# The Treatments of Tibial Shaft Fracture: An economic evaluation of conservative vs operative methods

Weerachai Kosuwon, M.D., Polasak Jeeravipoolovarn, M.D., and Kitiwon Vipulakorn, M.D.

*Department of Orthopaedics and Rehabilitation Medicine, Srinagarind Hospital, Faculty of Medicine, Khon Kaen University, Khon Kaen, 40002 Thailand.*

## ABSTRACT

**One hundred and twenty patients between the ages of eighteen and sixty five years who were admitted with fracture of the tibial shaft, during Jan 1988-Dec 1991 were included in the study. One hundred twenty patients were randomly allocated to the open reduction and internal fixation with compression plate (ORIF) group of 58 cases and the conservative treatment (CT) group of 62 cases. Healing rates at 10th week of the CT and the ORIF groups were 6 per cent and 20 per cent respectively. There were 38 patients in the CT group wearing the cast for 20 weeks period. At 20th week, there were 28 cases in the CT group developed bony union. Ten cases (17 per cent) in the ORIF had superficial infection.**

The total cost of treatments in the CT and the ORIF groups were $39,977 ($645 per case) and $79,299 ($1,367 per case) respectively. The costs of treatment of infection in the ORIF group were $524/case. The cost effectiveness ratio of the CT and the ORIF groups were $888 and $793 per healing rate respectively. The cost per case of healing in the CT and the ORIF groups were $1,427 and $1,367. Eventhough the ORIF costs more it achives more and thus the cost per healing rate or cost per case of healing is lower. The ORIF group is more cost effectiveness than the CT group. However the sensitivity analyses showed that the CT groups will be more cost effectiveness than the ORIF group if the healing rates in the CT groups are not less than 51 per cent; or the patient compliance rates of wearing a cast longer are not less than 70 per cent or; the infection rates in the ORIF group are more than 50 per cent or the costs of treatment in the ORIF group are increased more than 13 per cent.

The goal of treatment of fractures of the tibial shaft in adults is to restored anatomy and regained function as quickly as possible. To achieve this many technologies and treatment protocols have been described: closed reduction and immobilization and open reduction internal fixation with compression plating or intramedullary nailing. The treatment of tibial shaft has become one of the most controversial subjects in orthopaedic surgery. Many authors claimed that these fractures should primarily by treated with conservative methods[1,4,13-15,17]. On the other hand, plate fixation or intramedullary nailing has enthusiastic support[2,3,8-12,16].

It is now almost universally belived that the resources available to meet the demands for health care are limited even in the developed countries as United States and Canada. By the year 2000, it is estimated that the United States will be using 15 per cent to18 per cent of its gross national product for health care compared with 5 per cent four decades ago[18]. Many health care technologies, therefore, should be assessed both their costs and consequences. The treatments of tibial shaft fracture are not excluded. Therefore, these technologies should be evaluated in terms of their efficiency. There is no economic evaluation of the treatment of tibial shaft fracture.This study was undertaken in order to do an economic evaluation of conservative treatment versus open reduction internal fixation with compression plating.

## MATERIALS AND METHODS

One hundred and twenty consecutive adult patients, between January 1988-December 1991, who had sustained a closed or open fracture grade I unilateral fracture of tibial shaft and who presented at Srinagarind Hospital, Khon Kaen University were entered into the study. All of these patients were treated by closed or operative methods.

In the patients who were treated conservatively (CT), the standard initial treatment was closed reduction without anesthesia followed by immobilization in a long leg plaster cast. If repeat roentgenogram made through the plaster cast showed persistent angulation, the cast was wedged to

correct it. In cases with shortening, the longitudinal traction was applied to correct the displacement followed by immobilization in a long leg cast. In the case of open fracture, the systematic debridement, open reduction and fixation with one or two Krishner wires were performed after which a long plaster cast was applied and worn for four to six weeks. After discharge the patients were examined every three weeks at our out-patient clinic. The cast was changed, roentgenogram were made, and the stability of the fracture was checked. After four weeks, the long leg cast was changed to the patella tendon-weight bearing cast until the fracture was clinically and radiographical stable.

