

PARASPINAL MYOSITIS FROM LONG COVID AND IN POST-VACCINATION ONSET SITUATIONS: PRELIMINARY EXPERIENCE WITH OZONE THERAPY

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ABSTRACT

The Authors report their experience in the treatment of three cases of paraspinal myositis using oxygen-ozone therapy through paravertebral muscle infiltrations. In two cases, myositis developed in patients suffering from Long Covid, while the third case involved a recently vaccinated non-Covid patient (third dose). Patients included in the study were treated with intramuscular paravertebral infiltrations of an oxygen-ozone mixture, following informed consent, over ten therapeutic sessions: two per week. The results obtained were clinically assessed and subsequently confirmed by Magnetic Resonance Imaging seven days after the completion of treatment, demonstrating improvement in the imaging findings and substantial clinical recovery in the treated patients.

KEYWORDS: *paraspinal myositis, long Covid, post-acute Covid syndrome, ozonotherapy*

INTRODUCTION

Symptoms of Long Covid, which persist even after recovery from the acute phase of Covid infection, are numerous and varied. They include tiredness, chest pain or tightness, memory and concentration problems (commonly referred to as "brain fog"), insomnia, palpitations, dizziness, tingling sensations, joint and/or muscle pain, mood disorders such as depression and anxiety, tinnitus, digestive disorders, diarrhea, stomach pain, loss of appetite, cough, headache, sore throat, changes in smell or taste, skin rashes, and various symptoms that worsen after physically or mentally demanding activities, as well as fever (1-6). Reports of paraspinal myositis are increasingly documented in the literature (7-12). Additionally, during the period from January 2021 to February 2022, we clinically diagnosed and subsequently confirmed by Magnetic Resonance Imaging (MRI) eight cases of post-Covid myositis, six of which had bilateral involvement of the paraspinal muscles (Fig. 1), one showed unilateral involvement (Fig. 2), and there was a rare case of myositis of the left superior rectus muscle (Fig. 3). Furthermore, we recorded a ninth case of paraspinal myositis that arose after the third dose of the vaccine.

The causes of paraspinal myositis are to be found in the hematogenous spread and the direct invasion of the skeletal muscles through the Ace2 receptor, which have been proposed as pathogenic mechanisms that can lead to the genesis of such myositis. However, immune-mediated mechanisms are the most widely accepted, a hypothesis strengthened by similar cases described following the administration of the vaccine to underlie an autoimmune origin of the process (13-17). The diagnosis is initially clinical with subsequent confirmation by imaging, in particular the MRI

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examination without and with intravenous contrast medium administration that allows to appreciate the localization in the paraspinal muscles in the different planes of space. The therapy currently proposed is only based on anti-inflammatories.

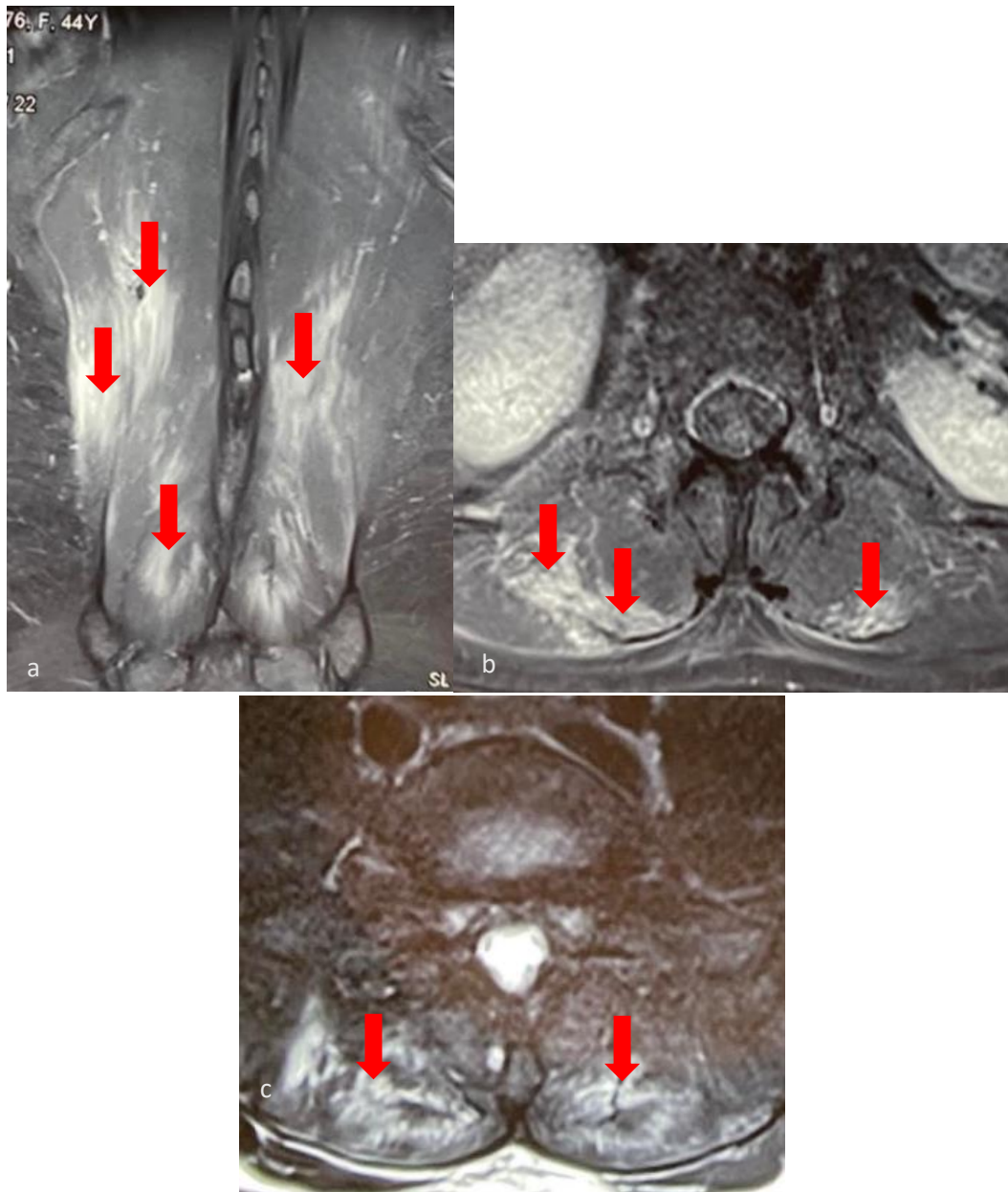


Fig. 1. (A-C): bilateral paraspinal myositis (arrows).

