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The Final thesis

Nonunion of Osteoporotic Pelvic Fractures

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1. Summary

This master's thesis reports a case of a 63-year-old woman who sustained a non-traumatic osteoporotic fragility fracture of the pelvis. The original imaging results showed only a small fracture of the upper and lower pubic ramus on the left, which resulted in her being treated conservatively. Over the course of a following weeks her symptoms worsened, and it was only then that it was discovered that she had also sustained a full fracture of the right ilium. Additionally, the imaging showed that the pubic ramus fractures had not healed properly, causing a fracture nonunion. At this point she was given a bone density scan which led her being diagnosed with osteoporosis. She was then started on bisphosphonates. Her fractures were still treated conservatively, and the added bisphosphonate regimen did very little to improve her condition. She was then moved from bisphosphonates to teriparatide. Just under a year after starting on teriparatide there was consolidation of bone, her mobility had improved, and her pain reduced. In this thesis the current research is examined regarding the use of teriparatide as a treatment option for osteoporotic patients with pelvic nonunion fractures. With the present data available this thesis looks at the benefits and limitations of using teriparatide both in the non-interventional and interventional treatment methods of pelvic nonunion fractures and attempts to make recommendations for future research.

1.1. Keywords

Fracture nonunion, Pelvic fracture, Osteoporosis, Osteoporotic fracture, Fragility Fracture, Parathyroid hormone, Teriparatide, Rommense classification.

2. Introduction

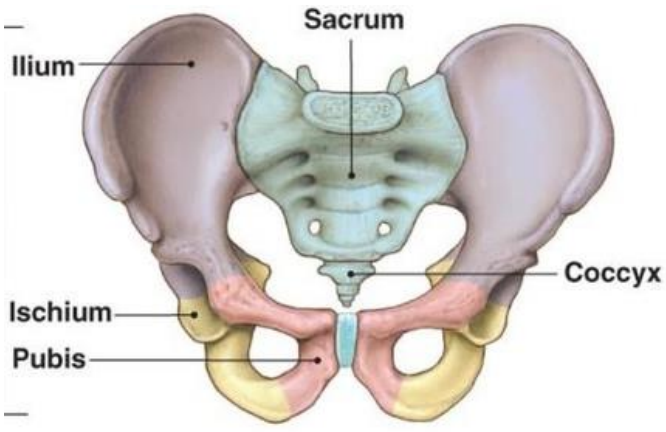
2.1. Anatomy of the pelvic girdle

The pelvic girdle is a multi-surfaced bone structure that transfers the weight of the upper body to the lower limbs, with both lower limb and trunk muscles attaching to it. The primary function of the pelvis is to create the support and stability for the different movements of the body such as standing, walking, and running among others. The bony pelvis forms an important load-bearing structure. It is

divided in to the anterior and posterior parts. The anterior part, also known as the pelvic girdle, consist of the 3 fused bones: pubis, the ischium and the ilium, sometimes called the innominate bones. The posterior part known as the pelvic spine, includes the coccyx and sacrum. The structure known as pelvic ring is made up of the sacrum and two innominate bones. The stability of the pelvic ring is dependent on the surrounding ligament structures. (1).

2.2. Supporting function of the ligaments

The ligaments of pelvic bones are crucial in providing flexibility in strength to the pelvic cavity and bring support to some of the internal pelvic structures. The ligaments of the pelvis that are the most crucial for the stability and function are the sacrotuberous, sacrospinous, and iliolumbar ligaments. The other ligaments in both sexes are the anterior sacroiliac, anterior sacrococcygeal, posterior sacroiliac, posterior sacrococcygeal, and pectineal ligaments. Further specific ligaments in the female pelvis are the broad ligament and ligaments of the ovaries and uterus. The sacrotuberous ligament provides both strength and stability to the posterior pelvis. The sacrotuberous ligament assisted by the sacrospinous ligament prevent the rotation of the ilium past the sacrum. The iliolumbar ligament both stabilise and strengthen the lumbosacral joint, thus by restricting the joints rotational movement. Sacroiliac ligaments provide structural support to the sacroiliac joint complex. The intraosseous sacroiliac ligament gives the largest and the sturdiest support of the sacroiliac joint (2).



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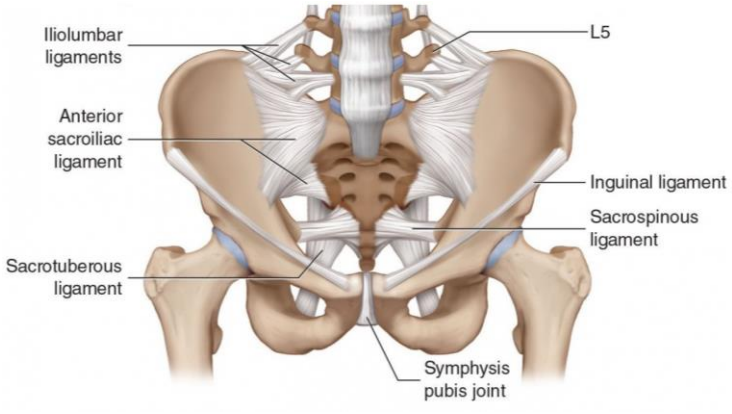
Picture 1 - The bones of the pelvis



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Picture 2 - The ligaments of the pelvis

2.3. Fragility fractures (and Fragility fractures of the Pelvis) and osteoporosis

Osteoporosis is the decrease in bone mineral density and bone mass that causes a reduction in bone strength and structure. There are several factors that increase a person's risk to develop osteoporosis, and even if osteoporosis can occur at any age, the risk of developing it increases with aging, thus the prevalence is mainly in the elderly population. The female gender, especially post-menopausal females, are of the highest risk to develop osteoporosis (5).