In the operative treatment (ORIF) group, operation was performed, if possible, within eight hours after injury. Because of delays in transportation, many patients were admitted too late for immediate operation. These patient were operated on after one week. All operation in the ORIF group were performed according to AO principles[10]. The majority of the operations were performed by experienced surgeons. The leg was then immobilized with posterior slab for seven days post operatively. After discharge, the patients were examined every three weeks at out-patient clinic. The roentgenogram were repeated until the fracture was considered to be healed and the patient had returned to work or normal activities. The implants were removed after two years and these patients were admitted for one week and followed a regimen of non weight bearing with crutches for eight weeks.

Normal healing was defined as union occurring within 20 weeks and delayed union as the lack after 20 weeks. The non union was defined as non occurrance of union after 24 weeks[10]. The shaft was defined as being between the level of tibial tuberosity and 10 centimeters above the horizontal articular surface of the ankle. The fracture were classified into three groups of fracture line according to Van der Linden and Larsson[9]. Displacement of fracture was also classified according to Edward[7].

The direct medical costs refer to the cost of each medical services such as out-pateient clinic, inpatient ward and orthopaedic operating theater included labour, capital and material costs. Capital costs (Buildings and machinery) were calculated in their present value in terms of equivalent annual cost[5] (discout rate 7 per cent). The cost of hospital stay was calculated from ward building areas, medical instruments and supplies, and labour costs which including their salaries and fringe benefits. There is no doctor fee in the government hospital, therefore, the cost of orthopaedic surgeons and anesthesiologist were calculated from their salaries, the value of their house which provided by the government and their fringe benefits, all of these costs divided by 10 hours per working day with 22 working days per month. Therefore, the cost of surgeon per minute was $2. The cost of plaster of paris and the AO implants were calculated by their market prices in the same period. The indirect cost of the patients is the productivity losses due to ill health[5]. It was calculated from the minimum wage rate in this province which was $US 2.4 per day (1991).

## RESULTS

One hundred and twenty consecutive patients between age of eighteen to sixty five year of ages who were admitted with fracture of the tibial shaft, during Jan 1988-Dec 1990 were included in the study. One hundred twenty patients were randomly allocated to the ORIF group of 58 cases and the CT group of 62 cases. The were 12 and 13 cases of open fracture in the CT and ORIF groups respectively. Other characteristics of fracture in both groups were comparable ($p>0.05$) and are presented in the table 1. There were 58 and 50 males in the CT and ORIF groups respectively. The mean ages were 26 years (range 16 to 54 years). Hospital stay of the patients in the CT and ORIF groups were 10±3 (range 7-14 days) and 15±5 (range 10-30 days).

All patients in the ORIF group complied with the treatment. Only 38 patients in the CT group wore the casts until 28 weeks. There were 24 cases took the casts off one month after the treatment. The clinical data for these 24 patients were collected by the village health volunteers.

Healing rates at 10$^{th}$ week of the CT and the ORIF were 6 per cent (4 cases) and 20 per cent (12 cases) respectively. There were 10 cases in the ORIF group had superficial infections. However, all of them developed bony union by 20$^{th}$ week. All of the patients in ORIF group had bony union by 20$^{th}$ week. There were, however, only 28 patients in the CT group. The malalignment of less than 5 degree in any plane and/or shortening less than 5 mm. were seen in 18 cases. Malalignment of more than 5-10 degree and/or shortening more than 5-10 mm. were seen in 6 cases. In the poor-compliance of the CT group, 4 cases developed malunion (angulation more than 10 degree and shortening more than 10 mm. in 3 cases) and 20 cases developed nonunion. Those poor compliance patients in the CT group needed further surgical treatments for non-union and malunion.

The direct medical costs per case in the CT and the ORIF groups were $482 and $819 respectively (Table 3). The total direct medical costs per case of infection in the ORIF group was $524 (range $476-$700) (Table 4).

At 20$^{th}$ week after treatment the indirect costs per case of the ORIF and CT groups were $458 and $349 respectively (Table 5). The total cost of the CT and the ORIF groups were $39,978 and $79,299 respectively. The cost-effectiveness (cost per healing rate by 20$^{th}$ week) ratio of the CT and ORIF groups were $888 and $793 per one per cent rate of healing or $1,427 and $1,367 per one case of bone healing respectively.

