

Original Article

A randomized prospective comparison of Intertan and Gamma3 for treating unstable intertrochanteric fractures

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Abstract: The incidence of intertrochanteric fractures is rapidly increasing. Intertan nail and Gamma3 nail are the common new generation of intramedullary fixations for the treatment of intertrochanteric fractures. In this study, we compared the results of unstable intertrochanteric fractures treated with Intertan nail and Gamma3 nail. From January 2011 to August 2014, 100 patients meeting inclusion criteria were enrolled and randomly divided into Intertan group and Gamma3 group. Each group comprised 50 patients. Preoperative variables included age, gender, fracture classification, preoperative Harris hip score (HHS), American Society of Anesthesiologists (ASA) score, duration of admission to surgery. The blood routine test at the day before operation and the first day after operation, the time required for the closed reduction, X-rayed times, operative time, estimated intraoperative blood loss, the number of transfused patients and units, time to mobilization, were recorded and analyzed. On the second postoperative day, anteroposterior and lateral radiographs of the affected hip were obtained to assess fracture reduction and measure the tip-apex distance (TAD). Patients were followed at 1, 2, 3, 4, 6, and 12 months after surgery. Operative complications, femoral neck shortening, fracture healing time, HHS were used to evaluate the outcome. Preoperative data were similar between the two groups. Operative time was significantly longer and intraoperative blood loss was significantly larger in the Gamma3 group than that in the Intertan group. The decrease in hemoglobin, the number of transfused patients and units were also statistically bigger in Gamma3 group than that in Intertan group. No significant difference was found in X-rayed times, reduction results, TAD, time to mobilization, operative complications, femoral neck shortening, fracture healing time, HHS. Both Intertan nail and Gamma3 nail are effective for surgical treatment of intertrochanteric fractures. Intertan nail has the advantage of shorter operative time and less blood loss.

Keywords: Hip fractures, operative time, blood loss, treatment outcome, intramedullary nail

Introduction

Intertrochanteric fractures are common low-energy injuries that occur from a fall from a standing or lower height in the elderly. As the population ages, intertrochanteric fractures of senile patients become much more prevalent and are associated with high mortality, long-term physical disability and enormous socio-economic burden [1]. The majority of these fractures require surgical intervention as definitive treatment. Surgical intervention allows patients mobilization and help return the patients to his previous level of function.

Successful treatment is visibly important both for the benefit of the individual patient, but also

for economic reasons due to the large amount of these fractures. The surgeon plays an important role in selecting the appropriate fixation device and its proper application after adequate fracture reduction.

Intertrochanteric fractures are practically termed stable or unstable depending on the status of the posteromedial cortex. For stable intertrochanteric fractures, the sliding hip screw fixation remains the gold standard [2]. For unstable fracture patterns, intramedullary nails offer greater rigidity and resist varus deformity more effectively than sliding hip screws [3]. Intramedullary implants have been increasingly used in these unstable fractures due to theo-

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retical advantages, such as minimally invasive application with reduced damage to the soft tissues and reduced likelihood of infection, probably less operative time [4, 5].

Shortening the duration of surgery and anesthesia appears to decrease the risk of relatively minor complications, such as postoperative nausea and vomiting, and serious complications including loss of neurological function, infection, thrombosis, hypothermia, and even mortality [6, 7]. Furthermore, the old people are at greater risk of surgical and anesthetic complications than young people. As is well-known, the less surgical blood loss means less injury and faster recovery for patients. Therefore, the internal fixation characterized by short operative time and less bleeding should be primarily considered to choose for geriatric intertrochanteric fractures.

Currently, TRIGEN Intertan (Smith & Nephew) nail and Gamma3 (Stryker) locking nail are the common new generation of intramedullary fixations and both the nail systems show high biomechanical stability [8]. The primary aim of this prospective study was to compare mean operative time, perioperative blood loss, complication rates and clinical outcomes between Intertan and Gamma3.

Materials and methods

General data

The ethical approval for this study was obtained from the local Ethics Committees of our hospital and informed consent was obtained from all patients or their family members if the patients were unable to consent before operation. From January 2011 to August 2014, 126 patients suffering from intertrochanteric fractures were admitted to our hospital and were considered for this randomized study.