In patients with osteoporosis the bone mass has depleted and the structure of the bone is destroyed to such an extent that the bone becomes fragile and fractures easily (6). A fragility fracture is a fracture that happens when a patient falls from a standing height or less. Fractures created by such low impact trauma, could only be sustained in the brittle, unstable osteoporotic bone structure (7). The terms fragility fracture, low energy fracture and osteoporotic fracture are often used synonymously as they all describe fractures that result after low energy trauma, that normally would not result in a fracture (8).

Not only are osteoporotic bones more susceptible to fractures, but their healing ability is also decreased compared to normal bone. There are several functions in the body that are influence by the aging of the person and the activities related to bone healing is one of them. The biological activity of osteoblasts, mesenchymal cells as well as formation of bone callus are all altered negatively in the elderly (9).

2.4. Nonunion of fractures

Nonunion of a bone is the body's inability to heal a fracture. Up to 95% of all fractures heal without any problems and nonunions happen only to a small percentage of fractures. A nonunion of the bone can be declared in patients that have no consolidation nine months post fracture and there are no radiographic progression of healing for three months (10). For bone healing to take place the bone needs to have good blood supply. The blood flow to the bone reduces with aging and in osteoporotic bone the blood flow is very reduced (11). Bones with limited blood supply either naturally or due to the bone's internal or external blood supply has been interrupted or destroyed by trauma are more prone to nonunion (12).

There are some differing results from studying osteoporotic bone and nonunions where some studies show that there is clear increase of fracture nonunion in patients with osteoporosis others show that even if the bone quality of the osteoporotic bone can be diminished, it does not influence the occurrence of nonunion (13,14). Even if there is a good blood flow to the pelvic girdle bones, up to 5% of all fractures of the pelvis result in malunion or nonunion. The nonunion of the pelvic structure most commonly happen where there is an unstable injury pattern that were initially managed conservatively or by external fixation only due to associated sever injury (15).

Due to the important role of the pelvic girdle as supporting and transferring the weight of the upper body as well as providing attachment points to the muscles of locomotion and posture, a fracture in the pelvis causes major disruption to the posture and movement of the body (16).

2.5. Fractures in osteoporotic bone

Due to the porous and frail structure of the osteoporotic bone, fragility fractures are often complex with more bone fragments than normal fractures. Even though the healing process in osteoporotic bone passes through the normal stages of bone healing that ends with the union of the fracture, this process is prolonged due to slower mineralisation and remodelling of the osteoporotic bone, as bone remodelling occurs on the osseous surfaces, which is decreased in osteoporotic bone, therefore having less surface available for bone remodelling (9,17).

The fractures in osteoporotic patients present a challenge when surgical fixation is needed as finding a stable fixation of an implant is difficult as the load transmitted at the interface of the bone-implant site can often exceed the tolerance of the osteoporotic bone (9). Thus, deciding factor on the best course of treatment for each patient is finding the treatment plan that would require none or only

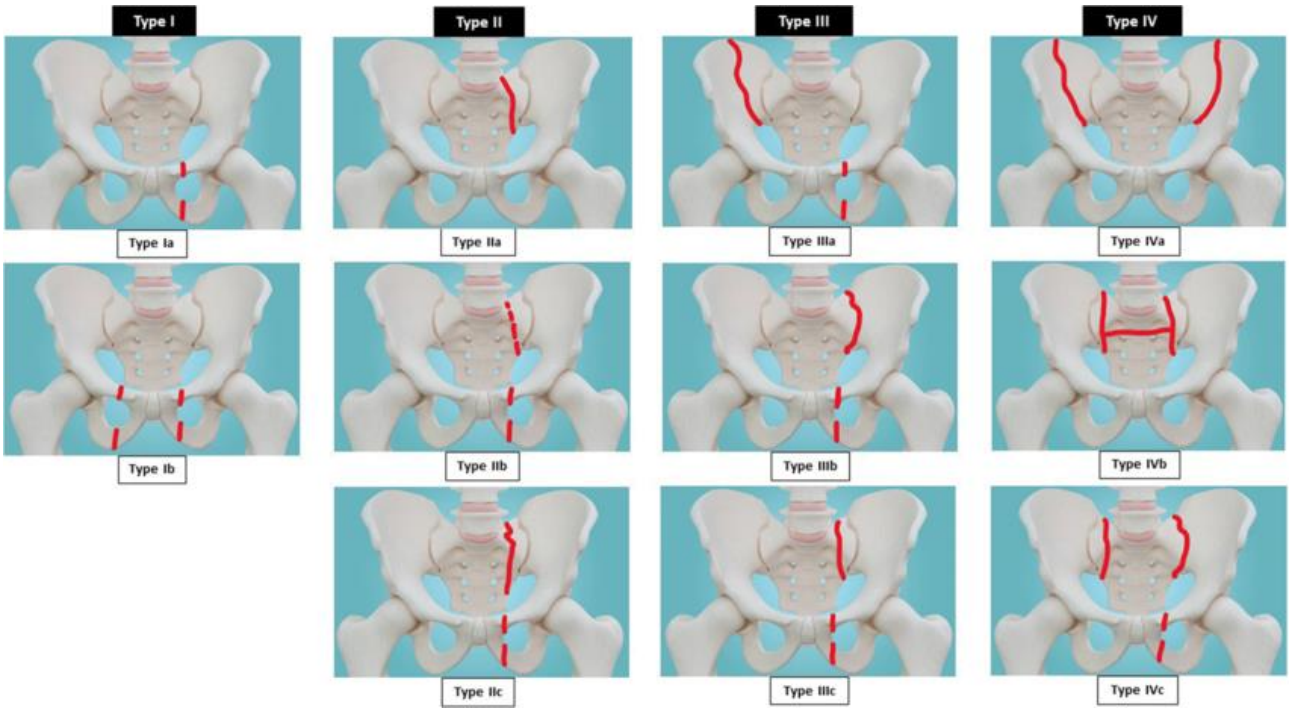
minimal revision. This means deciding between surgical and conservative approaches without knowing if the bone is stable enough to hold screws in place (7).