The one way sensitivity analysis showed that the results of the study will by sensitive to change if the bony healing rates in the CT group were more than 51 per cent (Fig 1) or the patient compliance rates of wearing the cast in the CT group were more than 70 per cent (Fig 2) or the infection rates in the ORIF group were more than 51 per cent (Fig 3) or the cost of the ORIF increased more than 13 per cent (Fig 4).

## DISCUSSION

The target population in this study was tibial shaft fracture either closed or open grade I, which are indications for either closed or operative treatments. Therefore, this condition is appropriate to do a decision analysis and economic evaluation because in this situation both the none operative or operative treatments can be selected. The charecteristics of the two groups of treatment were not different.

The average times to union for fracture of the tibial shaft in the two groups were similar to that reported by others using the same method of treatment[13-15]. The fracture treated with an compression plate healed more quickly than the conservative treatment. The healing rates of the conservative treatment group who complied with the treatment was 73 per cent, not different from the result of the previous studies[3,7]. The infection rate in this study was 17 per cent, mostly superficial infection due to the delayed of internal fixation after debridement. The duration of hospitalization was favorable to the conservative method.

The costs in the CT group included only the direct and indirect costs during the period of 20 weeks after treatment because the bony healing time was defined at this period and some of the non compliant patients have not been received and further treatments yet, therefore, we can not calculate the costs of further treatments.

Some patients in the CT group had low compliance rate of wearing a cast due to many reasons, for instance the hot climate in Thailand and the local belief of patients' relatives that using bamboo sticks would obtain satisfactory results.

The cost analysis showed that both direct and indirect costs of treatment in the ORIF group were more expensive than the CT group. In addition, if the clinical outcome was taken into account the cost per case of healing showed that the operative treatment was more cost effective than the conservative treatment. Fewer resources were utilized by the ORIF patients than the conservative patients, even the future costs of malunion and nonunion treatments in the conservative treatment group were not taken into accout. The ORIF group healed faster, therefore, the patients in this group were able to return to work earlier. The benefit of the treatment in terms of earning costs in the ORIF group should be more than the CT group.

The sensitivity analysis was performed to test the robustness of the results. The results from this study can be generalized by using the various values of the uncertainty variables such as healing rates, infection rates, compliance rates and the differences in the treatment cost in the operative method which be adopted to various orthpeadic sttings around the world. Because health care resources are limited, many types of orthopaedic treatment should be carefully evaluated for both the clinical outcomes and their costs. This study showed that the ORIF group was more cost effectiveness than the CT group. Therefore, in the hot climate or setting that patient compliance of wearing the cast was very low, the operative mangement for fracture tibial shaft should be appropriate.

Table 1 Charecteristic of fractures at first examination in both groups.

| Group | Type | | | Displacement | | |
|---|---|---|---|---|---|---|
| | Trans | Long | Comm | Slig | Mod | Mark |
| ORIF(58) | 28 | 20 | 10 | 20 | 18 | 20 |
| CT(62) | 30 | 22 | 10 | 24 | 20 | 18 |

Trans : Transvers
Long : Longitudinal
Comm : Comminuted
Slig : Slightly
Mod : Moderate
Mark : Marked

Table 2 Clinical outcomes after 10th week and 20th week for both treatment groups.

| ORIF group (No.58 cases) | | Closed reduction group (No.62 cases) | |
|---|---|---|---|
| At 10th week | | | |
| Bony healing | 12 (20%) | Bony healing | 4 (6%) |
| At 20th week | | Union | 24 (38%) |
| Bony healing | 46 (80%) | Delayed union | 10 (16%) |
| | | Non-compliants | 24 (39%) |

Table 3 The means of the direct medical costs and prices of the respirces were used in each group of the patients.

