Does Teriparatide Improve Fracture Union?: A Systematic Review

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We conducted an updated review of the evidence of teriparatide (TPTD) for fracture healing for the following questions. (1) Does it decrease fracture healing time?; (2) Can it be an alternative treatment for nonunion?; (3) Does it aid the union of atypical femoral fracture (AFF)? We searched PubMed, EMBASE, and Cochrane Library including “Fracture” AND “nonunion” AND “Teriparatide”. In total, 57 publications met our inclusion criteria were summarized. This systemic review of the available literature revealed that TPTD works positively with regard to enhancing fracture healing time and union of AFF. There are also many case studies on the use of TPTD could be a potential new safe treatment for nonunion with no side effects. However, level 1 studies on the evidence of TPTD are still lacking so far. Over the last decade, a growing body of evidence has accumulated suggesting that TPTD can be an adjunct to enhance fracture healing or a therapeutic option to treat nonunion, but greater evidences from large volume prospective trials are needed.

Key Words: Fractures, bone · Parathyroid hormone · Teriparatide

INTRODUCTION

Nonunion is the most frequent cause of reoperation and highly morbid complication as burden of fracture. The biologic process of fracture healing is complex and impacted by multiple factors, and this is prevalent in certain risk groups such as elderly, osteoporosis, in people with malnutrition.[1,2] At present, no pharmacologic treatments are available for nonunion, so there is an unmet need for medications that can stimulate bone healing.

Teriparatide (TPTD), a synthetic polypeptide hormone of the recombinant human parathyroid hormone is considered to be the most potent of the osteoporosis therapies with its marketed anabolic effect.[3] However, there has been a great interest in using TPTD to enhance fracture healing or to treat nonunion is off-label with potent bone-forming effects.[4,5] The existing basic science data suggest TPTD accelerate chondrocyte recruitment and differentiation, which are essential processes in early enchondral ossification.[6,7] Thus TPTD enhance fracture healing by improving the biomechanical properties of the fracture callus, increasing both cartilaginous and mineralized callus formation. Its anabolic effect is given by the stimulation of the osteoblast, and fibroblast growth factor 2 is also up-regu-
lated in TPTD treated individuals.[8-10]

There has been previous reviews that suggest the role of TPTD as alternate to induce fracture healing,[11-13] However, to date, many clinical trials have been undertaken to elucidate the efficacy of TPTD for inducing fracture healing in several situations, such as atypical femoral fracture (AFF). [14-16] A better understanding of the role of TPTD with greater evidences on fractures healing could help clinician to make their decision.

Thus, we conducted an updated review to evaluate the efficacy of TPTD on fracture healing. (1) Does it decrease fracture healing time?; (2) Can it be an alternative treatment for nonunion?; (3) Does it aid the union of AFF?

**LITERATURE REVIEW**

This review was conducted according to the updated guidelines of the Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols.[17] A multiple database search including PubMed, EMBASE, and Cochrane Library was performed using the search terms: (“recombinant human parathyroid hormone 1-34” [All Fields] OR “recombinant human parathyroid hormone 1-84” [All Fields] OR “teriparatide” [All Fields] OR “abaloparatide” [All Fields] OR “Forsteo” [All Fields] OR “Teribone” [All Fields]) AND (“fractures, bone” [MeSH Terms] OR (“fractures” [All Fields] AND “bone” [All Fields]) OR “bone fractures” [All Fields] OR “osteoporotic fracture” [All Fields]) between 1 January 1960 and 31 June 2020.

Studies were eligible for inclusion if patients were treated with daily 20 or 40 μg of recombinant human parathyroid hormone (PTH; 1-34) or weekly 56.5 μg to induce fracture healing or nonunion. We excluded patients with illnesses that affect bone or calcium metabolism underwent surgical treatment for pathologic fracture. After screening the studies identified by the search, 113 citations relevant articles were reviewed, and 57 key publications were selected (Fig. 1).

1. Does TPTD decrease the fracture healing time?

Shortening the healing time can be important, especial-
ly for elderly patients, who have a long healing time. For example, intertrochanteric fractures are usually fixed enough to load-bearing, but each step is painful over many weeks until the fracture is healed.[18,19] TPTD is occasionally used off-label to accelerate fracture healing and has been reported to improve mechanical properties of fracture callus, bone-implant contact, and strength at the fracture site.[15,20]