Fragility fractures of the pelvis (FFP) have received less clinical research than hip fractures even though they account for approximately 7% of all fragility fractures and are the cause of early mortality rate as high as 17-28% (18). The number of FFPs is showing to be increasing both in USA and Europe, this can be most likely explained by the advancing age of the general population (18).

Most pelvic fractures in osteoporotic patients occur after a low energy fall, although a small group of patients do present with fractures of the pelvis without having encountered any trauma at all (19).

The current practice in managing FFPs is surgical management, which has become more common, especially with the minimally invasive and percutaneous surgical methods. However the body of evidence regarding different treatment types for FFPs is still in its infancy without being able to show clearly what type of patients would benefit from the which type of surgical fixations (18).

The FFPs are categorised in the Rommens classification of fragility fractures of the pelvic ring is based on the degree of instability. This instability-based classification can assist in decision making regarding treatment as well as the extent of surgery. This is very helpful when treating the elderly patients that are subject to fragility fractures (20). Fragility fractures of the pelvis (FFP) are categorised into four main types with subcategories in each category. The main categories are FFP Type I, FFP Type II, FFP Type III and FFP Type IV. FFP Type I – anterior injury only, FFP Type II – non-displaced posterior injury. FFP Type III – displaced unilateral posterior injury. FFP Type IV – displaced bilateral posterior injury. These can be seen in Picture 3 below.



(18)

Picture 3 - Rommens classification of fragility fractures of the pelvis

The recommended treatment of different types of FFPs has also been included in the Rommens classification system. Such as it is recommended that Type I injures are managed non-surgically, Type II non-surgically or via percutaneous methods, and Type III and IV injuries can require more invasive or open techniques (18).

The goal of treating fragility fractures of the pelvis is to give back the best mobility and the highest degree of independence to the elderly patient. To reach this the patient's pain must be efficiently managed and starting the patient mobilisation as early as possible. Reducing the fracture anatomically and restoring the symmetry of the pelvis are less important (21). The ultimate goal of all is to get the patient as quickly as possibly painlessly mobilised and moved to their familiar environment (22).

There should be a well-structured treatment algorithm in place for the treatment and care of osteoporotic fractures of the pelvic ring to ensure appropriate treatment is started as soon as possible. If a surgical approach is chosen, the gold standard surgical methods for treating osteoporotic pelvic ring fractures are minimally invasive (MI) (22). However as pelvic ring fractures are often complicated, there are multiple treatment options available for a variety of requirements, no gold standard of fixations method exists (23).

In cases where surgery is needed it should be the least invasive as possible, the added strains to the body such as long surgeries that might include significant blood loss that causes high stress for the cardiovascular system with added possibility of hypothermia and coagulopathy are all associated with a prolongation in the recovery and greater risk of wound infections and healing problems. If possible, percutaneous procedures are preferred if adequate stability can be achieved for early mobilisation (21).

It has been shown that FFP cases of the posterior pelvic ring are almost always combined with fractures of the anterior pelvic ring. And the recommended surgical approach is that additionally to the stabilisation of the posterior pelvis, the stabilisation of the anterior pelvis should be performed at the same time(24).

Depending on the location of the ring fracture different techniques apply. For posterior ring fractures can be treated with open reduction and internal fixation (ORIF) or minimally invasive surgery including locking compression plates, reconstruction plates, spinopelvic fixation, and percutaneous sacroiliac (SI) screws. Furthermore, anterior pelvic ring injuries are mainly fixed by external fixation (EXFIX), ORIF, and minimally invasive surgery such as subcutaneous pedicle screw–rod system (INFIX), pubic ramus screw, and pelvic bridge(23).

Even if the most suitable treatment method is chosen, there is still a possibility for nonunion of the bone. To overcome this research has been starting to investigate ways to improve the quality of the bone matrix itself to improve the fracture healing (25).

2.6. Public health issues regarding osteoporosis and fragility fractures

Fragility fractures

With increased life expectancy and ever expanding size of the aging population the prevalence of osteoporosis in the population has increased over the last decades (19). In 2019 it was estimated that in Europe alone 32 million people are estimated to have osteoporosis and 4.3 million osteoporotic fractures were sustained (26).