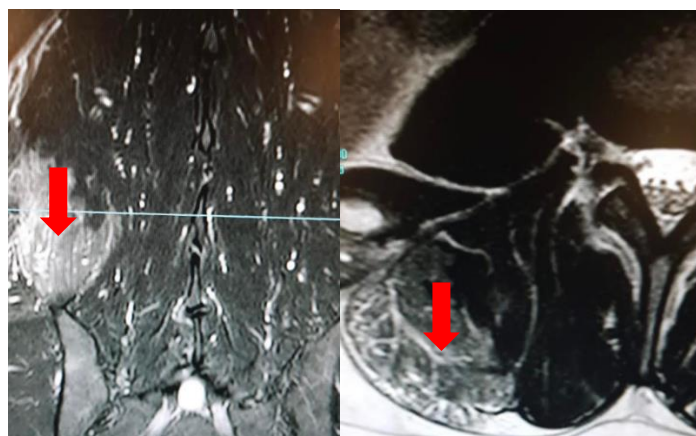


Fig. 2. (A-B): right unilateral paraspinal myositis (arrows).



Fig. 3. (A-C): myositis of the left superior rectus muscle (**arrows**).

MATERIALS AND METHODS

The authors report their experience in treating three cases of paraspinal myositis among a group of eight patients. In three of these cases, we proposed oxygen-ozone therapy (18-22), and the patients accepted this therapeutic option after providing informed consent. Two patients were affected by Long Covid (both females aged 52 and 57), while the third was a non-Covid patient (aged 72) who had recently received the third vaccination dose. Diagnosis in all cases was confirmed through MRI investigation, which documented an inflammatory state of the bilateral paraspinal musculature extending from the level of the last dorsal metamerer up to S1.

Patients were treated with paravertebral intramuscular infiltrations, using a 23 G needle (3 cm) with a blue color code, in the tract of muscle affected by the alteration of signal intensity evident in the MRI examination, injecting 2 cc of gaseous mixture for single-shot along the paravertebral muscle at a concentration of 20 $\mu\text{g/ml}$, with a notable reduction in pain symptoms already from the first therapeutic sessions.

We performed 10 therapeutic sessions every two weeks, at the end of which we repeated a control MRI examination, which highlighted in all three cases a clear improvement in the iconographic picture with partial resolution of the alteration of signal intensity of the paravertebral muscle affected by the disease (Fig. 4-6).



Fig. 4. Bilateral paraspinal myositis (**arrows**) in a patient with Long Covid.

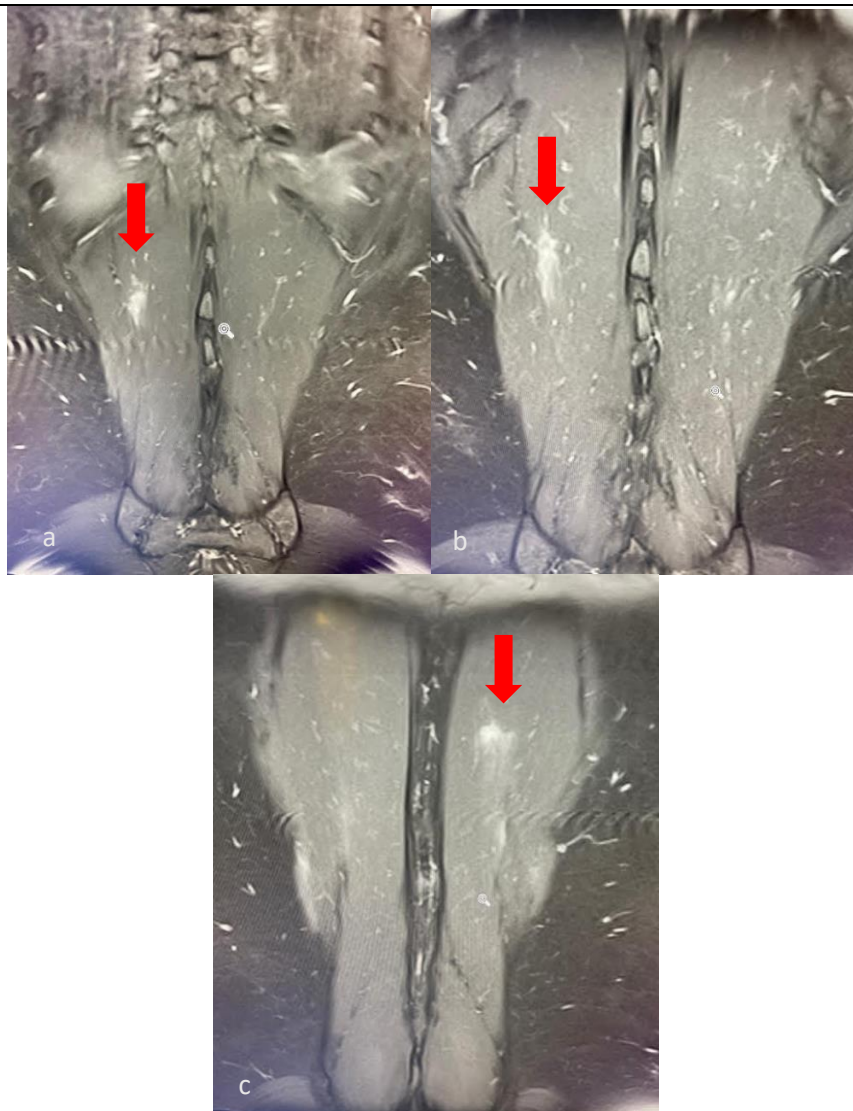


Fig. 5. (A-C): Check-up 7 days after the last infiltration with oxygen-ozone therapy (small residues are evident at the level of the paravertebral muscles bilaterally) (**arrows**).

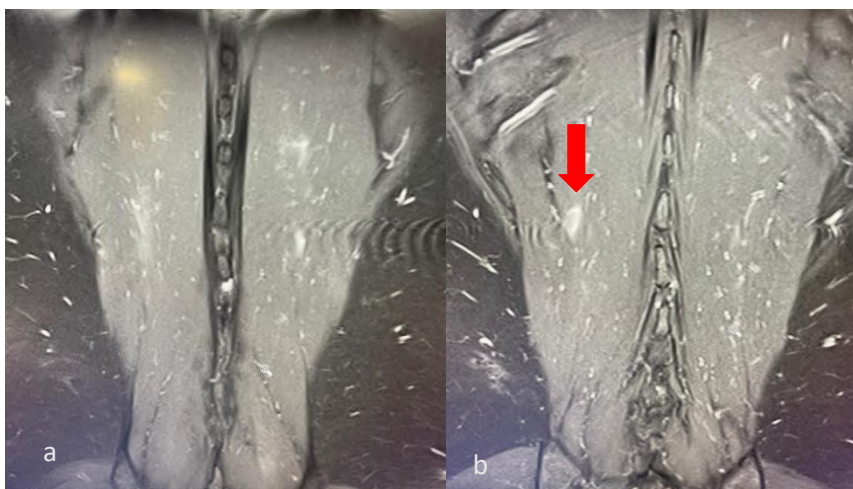


Fig 6. (A-B): one-month check-up: almost complete picture resolution, excluding a minimal residue in the right paravertebral (**arrow**).