In our study, the patients aged 60 years or older, with a diagnosis of uniquely unstable intertrochanteric fracture (AO/OTA classification, 31-A2.2 to 31-A3.3) caused by a low-energy trauma, were included. We excluded patients with polytrauma, high energy trauma, open fractures, pathologic fractures, American Society of Anesthesiologists (ASA) score of V, inability to work before injury, and presence of arthritis in the injured hip. Altogether, 100

patients were enrolled and randomly divided into Intertan group (treated with Intertan) and Gamma3 group (treated with Gamma3). Each group comprised 50 patients and randomization was performed using 100 sealed envelopes picked from a box.

Therapeutic method

All patients received prophylactic antibiotics (Cefuroxime 1.5 g) intravenously 30 minutes before skin incision and for 48 hours after surgery. All patients were treated with Rivaroxaban for 35 days from the first day after operation as prophylactic anticoagulation. Deep venous thrombosis (DVT) of the lower extremities were not found with Doppler ultrasound in all patients before operation.

All operations were performed by the two experienced orthopaedic surgeons. All the patients were placed supine on a fracture table after general anesthesia and closed reduction was confirmed by C-arm fluoroscopy before draping. Surgeries were performed according to the standard protocols of Intertan and Gamma3, which are recommended by the manufacturer. Intertan and Gamma3 nail were all injected with minimal invasive technique.

Intertan nail applied in this study is a solid titanium nail of 182 mm in length with a trapezoidal proximal end, whose neck angle is 125°. The diameter of proximal end is 16.25×15.25 mm and distal end is 10 mm. The proximal end of the nail accepts two cephalocervical screws: a larger superior 11 mm lag screw and a smaller inferior 7 mm compression screw. The smaller screw are integrated with the larger screw and has the effect of creating an oval screw with a composite diameter of 15.5 mm. Gamma3 nail used in the current study is a solid titanium nail, whose proximal diameter is 15.5 mm and distal diameter is 11 mm, with a length of 180 mm and a target angle of 130° and a lag screw diameter of 10.5 mm. The set screw was firmly engaged with the lag screw to prevent lag screw sliding within the nail and the distal locking screw was tightened with static locking pattern in Intertan and Gamma3.

Observation and measurement

The age, gender, fracture type, time between admission and surgery, ASA score, preopera-

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Table 1. Demographic data

| Variables | Intertan (n=50) | Gamma3 (n=50) | P values |
|------------------------------|--------------------|------------------|-------------|
| Age | 70.1 ± 9.2 | 71.3 ± 8.7 | 0.351 |
| Gender (Male/Female) | 21/29 | 19/31 | 0.683 |
| AO classification (A2/A3) | 40/10 | 41/9 | 0.799 |
| Preoperative HHS | 65.3 ± 7.9 | 66.7 ± 8.8 | 0.136 |
| Admission to surgery (hours) | | | 0.868 |
| < 24 | 15 | 17 | |
| 24-48 | 31 | 30 | |
| > 48 | 4 | 3 | |
| ASA score | | | 0.920 |
| 1 | 3 | 4 | |
| 2 | 18 | 17 | |
| 3 | 21 | 19 | |
| 4 | 8 | 10 | |

tive Harris hip score (HHS) [9], the blood routine test at the day before operation and the first day after operation, the time required for the closed reduction, X-rayed times, duration of operation (from skin incision to skin closure), estimated intraoperative blood loss (measured suction loss plus weight of loss in swabs), were recorded and analyzed. Patients were transfused if there was an hemoglobin (Hb) level below 70 g/l postoperatively. The number of patients receiving transfusion and transfused blood units was noted.

On the second day after operation, anteroposterior and lateral radiographs of the affected hip were obtained to assess fracture reduction and nail position for each patient. Adequacy of fracture reduction was assessed by the criteria proposed by Fogagnolo et al. and classified as good, acceptable or poor [10]. The tip-apex distance (TAD), used to assess differences in position of the implants, is the sum of the distance from the tip of the lag screw to the apex of the femoral head on an anteroposterior and lateral radiographs after controlling for magnification. TAD was measured on the second day postoperatively. At one year postoperatively, the decrease in the length of the femoral neck is determined as shortening in comparison with the second postoperative day radiographs.