| ORIF group | | Closed reduction | |
|---|---|---|---|
| Hospital stay ($16/day) | 15 days $240 | Hospital stay | 10 days $160 |
| Laboratory | $20 | Laboratory | $8 |
| Roentgenography pre & post operative period ($9.6/film) | $20 | Roentgenography pre & post reduction and after wedging the cast | $24 |
| Operating room cost | $48 | Reduction room cost | $6.4 |
| Doctor fee ($2/min) | $90 | Doctor fee | $25 |
| Anesthesiologist & Medication | $50 | | |
| Price of AO Plate & screws | $88 | | |
| Posterior slab & Procedure | $4.8 | Price of plaster of paris for long leg casting | $11.2 |
| | | Three weekly follow up of 6 visit and 6 time of PTB cast changing | $193.2 |
| Roentgenography during follow up period. | $51.64 | Roentgenography during follow up period | $54.56 |
| Sub total | $611.44 | | |
| Removal of plate & screws at two years after bony union | | | |
| - Operating room cost | $48 | | |
| - Doctor fee | $60 | | |
| - Anesthesiologist & Medications | $50 | | |
| - Hospital stay 5 day | $80 | | |
| Sub total | $238 | | |
| (The present value of $238 dicount rate 7%, two years=$207.88) | | | |
| Total | $819.32 | Total | $482.36 |

Table 4 The direct medical cost of treatment of infection due to surgery of ten cases in the ORIF group.

| | |
|---|---|
| - Labaratory cost (CBC, Culture & Sensitivity etc.) | $660 |
| - Doctor fee | $600 |
| - Anesthesiologist & Medications | $500 |
| - Antibiotic agentsí price (95% Cloxacillin) | $1,400 |
| - Operating room cost | $480 |
| - Hospital stay 10 days (7-21 days) $16/day | $1,600 |
| Total cost of 10 cases | $5,240 |
| or | $524/case |

Table 5 The indirect cost of the both groups.

| | | |
|---|---|---|
| Disability days of the ORIF group | | |
| - Hospitalization stayed 15 days | = 870 | days |
| - Ten cases had bone healing at 10th wk | = 10*7*10 | days |
| | 700 | days |
| - Fourty-eight cases had bone healing at 20th wk | = 48*7*20 | days |
| - Ten cases had infection | = 6,720 | days |
| - Eight wks and 5 days disability period after removal of the implants in 58 cases | = 3,538 | days |
| Total disability days | = 11,058 | days |
| Minimum wage rate/day | = $2.4 | |
| Total indirect cost of 58 cases | = $26,539.20 | |
| or | = $457/case | |
| Disability days of the closed reduction group | | |
| - Hospitalization 10 days of 62 cases | = 620 | days |
| - Four cases had bony | = 4*7*10 | days |
| Union at 10 wks | = 280 | days |
| - Twenty four cases had bony | = 24*7*20 | days |
| Union 20 wks | = 3,360 | days |
| - 34 cases had delayed | = 34*7*20 | days |
| Union at 20 wks | = 4,760 | days |
| Total disability days | = 9,020 | days |
| Minimum wage rate/day | = $2.4 | |
| Total indirect cost of 62 case | = $349/case | |

Table 6 The total cost of treatment (both direct and indirect costs) in the CT and ORIF groups.

| The Conseravtive group 62 patients | | The ORIF group 58 patients | |
|---|---|---|---|
| Direct cost 38 patients | $18,329 | Direct cost of ORIF in 58 cases | $35,463 |
| Indirect cost of 62 cases | $21,648 | Direct cost of treatment infection 10 cases | $5,240 |
| | | Direct cost or removal implants in 58 cases | $12,057 |
| | | Indirect cost of 58 cases | $26,539 |
| Total | $39,977 | Total | $79,299 |
| Healing rates at 20th wk | 45%(28 cases) | Healing rates | 100% |
| Cost/healing rate | $888.39 | Cost/healing rate | $792.99 |
| Cost/case of bony union | $1,427 | Cost/case of bony union | $1,367.23 |