RESULTS

Myositis is defined as inflammation of muscle tissue, which can arise from various causes: infectious (due to viruses, bacteria, or parasites), autoimmune (such as polymyositis and dermatomyositis), iatrogenic (drug-induced), or idiopathic (rare cases with no identifiable cause). Clinical symptoms of myositis include asthenia (muscle weakness), myalgia (muscle pain), muscle cramps, and muscle atrophy (reduction in muscle mass). Diagnosing myositis necessitates a thorough clinical examination, complemented by an in-depth patient history, laboratory tests, imaging, and possibly muscle biopsies.

With early diagnosis and treatment, a definitive cure is achievable in most cases. Treatment is etiology-specific, targeting the underlying cause. For autoimmune forms, high doses of corticosteroids should be initiated, with immunosuppressive agents added if necessary. In infectious myositis, rest and specific anti-inflammatory and antibiotic therapies are recommended. In cases of drug-induced myositis, the responsible medications should be promptly discontinued. Anti-inflammatories and pain relief medications are frequently utilized in cases of ossifying myositis, with abnormal bone tissue generally reabsorbing within weeks; surgical intervention is necessary if it does not. The Covid pandemic has led to a rise in post-Covid myositis cases, particularly in the paraspinal muscles (1-17).

Given the known anti-inflammatory and immunomodulatory effects of ozone therapy (18, 19), we proposed this treatment option for three patients suffering from paraspinal myositis (20-22). After obtaining informed consent, we initiated oxygen-ozone therapy for the three patients. All three displayed similar symptoms, characterized by significant myalgia and acute, disabling back pain.

The therapeutic regimen was also largely consistent: in two cases (one female aged 57 and one male aged 72), paracetamol at 1000 mg twice daily was prescribed, while the last patient received ibuprofen at 600 mg as well. During the oxygen-ozone injections, all patients continued their initially prescribed medication for the first week, which was later discontinued in light of clinical improvements associated with ozone treatment. A follow-up MRI was conducted one week after the treatment cycle for all patients, and one patient underwent an additional check-up one month later. Control MRI scans, in the face of a clinical improvement in the patients, allowed us to appreciate an improvement in the iconographic picture as well and in particular in the patient in whom we performed a second check-up one month later we were able to document the almost total normalization of the MRI picture.

DISCUSSION

Although our case study is limited to only three cases in light of the results obtained with complete resolution of the painful symptoms, we believe that oxygen-ozone therapy performed with paravertebral intramuscular technique is an excellent therapeutic option in the treatment of post-Covid and post-vaccination paraspinal myositis.

CONCLUSIONS

In conclusion, the encouraging results from our case study suggest that oxygen-ozone therapy may serve as a promising treatment modality for paraspinal myositis, particularly in patients experiencing complications related to Long Covid and post-vaccination reactions. Although our analysis is based on a limited sample size, the significant clinical improvement and corresponding MRI findings underscore the potential efficacy of this therapy. Given the growing prevalence of myositis in the context of Covid-related illnesses and vaccination, further investigation is warranted to establish more comprehensive treatment protocols and guidelines. Future studies with larger cohorts will help clarify the long-term benefits and mechanisms of action of oxygen-ozone therapy, potentially offering relief to patients suffering from debilitating myositis and contributing to the advancement of post-covid care strategies.

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Retrospective Study

HEMIARTHROPLASTY IN THE ELDERLY FOR FEMORAL NECK FRACTURES: IS THERE STILL ROOM FOR UNCEMENTED STEM? A RETROSPECTIVE STUDY

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ABSTRACT

Femoral neck fractures (FNF) are among the most common fractures in the elderly. Choosing the appropriate treatment is essential to achieve the best outcomes and reduce associated mortality. Despite several guidelines suggesting that cemented stem fixation in hemiarthroplasty for medial FNF is highly effective, the use of uncemented hemiarthroplasty (UCHA) still plays an important role. **Material and Methods:** From January 2013 to May 2018, we conducted a monocentric study that collected data on elderly patients with FNF treated with UCHA. Patients were followed up clinically and via X-rays at 1, 3, 6, and 12 months. The group was analyzed for complications, operative time, blood loss, loosening, and prosthesis survival. **Results:** A total of 638 patients (654 hips) were identified, with a median follow-up period of 25 months. Over time, 270 patients (41.3%) died. The mean age was 84.9 ± 5.41 years. Four patients (0.5%) experienced intraoperative periprosthetic fractures, and 13 patients (2%) underwent a second surgery. Ten patients (1.5%) showed calcar resorption on X-ray. The mean surgical time was 55 minutes, with an average blood loss of 245 cc. No perioperative deaths were recorded (within 0-2 days postoperatively). The implant survival rate was 98.2% at 1 year, 97.7% at 3 years, and 96.7% at 5 years. **Conclusion:** UCHA remains an excellent alternative, particularly for patients where reducing surgical time and blood loss is crucial while considering their comorbidities

KEYWORDS: femoral neck fractures, hemiarthroplasty, uncemented, cemented, prosthesis, hip, operative time, blood loss, femur, partial total hip

INTRODUCTION

Fragility fractures are increasing globally and are expected to continue rising over time. Although in some studies, age-adjusted rates seem to decline, the overall impact of hip fractures, as a significant type of fragility fracture, is widely recognized as a major health issue due to their social and economic impact (1).

In the European series, hip-fractured patients have a 30-day mortality of more than 10% and 1-year mortality of 25–30%, and it is estimated that the incidence of femoral neck fractures (FNF) with a charge of lifestyle will grow from 1.66 million in 1990 to 6.25 million in 2050 in the world. Therefore, FNFs are a growing issue in aging populations and are associated with high morbidity and mortality (2).

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Nowadays, especially in the elderly population, hip arthro/hemiarthroplasty (HA) is accepted as the ideal treatment for displaced FNF. Total hip arthroplasty (THA) is generally considered a better option for mentally competent, active, and independent patients in terms of low revision rates and better mid-long period functional results; hemiarthroplasty should be considered an effective treatment option when facing older or geriatric patients. The aim of treatment of a displaced FNF is to enable patients to walk soon on a stable and painless hip (3). According to the implant fixation method, hemiarthroplasty can be divided into 2 different types: cemented and uncemented (4).

However, controversies still exist regarding both techniques, as they have distinct advantages and complications. On the one hand, with the use of cemented arthro/hemiarthroplasty (CHA), the polymethylmethacrylate (PMMA) bone cement creates a solid bone-implant interference medium with the potential advantage of having less postoperative mid-thigh pain, lower prosthetic loosening because the femoral stem is more firmly fixed within the femur. On the other hand, in several studies, CHA is related to perioperative fat-embolic events (complications secondary to the toxic effects of cement or pulmonary embolization of bone-marrow contents and PMMA particles), cardiovascular disturbances, higher rates of early postoperative mortality and longer operative time (5, 6).