Follow-up

Patients were instructed to use walkers with touch-down weight bearing postoperatively and

the time to mobilization was documented for each patient. Six weeks after surgery, partial weight bearing with walker assistance was routine for all patients and full weight bearing was not permitted until sufficient bone consolidation. Patients were followed at 1, 2, 3, 4, 6, and 12 months after surgery. Clinical and radiographic examinations were taken for all patients at each follow-up for evaluating fracture healing and implant position. Fracture healing was interpreted as evidence of bridging callus across the fracture sites or the disappearance of the fracture lines on both anteroposterior and lateral views.

Statistical analysis

Statistical analysis was performed using SPSS version 13.0 for Windows. The continuous variables were declared as mean ± standard deviation. For continuous variables, such as age, BMI, blood loss, decrease in Hemoglobin (HGB) and Hematocrit (HCT), and operative time, independent sample t tests were used. Categorical variable, such as gender, was analyzed with the chi-square test. Statistical significance was determined as $P < 0.05$.

Results

Demographic and perioperative data

Intertan group was comparable with Gamma3 group on demographic data preoperatively. There were no differences between patients in the two groups, in terms of age, gender, type of fracture, preoperative HHS, time of admission to surgery, ASA score (**Table 1**). All the patients in the two groups underwent closed reduction and did not receive blood transfusion from the admission to hospital to the first day after operation. Mean operative time was significantly longer and mean intraoperative blood loss was significantly larger in the Gamma3 group than that in the Intertan group (**Table 2**). The Hb and decrease of Hb at the first postoperative day, the number of transfused patients and units were also statistically bigger in Gamma3 group than that in Intertan group (**Table 2**). No significant difference in preoperative Hb, X-rayed times, reduction results, TAD, time to mobilization (**Table 2**).

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Table 2. Perioperative data

| Variables | Intertan (n=50) | Gamma3 (n=50) | P values |
|----------------------------------------------|--------------------|------------------|-------------|
| Duration of closed reduction (min) | 7.4 ± 1.9 | 7.2 ± 2.1 | 0.216 |
| X-rayed times | 29.5 ± 5.6 | 30.1 ± 4.3 | 0.316 |
| Intraoperative blood loss (ml) | 80.3 ± 18.1 | 130.6 ± 22.5 | 0.025 |
| Operative time (min) | 52.3 ± 11.8 | 66.7 ± 13.4 | 0.034 |
| Preoperative Hb (g/l) | 121.51 ± 15.16 | 120.16 ± 22.16 | 0.195 |
| Postoperative Hb (1 st day) (g/l) | 105.17 ± 14.05 | 92.26 ± 18.39 | 0.024 |
| Hb (g/l) drop | 19.51 ± 3.16 | 25.69 ± 4.64 | 0.012 |
| Reduction results | | | 0.617 |
| Good | 41 | 39 | |
| Acceptable | 9 | 11 | |
| Poor | 0 | 0 | |
| TAD (mm) | 23.13 ± 3.79 | 22.47 ± 3.26 | 0.336 |
| Transfused patients | 21 | 32 | 0.028 |
| Transfused units | 2.1 ± 0.8 | 3.0 ± 0.9 | 0.039 |
| Time to mobilization (days) | 2.27 ± 0.79 | 2.36 ± 0.81 | 0.814 |

Table 3. Operative complications

| Variables | Intertan | Gamma3 | P values |
|--------------------------------|----------|--------|----------|
| Superior position of lag screw | 6/50 | 2/50 | 0.120 |
| Pulmonary embolism | 1/50 | 2/50 | 0.558 |
| DVT | 3/50 | 5/50 | 0.461 |
| Lag screw cutout | 1/47 | 5/45 | 0.081 |
| Hip pain | 3/47 | 4/45 | 0.650 |

Operative complications

In the first postoperative week, one case in Intertan group and two cases in Gamma3 group died of pulmonary embolism. Two patients treated with Intertan and three patients treated with Gamma3 were completely lost to follow-up. Therefore, a total of 47 patients in Intertan group and 45 patients in Gamma3 group had completed follow-up.

There was no wound infection, wound hematoma, non-union, periprosthetic fracture, screw back-out in both groups. The superior position of lag screw in femoral head occurred in 6 cases within Intertan group and 2 cases within Gamma3 group. In these 8 cases, the lag screw could not be fixed in the desired position due to the narrow width or varus geometry of the femoral neck, which was unavoidable. With regard to operative complications including pulmonary embolism, DVT, hip pain, superior position of lag screw, the results in two groups were equal (Table 3). 1 patient in Intertan group and 5 patients in Gamma3 group experienced cutout

of lag screw. The TAD for all patients who had a screw cutout was greater than 25 mm. All the cutouts occurred at first to third postoperative month and had revision surgery. The nails were removed and a total hip arthroplasty was implanted. No significant difference was observed in cutout between the two groups, despite the number of cutout in Gamma3 group is larger than in Intertan group (Table 3).