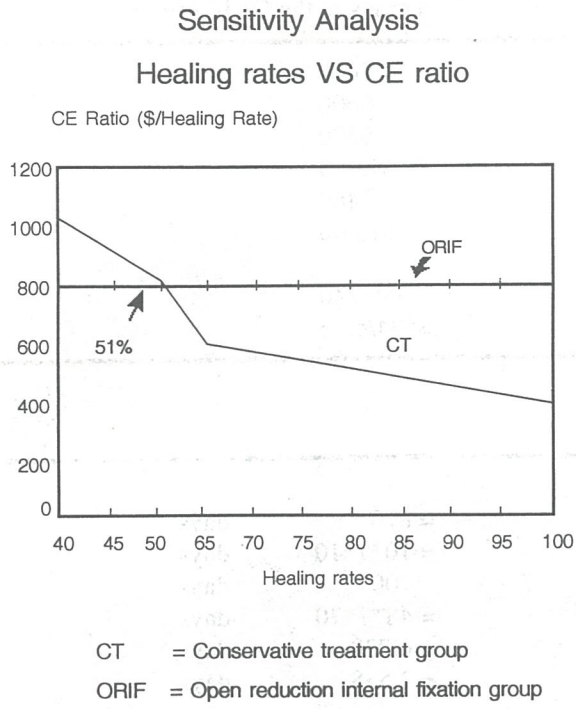


Fig 1 The sensitivity analysis of the various trates of bony healing and the cost effectiveness ratio of both the ORIF group and the conservative treatment group. At the 51% of bony union rates, the conservative treatment will be more cost-effective than the ORIF group.

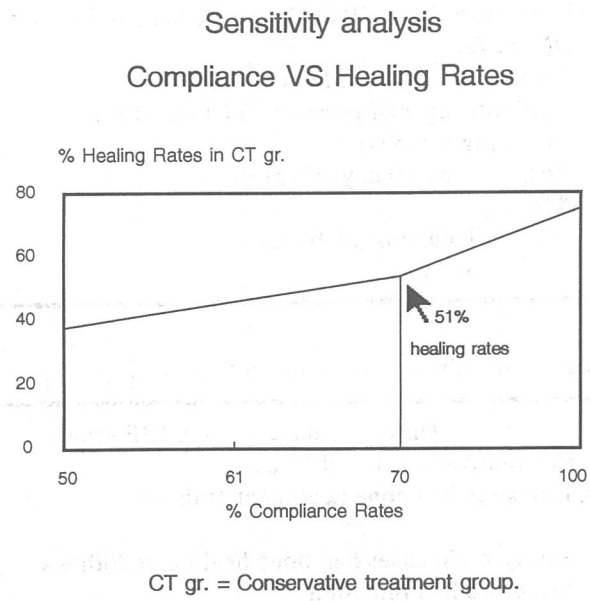


Fig 2 The sensitivity analysis of the various rates of compliance of wearing the cast and the healing rates of bony union rates in the CT group. The compliance rates in the CT group should be more than 70% then the healing rates are 51%.

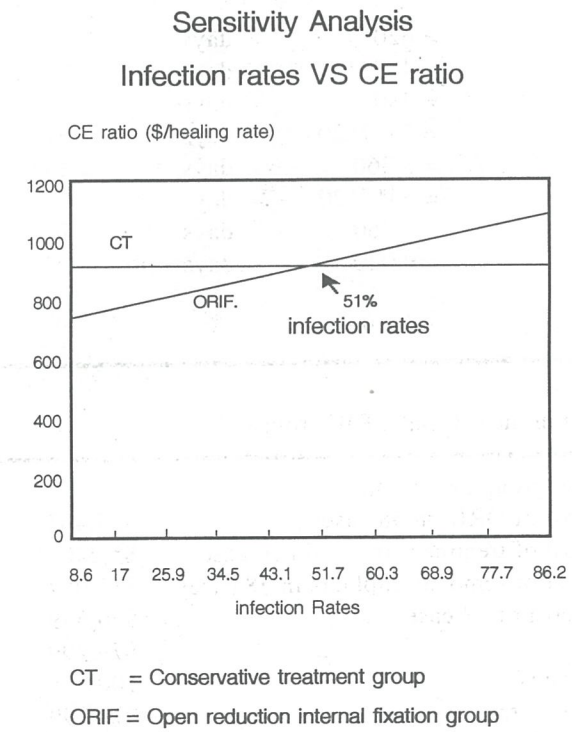


Fig 3 The sensitivity analysis of infection rates in the ORIF group and the cost effectiveness ratio. The infection rates in the ORIF group should not be more than 51%, otherwise the conservative treatment will be more cost-effective.