Some surgeons prefer uncemented arthro/hemiarthroplasty (UCHA) techniques since they may reduce operation time, intraoperative blood loss, and perioperative complications. Indeed, hesitation exists in the use of bone cement due to the possibility of bone cement implantation syndrome (BCIS), which may cause cardiovascular disturbances, pulmonary embolism, and, at worst, death of the patient (6).

Moreover, UCHA relies on the primary press-fit stability, with long-term stability occurring secondary to endosteal microfractures at the time of preparation and subsequent bone ingrowth. However, some authors report a higher rate of perioperative fractures and implant revisions due to subsidence, periprosthetic fractures, and lower postoperative functional scores (7, 8). Whereas other studies conclude that good results can be achieved using both techniques (8).

The National Institute for Health and Care Excellence guidelines in the UK (9) and the American Academy of Orthopedic Surgeons recommendations (10), as well as a Cochrane review (11), support the use of cemented fixation when performing arthroplasties for hip fractures in elderly patients.

A recent independent systematic meta-analysis and review, after having compared CHA and UCHA, concluded that 'there remains a need for methodologically sound, large multi-center RCT comparing modern cemented and cementless hemiarthroplasty stems in the medium and long term, not only focusing on mortality and complications but also on patient-reported outcome measures (12). However, data suggests that these guidelines are inconsistently followed in many parts of the world, and the effects of that need to be better characterized (13-15).

MATERIAL AND METHODS

In this mono-centric retrospective study, all patients referred to our Orthopedic and Trauma Department (Santa Maria delle Croci Hospital, Ravenna – Italy) for displaced FNFs and treated with UCHA from January 2013 to March 2018 were enrolled.

Inclusion criteria were displaced FNF (Garden classification type III-IV), patients aged >65 years old, and no concurrent joint disease or previous hip fracture. Exclusion criteria were patients having undisplaced or minimally displaced intracapsular hip fractures (Garden I–II), previous treatment to the same hip for a fracture, and those having rheumatoid arthritis or symptomatic osteoarthritis. We also excluded patients deemed unsuitable for surgical procedures by the anesthesiologist. The inclusion and exclusion criteria adopted in the patient selection for this study are shown in Table I.

Table I. *Inclusion and exclusion criteria.*

Inclusion criteria	Exclusion criteria
Displaced intracapsular hip fracture (Garden III-IV)	Age < 65
Age >65 yo	Previous treatment to the same hip for a fracture
No current joint disease	Diagnosis of rheumatoid arthritis or symptomatic osteoarthritis
Suitable for surgical procedures by the anesthesiologist	Unsuitable for surgical procedures by the anesthesiologist

Since 2010, our surgical team has routinely used UCHA, relying on the theoretical advantages of a shorter operative time and avoiding the specific cardiovascular complications related to the cementing technique.

All the patients were elderly, ranging from 65 to 105 years old, unfit for total hip arthroplasty because of preexisting comorbidities associated with low life expectancy and/or low functional demand and autonomy status or both. Two types of femoral stems were used over the years: the Zweymuller Alloclassic Zimmer stem and the Korus one.

Physical examination and radiographs were performed at the first access in the Emergency Department. All patients received perioperative antibiotic prophylaxis with Cefazolin 2g. All surgical procedures are performed through the recommended posterior-lateral approach. We always applied subfascial surgical drains. After 48 hours the drain was removed and the patient began the rehabilitation process, maintaining the sitting position on the first day and on the following day, starting with walker-supported walking. Patients' clinical and X-ray follow-up was after surgery at 1, 3, 6, and 12 months and then for any complications or clinical problems. All postoperative X-rays were performed in our hospital and recorded in the same database so we could easily check all further controls that were prescribed, such as the radiographic evolution of the affected hip. Standard views (anteroposterior and axial) were performed in X-ray control. We analyzed iatrogenic fractures, osteolysis area, and radiolucent lines in the stem region according to Vresilovic criteria (16). Calcar resorption, stem correct fitting, and heterotopic ossification were also assessed.

All data, including age, gender, type of treatment, intraoperative bleeding volume, intervention time, and mortality rate (during surgery until discharge), was collected in our surgical registry database, compiled after each operation, and sent to the RIPO regional register. The latter allowed us to monitor any postoperative complications that required revision surgery. The overall survival of the implant was further analyzed using the Kaplan-Meier method.

The main endpoint is the failure of any prosthetic component. The end of follow-up was December 2018, or if the patient's death date is before this date. Verbal and written informed consent was obtained from all patients before the beginning of the study. The present study was carried out in accordance with the approved guidelines.

RESULTS

Over five years, 638 patients (sixteen treated bilaterally for 654 implants) with FNF in Santa Maria delle Croci Hospital (Ravenna, Italy) underwent UCHA. 185 (28.3%) were men, and 469 (71.3%) were female. The mean duration of follow-up was reported to be almost 2.1-year follow-up (0-6 years range). The mean age was 84.9 during the surgery (range 65-105). 270 patients (41.3% of the whole) in total 272 prostheses died by the end of follow-up. 389 were type III hip fractures according to Garden classification, and 265 were type IV. We registered 4 cases of periprosthetic fractures (0,5%) (2 A and 2 B1 according to Vancouver classification) treated with cerclage wire or plate and screws. 13 patients (2%) had postoperative complications which required a second surgery: 3 patients (0.5%) suffered from cotyloiditis; 3 (0.5%) reported a dislocation of the implant and 3 cases (0,5%) had non-specific problems (focused pain in the operated limb, Trendelenburg limp or snapping sensation). Four patients (0,5%) developed septic loosening of the implant: 3 underwent debridement and prosthetic replacement, and 1 was treated with implant removal, antibiotic therapy, and revision implant at infection-index normalization (Table II).

Table II. *Intraoperative and postoperative total complication rate in uncemented group.*

<i>Complications</i>	<i>Number</i>	<i>Percent</i>
Cotyloiditis	3	0.5%
Primary instability	-	-
Dislocation	3	0.5%
Septic loosening	4	0.5%
Intraoperative fracture	4	0.5%
Calcar resorption	10	1.5%
Other	3	0.5%
Total	27	4.1 %

We noticed calcar resorption in 10 patients' X-ray controls (1,5%). The survival curves were calculated using the Kaplan-Meier method at 1, 3, and 5 years. Our population's implant survival rate is 98.2% at 1 year, 97.7% at 3 years,

and 96.7% at 5 years. The mean intervention time was 55 minutes (45 to 70 minutes), and the mean intraoperative bleeding volume was 245 cc. Among our patients, we registered no perioperative deaths (0–2 days postoperatively).