Clinical outcome

All the fractures healed within 6 months, except for the patients who died and lost as well as suffered from cutout. Both the Intertan and Gamma3 group showed good functional recovery and small femoral neck shortening at the final follow-up. Statistical analysis of the two treatment groups revealed that no significant difference was found in union time, femoral neck shortening and HHS (Table 4).

Discussion

At present, intertrochanteric fractures are common fragility fractures in the elderly. There are many devices available for treating them surgically, also there are a variety of controversial issues about the perfect fixation choice for them, especially unstable fractures, because there is still absence of evidence for the use of intramedullary implants instead of extramedullary implant [11]. Meanwhile, internationally, according to clinical and experimental study, many authors have gradually recommended the treatment of unstable intertrochanteric fractures with modern intramedullary devices because of their theoretical advantages, such as minimally invasiveness, stable centricity, better mechanical performance [2, 12].

Intertan, the fourth generation of intramedullary nail, was first introduced in 2005 and has become an increasingly popular option for treating intertrochanteric fractures, because of

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Table 4. Clinical outcomes

| Variables | Intertan (n=46) | Gamma3 (n=40) | P values |
|------------------------------|--------------------|------------------|-------------|
| Femoral neck shortening (mm) | 2.76 ± 0.23 | 3.01 ± 0.34 | 0.217 |
| Union time (weeks) | 15.19 ± 3.22 | 14.91 ± 4.16 | 0.286 |
| HHS (1 year) | 63.3 ± 6.7 | 64.7 ± 7.8 | 0.136 |

a good clinical outcome and a low number of complications [13]. This implant has two integrated cephalocervical screws that allow linear intraoperative compression of fracture end. The two integrated screws not only provide rotational stability of the head or neck fragment and better lateral cortical support, but also overcome Z-effect complications [14]. Gamma3 locking nail system, which is widely used clinically at present, is based on more than 15 years of Gamma nail experience and is the third generation of intramedullary fixation nails. Its new design seems superior to previous generations, giving promising outcomes and reduced mechanical complication rates [15]. Both Intertan and Gamma3 are designed to facilitate minimally invasive surgery. The clothespin distal tip of the Intertan nail reduces the overall cross-sectional stiffness of the implant to minimize the risk of iatrogenic fracture during insertion. The design of Gamma3 nail is short of the advantage and therefore easier to lead to the femoral shaft fracture [16]. Nüchtern JV et al. confirmed that Intertan system with two integrated screws was able to withstand higher loads than the Gamma3 system by their experiment [8].

During the operation, both Intertan and Gamma3 system need C-arm fluoroscopy to check the position of opening the medullary canal on the tip of greater trochanter, nail insertion depth, the position of guide pin and screw into femoral neck, so X-rayed times are not statistically different as we considered in advance.

Intertan system uses channel reamer to ream the proximal femur only once while Gamma3 system uses flexible reamers of various diameter to ream the shaft and proximal portion of femur in stages, which may be the primary reason that mean operative time is longer in Gamma3 group than Intertan group. In addition, cannulated set screw is placed into Intertan nail in advance, while the set screw is separate from Gamma3 nail, which contributes

to shortening the operation time. Wu et al. reported that a longer mean operative time and fluoroscopy time were shown in Intertan group compared to Gamma3 group for the reason that Intertan nail was more difficult to insert into a poorly reduced marrow cavity due

to a trapezoidal proximal end of the nail [16]. We did not have the difficulty of Intertan nail insertion, probably because the number of cases in our study is relatively small or the distal end of Intertan is 11 mm used in their surgeries while 10 mm in our surgeries. In the present study, mean operative time is different from previously reported [14, 16, 17]. We think that fracture complexity and skill levels of surgeons account for this diversity.