Osteoporotic fractures lead to reduced mobility and increased dependency in patients. They also have been associated with high rates of mortality (19). Even though the healing process in osteoporotic bone passes through the normal stages of bone healing that ends with the union of the fracture, this

process is prolonged due to slower mineralisation and remodelling of the osteoporotic bone, as bone remodelling occurs on the osseous surfaces, which is decreased in osteoporotic bone, therefore having less surface available for bone remodelling (9,17).

This extended healing period that these fractures require, causes for many patients to fear the loss of independence and it is with good reason as the reality is that many patients do become more dependent on additional care some only during the long recovery process, but others for the rest of their life. The long term care needed for the treatment of these fractures is very costly to both patients and the society (27).

Fragility fractures that occur in the pelvis are associated with a greater loss of mobility and independence for the patients. It is known that for some of the patients with fragility fractures of the pelvis (FFP) their need for assistance doubles after their fracture (18).

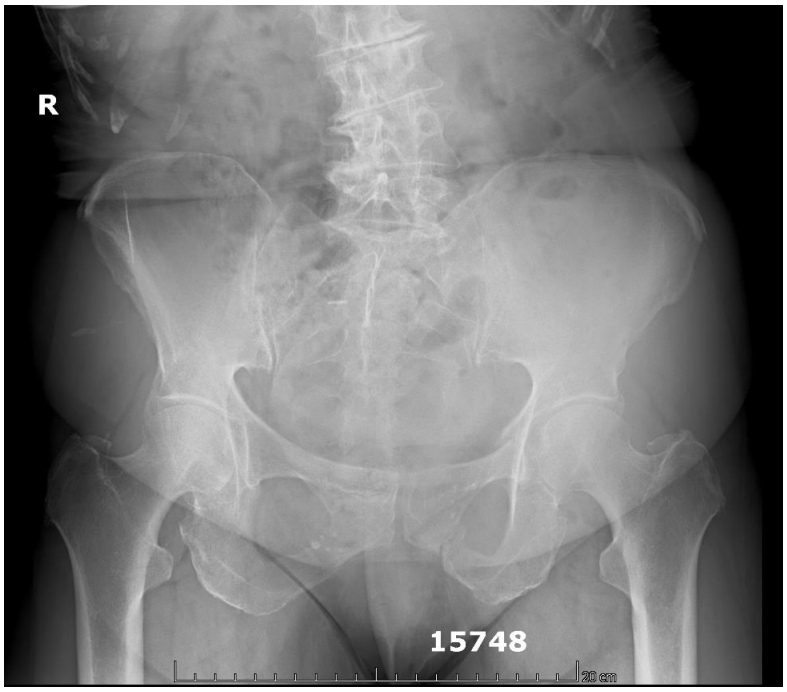
The standard treatment for fragility fractures of the pelvis can either be conservative or surgical largely depending on the type of fracture, quality of bone and what is considered to give the best result to the patient after fracture healing. Additionally, the use of parathyroid hormone has shown promising results in improving both fracture healing, mobility and reduced pain.

2. Clinical case

2.1. Case presentation

In early August 2017, a 63-year-old female patient with Parkinson' disease, presented to the Respublikinė Vilniaus universitetinė ligoninė (RVUL) hospital with back pain. She denied having experienced any trauma prior to her pain starting. The physical examination revealed that she was mobile and was able to walk.

The plain radiograph (Picture 4) showed a displaced fracture in the upper and lower pubic ramus on the left, as well as an intra-articular fracture is seen in the acetabulum. SI joints are normal. Left curved scoliosis was also visible.



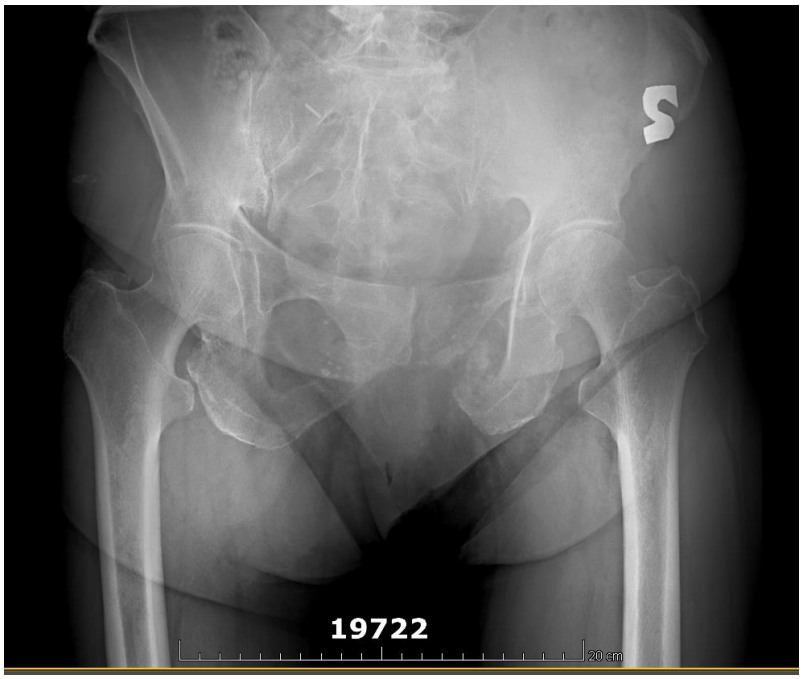
Picture 4 - Plain radiograph 4th of August 2017

The patient was treated conservatively including pain management and physical therapy and she got discharged.