DISCUSSION

The debate regarding the relative merits of UCHA versus CHA hips continues today as vehemently as it has since their introduction. With the trends of global aging, FNF has become an increasingly serious problem, especially for elderly patients (2). Comparisons between surgical techniques favored CHA fixation because of its superior pain relief, better postoperative hip functionality, and fewer loosening prostheses and periprosthetic fractures (17).

However, many hip-fractured patients endured significant cardiovascular and cerebral comorbidities with little functional reserve. In these frail patients, some surgeons prefer to apply the UCHA technique because they believe it may reduce the operation time and the intraoperative blood loss. Indeed, considerable evidence suggests that cementing has potential adverse physiological side effects. For example, cardiorespiratory collapse and cardiac arrhythmia, which occasionally occur upon cement application, are caused by the embolism of marrow contents forced into circulation or by the direct toxic effects of the cement (18).

Pitto et al. (19) showed severe embolic events and intraoperative pulmonary impairments during fixation of the cemented femoral component in total hip arthroplasty. In contrast, fixation without cement demonstrated lower risks of embolism. The use of cement in arthroplasty also raises concern regarding the relatively rare but significant complication known as BCIS. Although there is no standardized definition of BCIS, it is generally characterized by a collection of cardiopulmonary symptoms, including hypoxia, hypotension, arrhythmia, and cardiac arrest associated with fat and bone marrow embolization that may occur during femoral reaming and cementation (19).

Due to the spectrum of symptoms that encompass BCIS, the true incidence of this syndrome is difficult to identify (6). Therefore, guidelines minimizing the risk for bone-cement implantation syndrome both by surgeons and anesthesiologists have been published (20). In literature, mid-thigh pain is more prevalent in uncemented prostheses. However, the reported incidence differs tremendously (21).

Several factors can influence postoperative mid-thigh pain, including sizing, design, and prosthetic stiffness. Major doubts regarding UCHA in the literature have been generated by the propensity for intraoperative and postoperative periprosthetic fractures. Late postoperative periprosthetic fractures and revisions caused by failure of osteointegration are known risks when using uncemented stems in elderly patients (22).

Nonetheless, our results and findings were similar to those of DeAngelis et al. regarding intraoperative periprosthetic fractures in randomized controlled trials of 130 patients with 1-year follow-ups, which indicated that uncemented stems could be used for elderly patients with osteoporotic FNF without a high risk of periprosthetic fractures (8).

Based on our results, there are more advantages of using a UCHA: less intraoperative bleeding and a shorter duration of surgery. In our study, the mean operation time was 55 minutes, and the mean bleeding volume was 245cc, according to several studies in the literature. Also, Carpintero et al. and Klestil et al. showed that the mean time of surgery and bleeding volume were higher in the cemented group (23, 24).

More recently, Inngul and colleagues (25) conducted a randomized clinical trial among 141 patients undergoing arthroplasty for FNF in Sweden and found cemented fixation to be associated with fewer periprosthetic fractures, as well as better outcomes as measured by the Harris Hip Scale, Short Musculoskeletal Functional Assessment, and EuroQol-5D scores. The specific reasons for the improved outcomes observed among patients undergoing CHA have not been definitively elucidated. However, one theory is that cemented fixation may better resist periprosthetic fracture among patients with risk factors such as advanced age, osteoporosis, and/or a history of falls (26).

Despite these recommendations, most hemiarthroplasties performed in the US continue to use uncemented fixation. Among patients with hip fracture treated with hemiarthroplasty in a large US integrated health care system, uncemented fixation, compared with cemented fixation, was associated with a statistically significantly higher risk of aseptic revision. These findings suggest that US surgeons should consider cemented fixation in the hemiarthroplasty treatment of displaced FNF in the absence of contraindications (27).

In an analysis of 2017 data from the American Joint Replacement Registry, for example, uncemented stem designs were still used in 60% of all hemiarthroplasties performed. There are many possible explanations for the continued use of UCHA fixation in the US. On the one hand, some surgeons may be concerned regarding the risks of bone cement implantation syndrome; on the other hand, the cemented fixation takes more time, and if a revision surgery is needed in the future, cement removal can be difficult, so they may not feel as comfortable implanting a cemented prosthesis. This poses a paradox in which common practice does not reflect the available evidence. It is unclear why surgeons worldwide

are making this choice. Still, it is likely related to multiple factors, including the historical concern for “cement disease” (which describes osteolysis attributed to the cement, leading to implant loosening and failure), surgeon bias and training practices (28).

Compared to modern uncemented femoral stem designs, cemented stems yield lower rates of periprosthetic fracture requiring re-operation without increasing the risk of all-cause mortality. Tapered-wedge stems had similar re-operation rates due to periprosthetic fracture as reamed uncemented stems (29). The survival curves were calculated using the Kaplan-Meier method at 1, 3, and 5 years. In our population, the implant survival rate was 98.2% at 1 year, 97.7% at 3 years, and 96.7% at 5 years, and this result can be considered highly satisfactory.

There are earlier studies in the literature reporting increased early postoperative mortality in patients treated with cemented HA. These numbers may include deaths due to BCIS; nonetheless, this could not be confirmed as we did not have access to the cause of death. However, this difference vanished after adjusting data for age, gender, and ASA class, suggesting that the difference was not due to cementing (30). Among our patients, we found no perioperative deaths (0-2 days postoperatively). In the registry studies from Australia and the UK, there has not been an increase in early postoperative mortality when comparing cemented and uncemented implants. Cementing may still be a safe option in both elective and hip fracture arthroplasty. However, in the most fragile HA patient group, caution is needed during cementation (30).

CONCLUSIONS

Although cemented arthroplasty is considered the gold standard in literature for the treatment of displaced FNF in the elderly, many surgeons like us prefer to go on with uncemented technique since the postoperative mortality appears to be similar for UCHA and CHA.

Our study showed that uncemented implant survival is remarkable for 5 years, and there was a low number of re-operations among people who completed the follow-up. Furthermore, using the uncemented stem can still be an excellent alternative, especially for those patients who need it to reduce surgical time and blood loss. Consequently, the choice of whether to cement the stem remains open.