Only the proximal marrow cavity of femur is reamed during Intertan surgery while the entire medullary cavity of femur need to be reamed during Gamma3. The pulp cavity area of expansion is larger and mean operative time is longer for Gamma3 than Intertan, which could cause more bleeding and might explain more intraoperative and postoperative blood loss in Gamma3 group than Intertan group. According to general surgical experience, the shorter the operative time is, the smaller the blood loss is. Shorter operative time in Intertan group may help to reduce intraoperative and postoperative blood loss. The intraoperative blood loss is obviously inconsistent with the decrease in Hb and HCT, and the blood loss indicated by postoperative Hb and HCT is much more than intraoperative blood loss. The decrease in Hb is related to hidden blood loss besides intraoperative blood loss. Hidden blood loss in connection with operation for intertrochanteric fracture is substantial during the perioperative period, and intramedullary nailing could cause more hidden blood loss than other fixations and arthroplasty [18, 19]. Thus, we need to pay attention to monitor the Hb after operation and must not be misled by the small amount of intraoperative bleeding.

For treating intertrochanteric fractures, the sliding of the lag screw of an Gamma nail does not improve any clinical results and in certain cases, such as highly comminuted A1 and A2 fractures, can therefore even benefit from a locked lag screw by tightening the set-screw

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[20]. So, the set screw was firmly tightened when compression of the fracture gap had been completed, which effectively prevent femoral neck shortening.

It has been demonstrated that TAD > 25 mm is an important risk factor of implant cutout [21]. For this reason, hip screw placement should be performed attentively and should not be passed without ideal placement of the screws. Kim et al. reported that the cross-sectional area and width of the femoral neck is lower in Koreans than in Caucasian [22]. Accordingly, the two integrated lag screws were more frequently positioned in the superior part of the femoral head in the Asian patients. Superior position of the lag screw in the femoral head is a well-known risk factor of varus collapse with cut out requiring reoperation [23]. Hip pain is a common complication in intramedullary nails for treating intertrochanteric fractures [24]. The inevitable damage to the mesogluteus during appropriate placement of the intramedullary nail or the chronic muscle injury caused by the long proximal end of the nail protruding above the greater trochanter may explain the hip pain. Proper modifications on Intertan nail and Gamma3 nail, such as reducing diameter of two integrated lag screws and shortening the proximal end of nails, are necessary for Asian patients with narrow femoral neck width or varus neck geometry.

In our study, both the bone healing rate and hip function one year postoperatively are similarly high and satisfactory. It is evident that Intertan nail and Gamma3 nail are all useful and effective to secure the unstable intertrochanteric fracture. Queally et al. performed limited meta-analysis from the randomized trials and concluded there were not sufficient evidence to determine whether there are important differences in outcome (functional score, mortality, re-operation, fracture fixation complications including operative fracture of the femur, cut-out, non-union and later fracture of the femur) between different designs of intramedullary nails (Intertan nail, PFNA-II, Gamma nail) used in treating extracapsular hip fractures [25]. Hence, it seems more important for treating geriatric trochanteric fractures that selecting an intramedullary implant with the features of simple manipulation, minimal trauma, shorter operative time and less bleeding.

Surgical technique, implant positioning, and the choice of implant play roles in the successful treatment of intertrochanteric fractures. Every internal fixation implant has advantages and shortcomings. Almost all intraoperative complications (such as iatrogenic femoral shaft, lateral greater trochanter fracture, distal interlocking problem) and some postoperative complications (such as hip pain and cut-out) are closely related to the surgical techniques. Surgeons need to have sufficient theoretical knowledge and practical ability, and master the surgical procedure of instrument in order to choose optimal instrument for achieving the ideal treatment effect.

Although the cases of intertrochanteric fracture treated with Intertan nail are not very much in our department, we realize that the operation steps of Intertan nail are relatively simple and the active compression effect on fractures achieved through a linear motion without rotation is preferable, which was not confirmed by our study notwithstanding. In our department, we have standardized the use of Intertan nail for the treatment of intertrochanteric fractures.

However, our study had limitations. The sample size of total patients is relatively small and problems associated with Intertan nail and Gamma3 nail may occur during longer-term manipulation, so we need to increase the sample in the future.

Conclusion

Within the limits of this study, Intertan nail and Gamma3 nail are all effective for surgical treatment of intertrochanteric fractures. Intertan nail has the advantage of shorter operative time and less blood loss. The use of the Intertan system may be an improvement in surgery, compared to Gamma3 system.

Disclosure of conflict of interest

None.

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