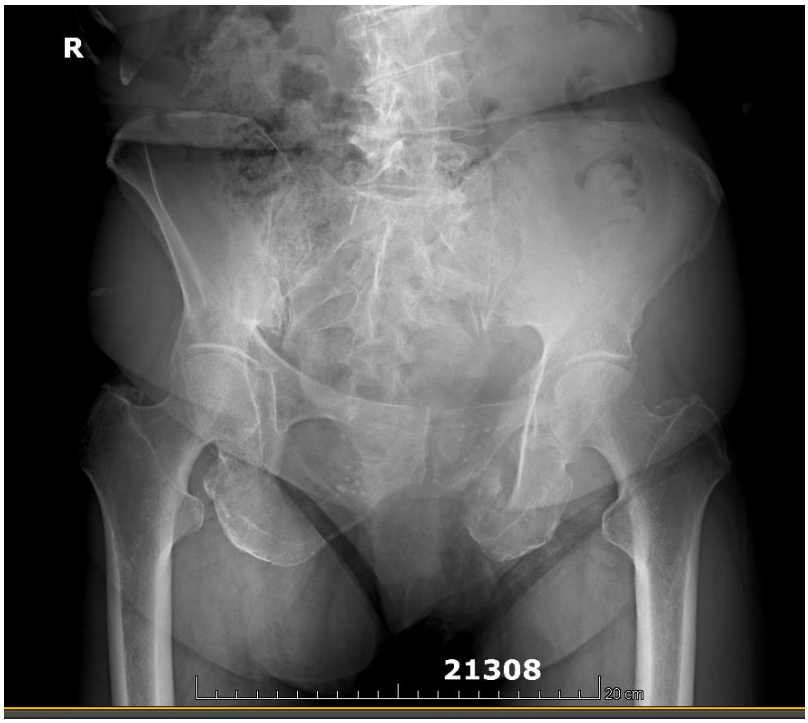
In early October 2017 she returned to her local hospital with increased pain in the back and on the right side. As a new symptom her ability to walk had declined drastically.

On 9th of October the pelvic x-ray (Picture 5) showed that the ramus fracture had displaced further. The upper ramus shows some callus development; however the lower ramus is not ossified, and the deformity can be seen here. The fracture of the acetabulum shows no change.

With almost no improvement, a second set of imaging (Picture 6) was done on the 30th of October. These showed that the situation is unchanged from the previous picture, however additionally a small nodule is visible in the ilium which may indicate a developing of a fracture.