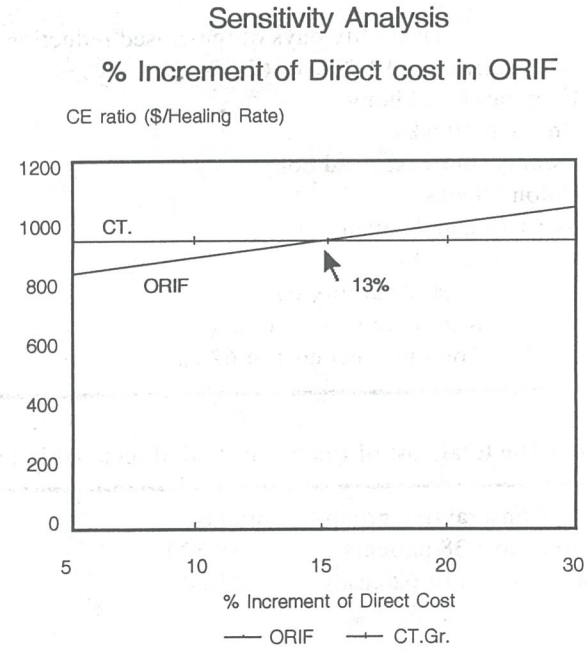


Fig 4 The sensitivity analysis of the various percentage of the direct cost of the ORIF group. At more than 13% of the increment of the direct cost in the ORIF group is more cost-effective.

## REFERENCES


1. Brown PW, Urban JG. Early weight-bearing treatment of open fractures of the tibia: An end result study of sixty-three cases. J Bone Joint Surg(Am) 1969;51:59-75.
2. Burwell HN. Plate fixation of tibial shaft fractures. A survey of 181 injuries. J Bone Joint Surg(Br) 1971;53:258-71.
3. Clifford PR, Beauchamp GC, Kellam FJ, Webb KJ, Tile M. Plate fixation of open fractures of the tibia. J Bone Joint Surg(Br) 1988;70:644-48.
4. Dehne Ernst. Treatment of fractures of the tibial shaft. Clin Orthop 1969;66:159-73.
5. Drummond FM, Stoddart LG, Torrance WG. Methods for the economic evaluation of health care programs. Oxford Medical Publications, 1987.
6. Edwards Per. Fracture of the shaft of tibia: 492 consecutive cases in adults. Acta Orthop. Scandinavica, Supplementum, 1965;76.
7. Johner R, Wruhs O. Classification of tibial shaft fractures and correlation with results after rigid internal fixation. Clin Orthop 1983;178:7-25.
8. Linden VW, Larsson K. Plate fixation versus conservative treatment of tibial shaft fractures. A randomized trial. J Bone Joint Surg(Am) 1979;61:873-78.
9. Muller ME, Allgower M, Willenegger H. Technique of internal fixation of fractures.Revised by Segmuller G. New York: Springer-Verlag, 1965.
10. Nicoll EA. Fracture of the tibial shaft. A survey of 705 cases. J Bone Joint Surg(Br) 1964;46:373-87.
11. Nicoll EA. Closed and open management of tibial fractures. Clin Orthop 1974;105:144-53.
12. Sarmiento A, Gersten ML, Sobal AP, Shankwiler AJ, Vangsness TC. Tibial shaft fractures treated with functional braces. J Bone Joint Surg(Br) 1989;71:602-9.
13. Sarmiento A. A functional below-the-knee cast for tibial fractures. J Bone Joint Surg(Am) 1970;52:295-311.
14. Sarmiento A, Latta LL. Closed functional treatment of fractures. Berlin: Springer-Verlag, 1981.
15. Thunold J, Varhaug JE, Bjerkeset T. Tibial shaft fractures treated by rigid internal fixation. The early results in a 4-year series. Injury 1975;7:125-33.
16. Weissman SL, Herold HZ, Engleberg M. Fractures of the middle two-thirds of the tibial shaft. Results of treatment without internal fixation in one hundred and forty consecutive cases. J Bone Joint Surg(Am) 1966;48:257-67.
17. Weinstein NJ. Clinical efficacy and outcome in the diagnosis and treatment of low back pain. New York: Raven Press, 1992.