There were 2 studies that showed that short-term daily TPTD use improved radiographic fracture healing of a hip fracture and reduced complication rates. Huang et al. [21] retrospectively reviewed 255 intertrochanteric fractures (AO type 31-A1 fractures and limited to patients treated using a dynamic hip screw). A significantly shorter time-to-union (mean, 12.3 vs. 10.6 weeks, respectively \( P=0.002 \)) and improved pain function score were found in the TPTD-treated groups [21] Kim et al. [22] retrospectively assessed 112 unstable intertrochanteric fractures that had been treated using proximal femoral nail and a daily subcutaneous injection of TPTD was used in 52 of 112 patients. TPTD significantly decreased mean time to fracture healing (12.1 vs. 14.8 weeks; \( P=0.002 \)) and VAS pain scores (\( P=0.008 \)) and increased function score (\( P=0.02 \)). The frequency of patients reporting postoperative surgery-related complications was also markedly lower in the TPTD-treated groups in both studies.[22,23]

Intermittent TPTD administration also has been reported to accelerate pelvic fracture and distal radial fracture healing by enhancing callus formation.[24-26] Sixty-five patients who had been treated with pelvic fractures divided into 21 patients received a once-daily injection of 100 mg of PTH 1-84, and 44 patients served as the control group. At week 8, all fractures in the treatment group and 4 fractures in the control group had healed (healing rate, 100% vs. 9.1%) and mean pain and function score (time up and go test, 22.9 vs. 54.3 sec; \( P<0.001 \)), even nonunion was not detected at the latest visit.[27]

To date, 2 meta-analyses have been performed to determine the effectiveness of TPTD on fracture healing time, and their results were in conflict. One meta-analysis of patients with osteoporotic fractures found a significantly shorter healing time in the TPTD-treated group.[28] Another meta-analysis, including nonosteoporotic fractures did not demonstrate effectiveness for TPTD with regard to faster union, but only 2 studies were analyzed in this meta-analysis.[29]

One study reported radiographic features of TPTD-induced healing in femoral insufficiency fracture.[30] Callus formation was found at a very early stage at 2 weeks after treatment. Moreover, abundant callus formation was found circumferentially around the cortex with a ‘cloud-like’ appearance. They also found that normal remodeling of the TPTD-induced callus was observed on plain radiographs after 1 year. These findings indicate that TPTD can be used as an adjuvant therapy as induce in the management of femoral insufficiency fractures.[31,32]

We believed that clinicians may still expect that TPTD use can contribute to fracture healing time and functional recovery in osteoporotic fracture patients. It is still not known whether a standard dose or duration of TPTD is optimal, and these results were limited by the paucity of the randomized studies, so more high-quality randomized controlled trials (RCTs) are still needed.[33]

2. Can TPTD be an alternative for nonunion?

The nonunion of fractures remains a challenging and clinically important problem in orthopaedic surgery. In the last years, many case reports about the efficacy of the use of TPTD off-label in the therapy of nonunions were presented.[34-37]

Many cases have reported the successful use of TPTD in many different fracture nonunion sites such as: the sternum, odontoid, radius, humerus, femur, and ulna and even Charcot arthropathy.[35,37-41] Treating nonunions with TPTD could be of great interest mainly because it allows patients to avoid another surgery and autograft associated problems, such as donor site pain or neurovascular injury.[42,43] In addition to its effectiveness in treating nonunion, there were no side effects that occurred in all case reports during the follow-up period. Several animal studies have shown that PTPD by dual mechanism of action, influencing both bone formation activity and bone resorption.[8,9,44,45] PTPD up-regulate gene markers associated with osteoblast differentiation and an inhibitor of the Wnt pathway.[6,46]

Successful attempt to use of TPTD even after revision surgery of nonunion has been published.[47] Surgeons can be very frustrated when nonunion not allowing its healing even if revision is well-performed according to the principles (surgical restabilization and provision of biological
A 45-year-old man with femoral shaft fracture nonunion at which the original intramedullary nail was revised with internal fixation using an anatomical plate together with autogenous bone graft. However, reoperation again failed to heal the fracture in the next 12 months. Successful union was obtained after once-daily administration (20 μg/day) of TPTD for 9 months. This report highlights the needs for prospective randomized clinical trials with larger patient groups to compare the effectiveness of TPTD and autogenous bone grafting in treating fracture non-union.[43,47,50]

The accumulated evidence suggests that TPTD treatment can enhance fracture healing, but the optimal timing, treatment duration, dose, dosing interval, and form of TPTD remain uncertain.[51-54] In humans, PTH doses that are approved to treat postmenopausal osteoporosis: 20 mg/day TPTD (4.9 nmoles, in the US) or 100 mg/day PTH 1-84 (10.6 nmoles, in Europe). With regard to the form and dose of PTH, most reports describe the use of daily TPTD. The reported TPTD treatments at 20 μg/day for 3 to 9 months resulted in a successful union in all reports (Table 1).