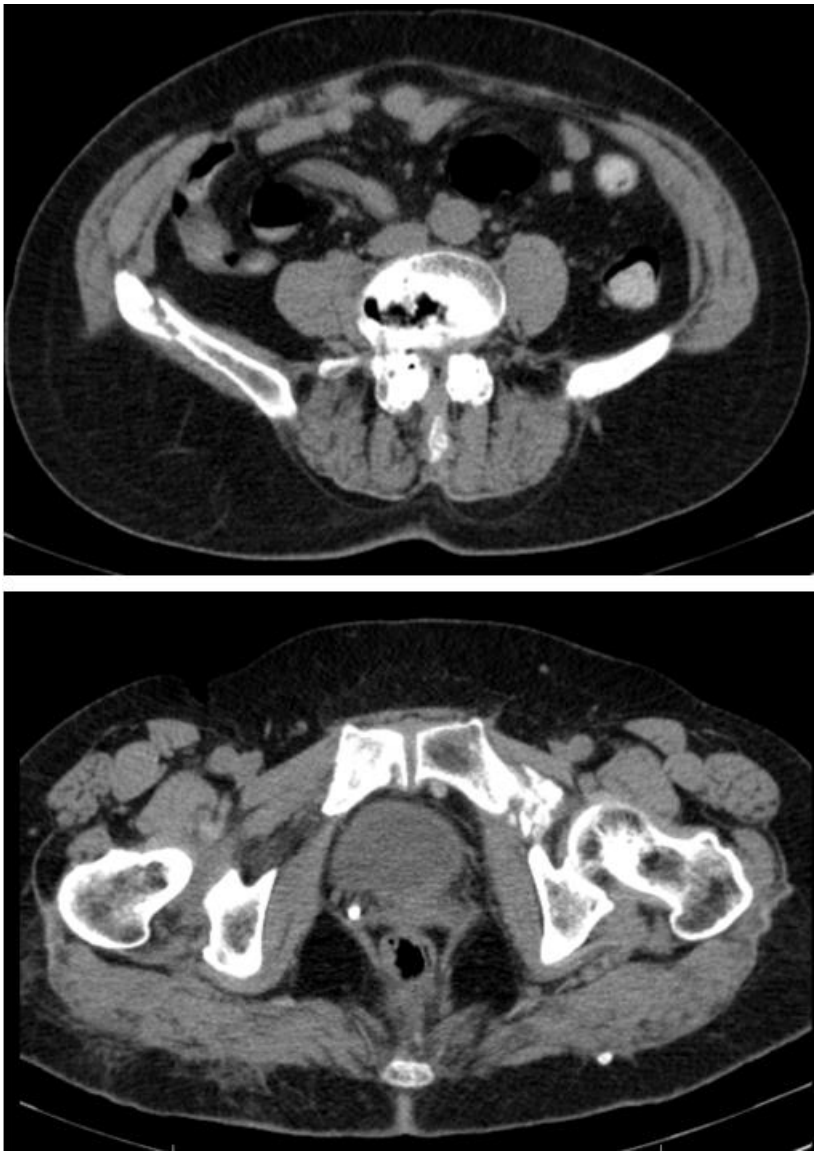


Picture 5 - Plain radiograph 9th of October 2017



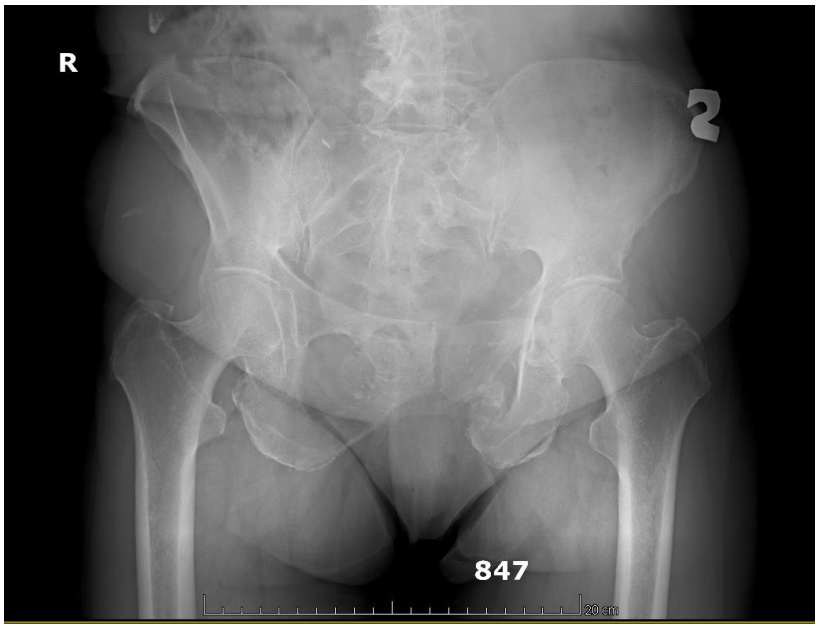
Picture 6 - Plain radiograph 30th of October 2017

To confirm the extend of the fracture, she had further imaging test done through Computer Tomography (CT) imaging that showed a trans iliac fracture of the full right ilium (Picture 7). She was then sent to (RVUL) for further treatment.



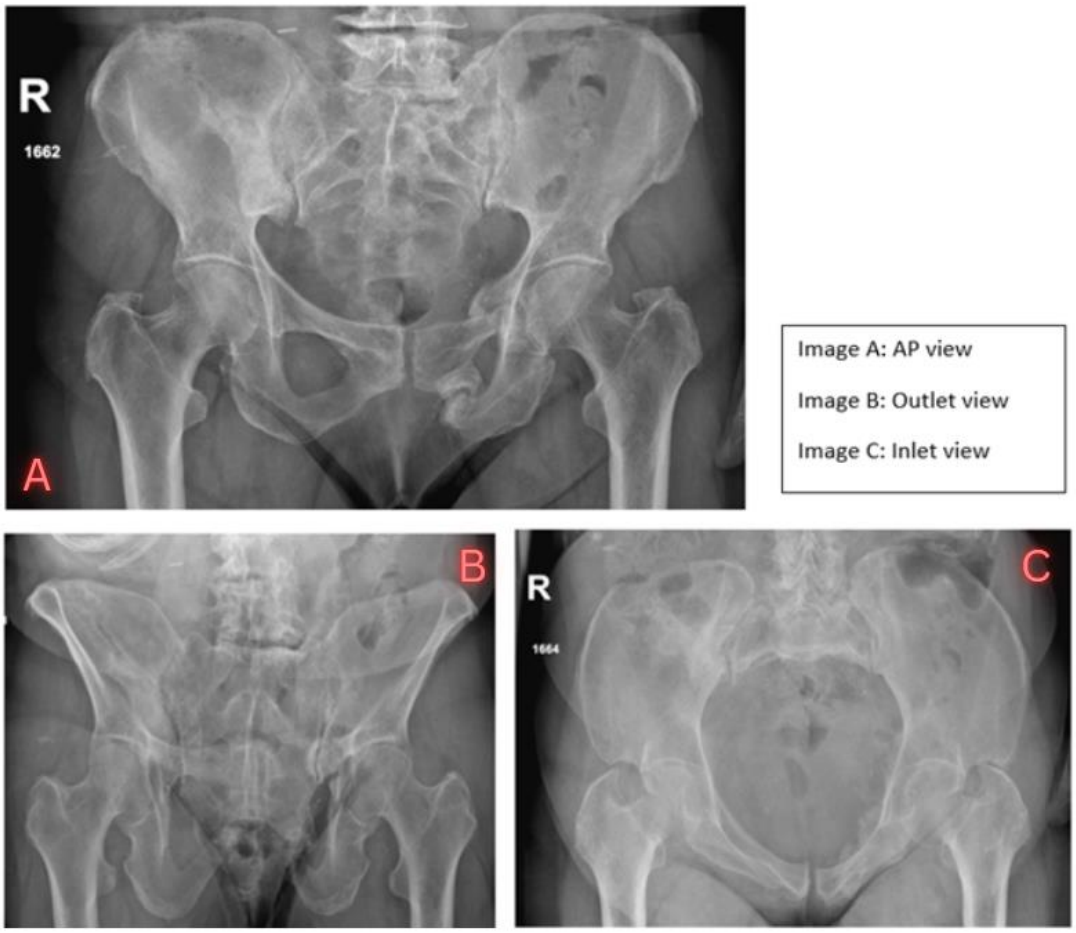
Picture 7 - CT image 30th of October 2017