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Retrospective Study

COMPARATIVE OUTCOMES OF EARLY VERSUS DELAYED WEIGHT-BEARING IN FIFTH METATARSAL BASE FRACTURES: A RETROSPECTIVE STUDY

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ABSTRACT

Fractures of the fifth metatarsal base are common foot injuries, especially in athletes and active individuals. Treatment strategies vary between early and delayed weight-bearing, but limited evidence exists on which approach leads to better clinical and functional outcomes. This retrospective, single-center study compares the effects of early versus delayed weight-bearing on clinical and functional recovery in patients with fifth metatarsal base fractures between January 1, 2020, and December 31, 2021. Data from 40 patients treated at a single center for fifth metatarsal base fractures were analyzed. Patients were divided into two groups according to treatment decision: 20 in the early weight-bearing group (within 2 weeks post-injury) and 20 in the delayed weight-bearing group (after 4-6 weeks of immobilization). Clinical and functional outcomes, including return to activity, pain levels measured with Visual Analogue Scale (VAS), Foot and Ankle Disability Index (FADI), satisfaction rates, and complications, were assessed and compared at 6 months follow-up. The study included 14 male and 26 female patients, with a mean age of 43.5 ± 15.5 years. No significant difference in subjective satisfaction and FADI score was found between early and delayed weight-bearing at the final follow-up assessment ($p > 0.05$). However, a significantly earlier return to sports and physical activity was observed in the early weight-bearing group ($p < 0.001$). In conclusion, early weight-bearing in fifth metatarsal base fractures allows for an earlier return to activity without compromising patient satisfaction or increasing complications. These findings support early weight-bearing as a viable option for promoting faster recovery in appropriately selected patients without compromising clinical outcomes.

KEYWORDS: *fracture, bone, foot, metatarsal, weight-bearing*

INTRODUCTION

Metatarsal fractures are one of the most common injuries of the foot, with an incidence of up to 75 persons per 100,000 per year among adults (1-3). More than half of all metatarsal fractures involve the fifth metatarsal bone, and the majority are located at the proximal end (1, 3). The peak incidence of fifth metatarsal fractures in men is below 40, whereas mostly women older than 50 are affected (3, 4).

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The fifth metatarsal plays a crucial role in mechanics and stability during weight-bearing activities, playing a significant role in walking and balance due to fibularis brevis and tertius tendon insertion (5). Despite its biomechanical importance, the base of the fifth metatarsal bone has a poor and retrograde blood supply, primarily from the diaphyseal and metaphyseal arteries. This limited blood supply contributes to a higher risk of delayed union or non-union of fractures (6).

Different classification systems were developed over the years according to the location and number of fragments (7-11). Several treatment options have been proposed (12-18) without a clear consensus among orthopedic surgeons. Weightbearing is a critical factor in the management of fifth metatarsal base fractures. While early weight-bearing can promote muscle function and joint mobility, there is concern that premature loading of the fractured area may increase the risk of delayed healing, non-union, or re-fracture, particularly in Jones's fractures (19). Conversely, delayed weight-bearing may protect the fracture site but prolongs immobilization and recovery time, potentially leading to muscle atrophy, joint stiffness, and longer rehabilitation periods (20).

The optimal timing for weight-bearing in these fractures remains still debated. The aim of this study is to compare functional outcomes retrospectively, return to activity and satisfaction rate of two different conservative protocols on patients with fifth metatarsal base fractures who underwent either early or late weight-bearing protocols. The hypothesis of this study is that early weight-bearing provides a quicker return to activity without compromising clinical outcomes.

MATERIAL AND METHODS

Study characteristics

Patients affected by a fracture of the base of the fifth metatarsal bone from January 1, 2020, to December 31, 2021, were screened by consulting the institutional database. Inclusion criteria were avulsion type (pseudo-Jones) fractures, proximal articular fractures (Jones fractures), and proximal extra-articular fractures (march fractures) with conservative indication.

Exclusion criteria were non-healing fractures with surgical indication (21), open or pathological fractures, concurrent lower-extremity injuries (such as Lisfranc or cuboid fractures), and those with obesity (BMI >30 kg/m² or weight >100 kg), diabetes, or neuroarthropathy were excluded, as these factors could negatively impact recovery to pre-injury activity levels.

Patients were screened, selected and divided by treatment decision into two groups. In the early weight-bearing group, the orthopedic surgeon prescribed a hard sole with partial weight-bearing with crutches for 4 weeks. In the delayed weight-bearing group, the orthopedic surgeon prescribed a splint without weight-bearing for 4 weeks. After splint removal, progressive partial weight-bearing was then recommended. Table I summarizes the general features of the population.

Table I. *General features of the population included.*

	Early weight-bearing	Delayed weight-bearing	P-value
Patients	20	20	-
Age (years)	44.8 ± 17.3 (95%CI from 36.7 to 52.8)	42.2 ± 13.8 (95%CI from 35.7 to 48.7)	0.610
Gender (M/F)	9 (45%) / 11 (55%)	5 (25%) / 15 (75%)	0.081
Follow-up (months)	7.3 ± 0.8 (95%CI from 6.8 to 7.6)	7.6 ± 0.4 months (95%CI from 6.9 to 7.7)	0.142

Primary and secondary outcomes

The primary outcome measured was the patient's return to pre-injury activity levels. Secondary outcomes included pain levels, which were assessed using the Visual Analog Scale (VAS), the Foot and Ankle Disability Index (FADI) score, and patient satisfaction, which were categorized into three groups: satisfied, fair, and very satisfied.

The FADI score is a questionnaire-based tool that evaluates the foot and ankle function, which is particularly useful after injuries or surgeries. This score reflects the patient's self-reported level of disability and functional ability in

performing daily activities. It is commonly used by clinicians to assess treatment effectiveness and monitor recovery progress over time.

Statistical analysis

Statistical analysis was conducted using IBM SPSS Statistics (IBM Corp., Armonk, NY, USA). Categorical variables were expressed as the absolute number of cases and/or percentage. The Shapiro-Wilk test was used to identify normally distributed parameters. Differences between means were calculated with the t-test for continuous variables or with the Mann-Whitney U test if not normally distributed. The Wilcoxon log-rank test was used to compare unpaired values that were not normally distributed. Categorical variables were calculated using the chi-square test or Fisher's exact test. A p-value of $<.05$ was considered statistically significant.

RESULTS

Primary outcome

The statistical analysis indicated that an early return to weight-bearing (within 2 weeks from trauma) with hard sole was associated with a significantly quicker return to overall physical activity ($p<0.01$) (Fig. 1). The early weight-bearing group had a mean return time of 8.4 ± 0.9 (95% CI from 7.9 to 8.9) weeks, compared to the delayed group, which had a mean return time of 10.8 ± 1.6 (95% CI from 9.9 to 11.7) weeks with a mean difference of -2.4 weeks (<0.001) (Table II).

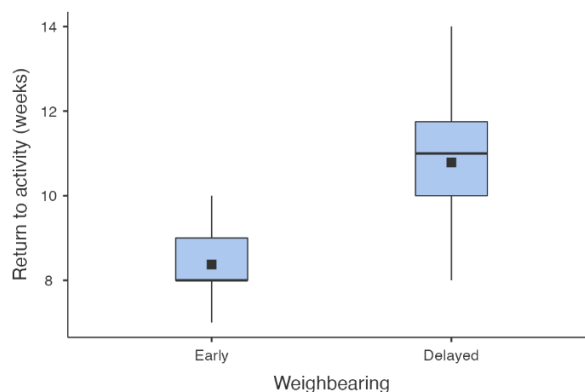


Fig. 1. Graphical expression of return to activity following two different managements showing the significant superiority of early weight-bearing and earlier return to activity of daily living.

