \(^{28}\) found average operation times were 67 min, 56 min and 62 min, while average intraoperative fluoroscopy times were 52 s, 62 s and 109 s, thus all these intraoperative fluoroscopies were longer than 50 s.

There could be assumed the similarity between Dynamic Hip Screw and Selfdynamisable Internal Fixator due to the extramedullary principles in both methods. Kelly et al. \(^{18}\) analyzed DHS fixation of trochanteric fractures, where intraoperative fluoroscopy time was 39 s, almost identical as in SIF group in our study. Muller et al. \(^{29}\) and Arirachakaran et al. \(^{28}\) found that average operation times in DHS fixation of trochanteric fractures were 63 min and 54 min. These results are similar as for Selfdynamisable Internal Fixator in our study (average operation time in SIF group takes the value between the two above mentioned average results for DHS).

**Conclusion**

Operation time and intraoperative fluoroscopy time are expected to be longer if the third generation Gamma Nail is used, as an intramedullary method, in relation to the use of Selfdynamisable Internal Fixator, as an extramedullary method. Operation time can have the influence in daily number of surgical interventions. Additional analysis including radiation dose assessment is desirable to clarify if shorter intraoperative fluoroscopy time in Selfdynamisable Internal Fixator method can have the influence in medical staff x-ray protection clothing during the surgery of trochanteric fractures fixation.

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|                  | GN group (Mean ± SD) | SIF group (Mean ± SD) | t/z  | p        |
|------------------|----------------------|-----------------------|------|----------|
| operation time (min) | 67.5 ± 17.1          | 56.0 ± 17.0           | 3.195| 0.002*   |
| intraoperative fluoroscopy time (s) | 84.8 ± 30.2          | 36.7 ± 19.8           | -7.079| <0.001†  |

Operation time and intraoperative fluoroscopy time in trochanteric fractures treatment by third generation Gamma Nail and by Selfdynamisable Internal Fixator.

*T-test
†Mann-Whitney U test
Table 2

| operation time and intraoperative fluoroscopy time correlation parameters | GN group | SIF group |
|---|---|---|
| | p=0.173 | p=0.005 |
| | r=0.267 | r=0.405 |

Correlations between operation time and intraoperative fluoroscopy time in trochanteric fractures treatment by third generation Gamma Nail and by Selfdynamisable Internal Fixator.
Selfdynamisable Internal Fixator in a trochanteric fracture; 1 – trochanteric unit; 2 – clamp; A – dynamization in the femoral neck axis; B – dynamization in the long femoral axis, which is spontaneously activated after delayed unlocking of the clamp by local biomechanical forces if the contact between fracture fragments is insufficient.
Intraoperative fluoroscopy is required in three phases of trochanteric fracture surgery by Selfdynamisable Internal Fixator: checking the position of just a K-wire and implant body, checking the position of the first lag screw and a K-wire with implant body (A) and final check of the fixation (B).

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