Due to her fractures, she was sent to get her bone mineral density evaluated. Her DEXA (dual x-ray absorptiometry) scan was done where her T-score was below –2.5, meaning she was in the osteoporotic level. The patient started osteoporotic treatment with bisphosphonate for 6 months until January 2018 when a new set of radiographs were taken (Picture 8). The revision imaging shows that the upper and lower ribs have some calluses compared to previous photos, but the fracture lines are still visible. In addition, a new fracture running across the right side of the iliac wing is visible, with some sclerosis accumulated. No acute sclerosis visible on the right side of the hip.



Picture 8 - Plain radiograph 11th of January 2018

The patient carried on with bisphosphonate treatment until November 2018 when she was switched to teriparatide, a synthetic parathyroid hormone treatment. By October 2019 there was consolidation of the bone (Picture 9).



Picture 9 – Plain radiographs 17th of October 2019

Even though she was experiencing chronic back and right sided hip pain, she was now able to walk and be mobile. Unfortunately, after this she was lost in follow-up.

2.2. Course of treatment and outcome

The patient had a 2 year follow-up. Originally the fracture seen on imaging was a Rommense Type Ia fracture, where the recommended treatment is conservative. Thus, her initial treatment plan was conservative treatment. However, after the initial treatment, the fracture was not healed and there was a nonunion. The nonunion caused instability and reduced her ability to walk, additionally the pain increased. After the full extent of the fracture was discovered to include the ilium, changing the classification into Rommens Type IIIa fracture, where the recommended treatment is by open reduction and internal fixation (28). As she was not considered to be a good surgical candidate and she was herself opposed to surgery, she was then treated by a round of bisphosphonate which was later changed to teriparatide. Only after the teriparatide treatment consolidation of the bone was finally seen and she had regained ability to walk.

3. Discussion

Bones that have not fused after a fracture often lead to long term pain and reduced mobility. By improving the healing and stability of the nonunion fractures, not only improves the lives of the patients but also considerably reduces the burden of care for the society. In important skeletal structures, such as the pelvic girdle, non-fused bone reduces the weigh bearing of the upper body and reduced stability in walking and other movements, also makes moving painful. The porous make-up of the osteoporotic bone creates challenges in bone healing after a fracture. It takes longer to form new bone structures due to the reduced amount of bone matrix and in cases of nonunion the fractured bones never fuse.

Due to these challenges research has start to look ways to improve the quality of the bone matrix to improve surgical fixation and fractures healing. Using treatments that improve the bone mass density of osteoporotic patients not only accelerates the healing of the fractures but also strengthens the bone matrix to better resist future breaks.

Treatments focusing on bone structure such as bisphosphonate has been used as antiresorptive agent for osteoporosis from the late 1960's and teriparatide from the late 1980's (25).

3.1. Use of parathyroid hormone treatment for osteoporotic bone

There are many treatments available for women who have postmenopausal osteoporosis. Treatments that reduce bone resorption and moderately increase bone density include oestrogens, bisphosphonates, selective oestrogen-receptor modulators, calcitonin, vitamin D and calcitriol. Some of these reduce the risk of fracture but they do not restore the bone mass or bone strength. Treatments that stimulate bone formation are being considered as an improved treatment option (29).

Not only does parathyroid hormone promote bone formation and resorption, but it is also able to increase bone mass. Studies show that parathyroid hormone prevents, stop or can even somewhat reverse bone loss in humans (29). The use of a human parathyroid analogue, was approved by the European Medicines Agency in 2003 to be used as treatment for established osteoporosis (30).

3.2. Teriparatide

Teriparatide is a genetically engineered analogue of human parathyroid hormone (PTH). It is an anabolic drug that increases both osteoblastic and osteoclastic activity. It has shown great results in

treating patients with osteoporosis (31). Due to its mechanism of action parathyroid hormone produces large increments in bone mass compared to antiresorptive therapies. PTH induced bone growth allows for the restoration of the bone's microarchitecture including enhanced trabecular connectivity and increased thickness of the cortical bone. Additionally, periosteal surface bone formation could also be induced, thus it is believed to affect bone size and geometry of the bone given additional benefits to bone strengths, however these aspects have not yet been decisively confirmed (32). The recommended treatment dosage for Teriparatide is a daily subcutaneous injections of 20µg, with the treatment length being currently limited to maximum of 24 months (33,34).

The efficacy of teriparatide has been shown across a variety of studies, most notably in postmenopausal women for faster bone healing (35). Additionally it has shown to prevent vertebral and non-vertebral fractures and fracture related pain (36). It has also shown to reduce hardware related complications arising from spinal fusion (37). In a case study with only one osteoporotic patient the use of once-weekly administered teriparatide was able to create a successful bone fusion after a nonunion of a periprosthetic fracture of a total knee arthroplasty. Prior to the treatment they had been unsuccessful in achieving bone union even after internal fixation and bone grafting twice (38).