Table II. Details of measured outcomes with mean difference (MD). Significant values are highlighted with asterisks.

	Early weight-bearing	Delayed weight-bearing	MD	P-value
Return to activity (weeks)	8.4 ± 0.9 (95% CI from 7.9 to 8.9)	10.8 ± 1.6 (95% CI from 9.9 to 11.7)	-2.4	<0.001 *
Pain level (VAS points)	1.9 ± 1.0 (95% CI from 1.3 to 2.4)	2.1 ± 0.7 (95% CI from 1.8 to 2.5)	-0.3	0.577
FADI score (points)	101 ± 2.6 (95% CI from 99.9 to 103.0)	101 ± 1.4 (95% CI from 99.8 to 101.0)	+0.7	0.150

Secondary outcomes

Secondary outcomes included pain, which was assessed by the VAS, the FADI score, satisfaction rate, and complications. The pain was evaluated at the final follow-up assessment using the VAS. The early weight-bearing group reported a mean pain score of 1.9 ± 1.0 (95% CI 1.3 to 2.4) points, while the delayed weight-bearing group had a mean

pain score of 2.1 ± 0.7 (95% CI 1.8 to 2.5) points. Although the early weight-bearing group showed a lower pain score, this difference was not statistically significant ($p > 0.05$) (Table II).

The FADI score was evaluated at the final follow-up to assess self-reported levels of functional activity and disability. The statistical analysis showed no differences in reported functional scores. The early weight-bearing group reported a FADI score of 101 ± 2.6 (95% CI 99.9 to 103.0) points, while the delayed weight-bearing group had a score of 101 ± 1.4 (95% CI 99.8 to 101.0) points. The mean difference between the groups was +0.7, with a p-value of 0.150. This indicates that the score was slightly higher in the early weight-bearing group, though the difference was not statistically significant (Table II).

The satisfaction rate was assessed at the final follow-up assessment in both groups, with outcomes categorized into three levels: satisfied, fair, and very satisfied. In the early weightbearing group, 15 patients reported being satisfied, 1 reported fair satisfaction, and 4 reported being very satisfied. In the delayed weightbearing group, 17 patients reported being satisfied, 2 reported fair satisfaction, and 1 reported being very satisfied (Table III). Overall, most patients reported being satisfied, regardless of their group. No significant difference in subjective satisfaction was observed between the groups at the end of the follow-up period ($p = 0.492$) (Fig. 2). Complications (non-union, mal union, delayed union, infection) were not detected either in the early weight-bearing groups nor in the late weight-bearing group.

Tab. III: Contingency table with details of measured subjective satisfaction at the end of the follow-up period.

Satisfaction	Weightbearing		Total
	Early	Delayed	
Satisfied	15	17	32
Fair	1	2	3
Very Satisfied	4	1	5
Total	20	20	40

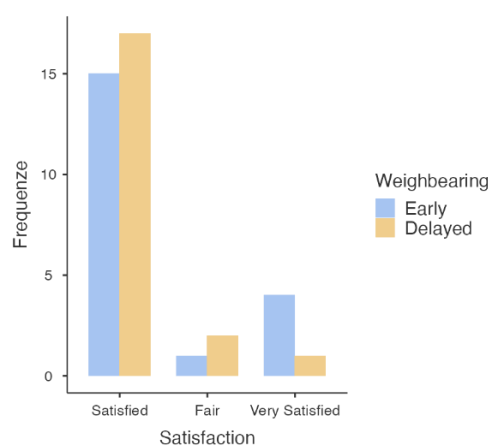


Fig. 2. Graphical expression of subjective satisfaction following two different management.

DISCUSSION

The main finding of this study is that early weight-bearing in the conservative management of fractures at the base of the fifth metatarsal allows for a significantly reduced recovery period and faster return to regular activity without increasing complication rates or negatively impacting clinical outcomes.

The anatomical position of the fifth metatarsal base, situated at the transition between the midfoot and forefoot, subjects it to substantial biomechanical stress, primarily due to its tendon and fascial insertion (22). These anatomical structures provide critical support and lateral stability to the foot, particularly during dynamic actions like pivoting, sidestepping, and directional changes, which are frequent in both daily and athletic activities. This high demand for stability and the forces generated during such movements often make fractures in this region more challenging to heal,

with an increased risk of complications such as delayed union or non-union due to limited vascular supply and repetitive mechanical stress on the fracture site.

Early weight-bearing strategies aim to take advantage of the biological and mechanical responses to controlled load-bearing. By initiating gradual weight-bearing soon after injury, there is an increase in mechanical loading at the fracture site, which promotes callus formation through improved circulation and cellular activity (23-24). Enhanced blood flow and micro-movements at the fracture site stimulate bone healing, leading to a more robust callus and promoting bone remodeling. Thus, carefully monitored weight-bearing not only aids in the biological healing process but can also minimize muscle atrophy, joint stiffness, and psychological barriers to resuming activity, which can otherwise result from prolonged immobilization (24).

In comparison to a previous study by Marecek et al. (24), where unrestricted weight-bearing was adopted immediately after a Jones fracture, the current study provides further analysis of specific pain and functional outcomes that are highly relevant in clinical decision-making. Marecek et al. (24) indicated that unrestricted weight-bearing did not elevate the rates of non-union or delayed union, supporting the notion that early loading may not compromise fracture stability. Their findings demonstrated favorable outcomes in terms of healing time, patient comfort, and functional recovery, underscoring that early weight-bearing may safely accelerate rehabilitation. This study builds upon these insights by examining a wider set of functional outcomes, including scores on the FADI. Although the early weight-bearing group showed slightly higher FADI scores, these were not statistically significant, the trend suggests a potential functional benefit. Additionally, patient satisfaction remained comparably high across groups, highlighting that early weight-bearing did not compromise comfort, quality of life, or overall satisfaction with treatment.

The practical implications of this study are particularly significant for athletes and physically active individuals who may benefit from a shorter recovery and early return to sport without compromising the process of fracture healing. By facilitating an earlier return to activities and maintaining functional strength, the early weight-bearing protocols could be valuable in minimizing both the physical and psychological impacts of prolonged inactivity, which are especially critical in competitive sports settings where rehabilitation time is limited. This approach offers a balanced pathway for conservative management, enabling safe and effective healing while optimizing recovery times.