Periprosthetic fracture after arthroplasty also considered as a fracture with a high risk of nonunion, especially in elderly patients with severe osteoporosis. Thus, TPTD is widely used to preserve or improve periprosthetic bone mineral density after total knee arthroplasty (TKA) or total hip arthroplasty for osteoporotic patients.[55] Several reports suggest that TPTD may give a further boost in healing process in periprosthetic fracture.[14,56] One case report has shown that nonunion of periprosthetic fracture after TKA, that occurred even after the patient underwent internal fixation and bone grafting twice, was successfully fused after simple administration of once-weekly TPTD.[53]

Based on the recent reports, the use of TPTD can be a promising treatment to improve the healing of nonunion, when fracture environments do not permit its healing. However, the general principles in the treatment of nonunion mandatory and infection also should be excluded before the use of TPTD.

3. Does TPTD aid the union of AFF?

There are several studies that TPTD treatment can aid fracture healing in patients with AFF.[57-60] One retrospective study compared 2 groups, AFFs were treated TPTD (n = 21) and not-TPTD (n = 24) groups. All TPTD group showed faster healing time (5.4 ± 1.5 vs. 8.6 ± 4.7 months; P = 0.012), and low frequency of delayed healing or nonunion (P = 0.012). [61] Yeh et al. [62] also retrospectively examined 13 female patients with a total of 16 AFFs that all treated with an intramedullary fixation and divided into 2 groups (8 AFFs in TPTD-treated group vs. 8 in non-TPTD group). The mean time to bone union was shorter in the TPTD-treated group (4.4 vs. 6.2 months; P = 0.116), and union rate within 6 months was also higher in the TPTD-treated group (75% [6/8] vs. 50% [4/8]; P = 0.3) achieved.

In 1 prospective study involving 14 consecutive AFF patients, 5 patients treated with TPTD for 6 months was associated with increased bone remodelling and partial or complete healing of atypical fractures and pain relief.[63] TPTD might increase bone remodeling resulting in the removal of more completely mineralised bone and replacement with newly synthesized and less densely mineralised bone. [12] One multicenter study retrospectively reviewed 46 AFFs from 7 institutions, and TPTD decreased the time to union (24.9 vs. 19.7 weeks; P = 0.08).[1]

But the studies are not sufficiently powered because

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**Table 1. Review of case studies which reported successful treatment of nonunion by use of teriparatide**

| References     | Year | Site                        | Age of patient (yr) | Type of nonunion | Use of teriparatide | Duration of treatment (months) | Time to complete union after therapy (months) |
|----------------|------|-----------------------------|---------------------|------------------|---------------------|-------------------------------|-----------------------------------------------|
| Tsai and Hu    | 2019 | Femur shaft                 | 60                  | Atrophic         | 20 μg/d             | 6                             | 6                              |
| Yu and Guo     | 2017 | Femur shaft                 | 45                  | Hypertrophic     | 20 μg/d             | 9                             | 6                              |
| Xiaofeng et al | 2017 | Femur and tibia shaft       | 44                  | Hypertrophic     | 20 μg/d             | 8                             | 12                             |
| Mancilla et al | 2015 | Femur and tibia shaft       | 19-64               | Atrophic         | 20 μg/d             | 3-9                           | 3-9                            |
| Mitani         | 2013 | Femur neck                  | 88                  | Atrophic         | 56.5 μg/wk          | 9                             | 6                              |
| Ochi et al     | 2013 | Periprosthetic fracture     | 74                  | Atrophic         | 20 μg/d             | 6                             | 6                              |
| Giannott et al | 2013 | Distal femur metaphysis     | 80                  | Atrophic         | 20 μg/d             | 3                             | 3                              |
| Lee et al      | 2012 | Femur neck and shaft        | 29-64               | Oligotrophic/Atrophic | 20 μg/d             | 3-9                           | 3-9                            |
they were all case reports and case series and there is still a lack of level 1 studies on the evidence of TPTD in promoting bone healing in AFF. It is difficult to set up an adequately powered study because of the low incidence of AFF and healing of AFF can be affected by variables such as lower limb geometry (greater curvature of the femoral diaphysis) and location of fracture (subtrochanteric or diaphysis).[64-66] Above all, these results should be implied that TPTD works best when the fracture site is stable, either inherently or with surgical fixation.[67,68]

The European Calcified Tissue Society suggested the use of TPTD after surgery of AFFs, even though strong evidence for improved fracture union is lacking.[59] However, there is a clear need for RCTs to evaluate whether TPTD enhances the union of AFF may contribute to the risk of AFF.

CONCLUSIONS

Although TPTD might reduce the risk of nonunion, it appears from animal data as well as the present study that the main clinical advantage of using TPTD would be an acceleration of time to fracture healing and enhanced bone formation. Thus, one could hypothesize the possibility of medical treatment with TPTD both as a preventive way and also as a support to the synthesis in high risk of nonunion fractures and complexed fractures in osteoporotic bone.

DECLARATIONS

Ethics approval and consent to participate
Not applicable.

Conflict of interest
No potential conflict of interest relevant to this article was reported.

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