In cases where the treatment was replaced to teriparatide, it showed that switching from alendronate to teriparatide contributed to improved fracture healing (41). This has been proven as studies show that teriparatide is superior in increasing bone mass density in postmenopausal osteoporosis compared to alendronate (23).

3.3. Teriparatide usage in osteoporotic nonunion fractures

Only a few studies have been completed with the use of teriparatide in osteoporotic nonunion fractures. With the ones currently available the results are mixed.

A small placebo-controlled study of pelvic fractures that had occurred with minimal trauma on patients over 50 years showed that in both placebo and teriparatide groups, in 3 months there was no impact on pelvic fracture healing or pain in the teriparatide treated group but there was a small but significant improvement in physical performance in teriparatide group compared to placebo group. The Continuous Summary Physical Performance Score (CSPPS) and Time up and Go (TUG) were used to assess the physical performance of the patients. When comparing the results of CSPPS was significantly higher in the teriparatide groups also TUG score was improved in the treatment group compared to placebo, however after controlling for age, physical function at baseline and pain, there

was no difference in TUG between the groups (39). This is a promising result as poor physical function is associated with great impending risk for another fracture.

In another small study that looked at the differences of treating sacral insufficiency fractures on osteoporotic women, where 6 months of teriparatide treatment was compared with sacroplasty. The results were based on visual analogue score (VAS), Oswestry disability index (ODI) and radiographic studies. The study showed that after 6 months teriparatide treated patients had a significantly lower VAS score compared to sacroplasty patients, teriparatide patients also had a significantly lower ODI than the sacroplasty patient group (40).

The use of teriparatide in treating pelvic fractures was observed in a small, randomised study, the study found that at the 3-month mark there was no impact on the pelvic fracture healing when measured by CT or the amount of pain between teriparatide and placebo groups. However, a small but significant improvement was seen in physical performance in the teriparatide group compared to placebo (39).

In a meta-analysis of randomised controlled trials looking at treatment outcomes on patients using teriparatide on osteoporotic hip and pelvic bone fractures. A treatment failure was defined as nonunion, perforation of the lag screw, and if revision was required in cases due to mechanical failure of the implant during the follow-up period. Here the treatment failures in the teriparatide group was 11.0% (n=20, out of 181) compared to placebo group 17.6% (n=36 out of 205). Even if the teriparatide group had a lower treatment failure, this difference was not significant (25).

3.4. Teriparatide and surgery

On deciding on the best course of treatment for the patient many different parts play an important role. It is important to take into consideration the extent of the fractures as well as the extent of the fragility of the osteoporotic bone, as some bone is too fragile to even consider surgical intervention.

Surgical fixation of osteoporotic bone has it challenges, as there is a high rate of screw loosening that can require revision surgery. In pelvic fractures the most commonly screw loosening is located near the pubic symphysis. To reduce revision surgeries it has been recommended that doing a double plate osteosynthesis, where one plate is fixed at the pelvic brim and the other plate anteriorly, there is are less cases with screw loosening, also the screw loosening are less sever and the screws loosen at a later onset compared to a single plate osteosynthesis where the plate is at the pelvic brim (24).

The screw loosening comes down to the lower bone mineral density of osteoporotic bones affect negatively to the pullout strength, cutout torque and maximum insertional torque (41). Thus, the bone is unable to create a secure fixation between bone and screw. This would suggest that improving the quality of the bone matrix would improve the outcomes of the surgical procedures.

Study that compared the effects of non-surgical teriparatide treatment with surgical fixation and teriparatide treatment and just surgical fixation in thoracolumbar fixations. There it was shown that the 12-month functional outcomes were similar in the non-surgical treatment with teriparatide compared to surgical fixation with fusion (42). Additionally in a case where aseptic loosening of a hemiarthroplasty of an osteoporotic patient who received teriparatide treatment for 24 months, there was clinical improvement that could be associated with the disappearance of radiographic signs of loosening of the implant and a decrease in pathological radiotracer uptake in the bone scan. All of which are signs of osteointegration after teriparatide treatment (43).

4. Limitations

There are only a few studies done on the use of teriparatide on pelvic ring fractures. The number of studies and study groups have been very small in number. This has led to some of the results being inconclusive due to the results not always being consistent between studies.

5. Conclusion

Although not many studies have been conducted solely on the use of teriparatide on nonunion of the pelvic ring, a number of studies have shown that the benefits of using teriparatide to improve bone healing in osteoporotic fractures. The studies among the case study showed that using teriparatide for treating fracture nonunion can reduce pain and improve mobility even if the radiographic evidence might not be any change showing in radiographic imaging.

The research available on the topic shows that the use of parathyroid hormone analogues has provided improved outcomes after fragility fractures of the pelvis and other bones. Although results show that on CT scans the fractures do not seem to have improved with PTH treatment, however the long-term outcomes for both patient mobility and reduced pain has been shown to improve with the treatment of PTH analogues.

The studies do not show conclusive evidence that using teriparatide would be beneficial compared to placebo groups, however some studies have shown that some patients have had improved end results after using teriparatide as part of their treatment regime.

6. Recommendations

Due to the small number of studies, more research is needed in pelvic ring nonunion fracture healing and the use of parathyroid hormone within the healing of nonunions. For more comprehensive understanding of the benefits of parathyroid hormone use in pelvic nonunion fractures, more studies should be completed. However

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