Despite the precise design this study has certain limitations, including the limited sample size and the potential influence of variables such as fracture severity and patient adherence to weight-bearing guidelines. Further, while the study controlled for some key factors, variables such as the severity of the fracture, variations in individual healing responses, and adherence to prescribed weight-bearing guidelines may have influenced the outcomes observed. In clinical settings, these factors could impact the effectiveness and safety of early weight-bearing protocols. Finally, this is a retrospective, non-randomized monocentric observational study and treatment decision exclusively based on orthopedic surgeon preference and technical confidence. Future studies should focus on addressing these limitations through larger, randomized, multicenter trials that incorporate a broader spectrum of patient demographics and injury types. Such studies could also explore stratified rehabilitation approaches, where patients with different fracture severities or activity levels receive tailored weight-bearing guidelines. Additionally, objective measures of bone healing, such as advanced imaging or biomarkers, could provide more precise assessments of the effects of early weight-bearing on fracture consolidation. These studies would ultimately contribute to refining early weight-bearing protocols, potentially establishing individualized rehabilitation strategies that maximize healing while minimizing downtime.

CONCLUSIONS

In conclusion, the study's findings suggest that early weight-bearing provides meaningful benefits by reducing healing time and enabling a quicker return to activity, without increasing complication risks. This is particularly valuable given the biomechanical role of the fifth metatarsal in foot stability, weight distribution, and propulsion.

Early weight-bearing may enhance recovery by promoting bone remodeling and maintaining soft tissue strength around the fracture, ultimately supporting a safe and efficient return to full functionality for patients, especially athletes and those with high physical demands.

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SUTURE FIXATION VERSUS METALLIC CERCLAGE FOR ARTICULAR PATELLAR FRACTURE: A MINIMUM 1-YEAR, RETROSPECTIVE COMPARATIVE STUDY

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ABSTRACT

Surgical treatment of patellar fractures with traditional metallic wires results in high rates of complications, with many patients requiring reoperations. Non-metallic implants for the fixation of patellar fractures have shown promising results. This study compares the outcomes of surgical fixation of patellar fractures with metallic wires to suture fixation. Patients with closed patellar fractures requiring surgical fixation were treated with 1.25 mm cerclage wire or suture fixation. Inclusion criteria were fractures with an intra-articular step-off >2mm, displacement >4mm, or impairment of the extensor mechanism. Outcomes were Kujala and WOMAC scores, ROM, and prevalence of postoperative complications. Failure was defined as the need for revision surgery, loss of reduction, malunion or non-union, or poor outcome. The radiographic examination assessed patellar height, radiographic union, secondary displacement, and implant breakage. Thirty-eight patients underwent surgical fixation with metallic cerclage wire, while 32 patients underwent suture fixation with a mean follow-up of 46.6 ± 24.2 (range: 12 to 100) months. No clinical or radiological differences were seen at the final follow-up evaluation. No significant differences among reported complications were found. Patients who underwent metallic fixation experienced significantly higher reoperation rates ($p < 0.001$). Surgical fixation of displaced articular patellar fractures showed no significant differences in complication rates and clinical and radiographical outcomes when treated with metallic cerclage wires compared to suture fixation. However, patients treated with metallic wire fixation had significantly higher reoperation rates. Further studies are requested to thoroughly investigate the results and indications of suture fixation.

KEYWORDS: *patellar fracture, surgical fixation, metallic cerclage wire, fibrewire® suture, symptomatic hardware*

INTRODUCTION

The patella is the largest sesamoid bone of the musculoskeletal system and plays a key role in the extensor mechanism. Patellar fracture is a relatively uncommon injury of the lower limb, representing 1% of all fractures in adults with increasing incidence in the general population (1).

Over the years, several strategies and surgical techniques have resulted in high union rates (2). However, surgical treatment of patellar fractures with traditional metallic wires has high rates of complications ranging from 18 to 50%,

with many patients requiring reoperation (3, 4). Typical complications include broken implants, migrating wires, and irritation due to symptomatic implants (5, 6). For these reasons, different authors promoted non-metallic implants or non-absorbable suture materials for the fixation of patellar fractures, showing promising results (7-10). Despite the growing interest in new materials for treating patellar fractures, only a few studies report comparative results of metallic implants and non-absorbable suture fixation for articular displaced patellar fractures.

This study aims to compare clinical and radiographic outcomes, complications, and reoperation rates of consecutive series of patients who required surgical fixation of a patellar fracture with metallic wires or suture fixation.

MATERIAL AND METHODS

Medical records of patients diagnosed with patellar fractures treated at a single University hospital from January 2013 to September 2021 were retrospectively reviewed.

Inclusion criteria were closed articular patellar fractures with intra-articular step-off greater than 2 mm, fracture displacement greater than 4 mm, or impairment of knee extensor mechanism. Exclusion criteria were open fractures, non-displaced fractures, polytrauma patients, pluri-fractures, previous surgeries on the affected knee, incomplete medical records, and patients medically unfit for surgery.

Patients were divided into two groups according to fixation method: one group treated with 1.25 mm metallic cerclage wire and one group treated with suture fixation with n.5 fiberwire® (Arthrex Inc, Naples, FL, USA). Data from two groups of patients were compared. The study size was determined based on the number of patients that met the inclusion criteria within the single university hospital between the dates of interest. All medical records and surgical details were retrieved, and data on age, sex, BMI, smoking status, previous surgeries, therapies, and comorbidities were collected.

The preoperative Charlson's index (11) was calculated to identify patients' comorbidity conditions at surgery. All the fractures were classified according to the AO/OTA classification (12). Surgical procedures were performed by four different trained orthopedic surgeons (>100 procedures per year) using the standardized surgical technique. The surgical technique and fixation method were based on surgeon preference.

The cohort studies have been evaluated using the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines (13).

Surgical technique and postoperative indications

Open reduction and internal fixation were performed through a midline longitudinal approach centered over the patella. The knee joint and fracture site were irrigated and cleared of blood clots and small debris. Fracture reduction was obtained using Weber clamps and monitored by fluoroscopy and palpation of the retropatellar articular surface through a small arthrotomy to avoid minor step-off.

Metallic fixation was completed with two 1.25 mm cerclage wires (deep and superficial) properly tightened and twisted. Suture fixation was completed with two n.5 fiberwire® (Arthrex Inc, Naples, FL, USA) and manually tightened and locked with a sliding self-locking knot. Final fluoroscopy through 60-degree range of motion was completed before wound closure to assess fixation stability.

The postoperative protocol was the same for the two groups: full weight-bearing with crutches was allowed with a knee brace locked in extension for 3 weeks. Progressive passive range of motion was encouraged after 3 weeks, and active range of motion was allowed at 6 weeks. The knee brace was removed after 8 weeks, and quadriceps strength exercises were prescribed.

Patient assessment

Patients were called to be clinically assessed at the final follow-up by two blinded orthopedic residents using the Kujala Score (14) and Western Ontario and McMaster Universities Arthritis Index (WOMAC) (15). The visual analog scale (VAS) (16) was used to assess the maximum subjective level of pain. Subjective satisfaction was investigated using a rating scale ranging from 0 (no benefits) to 10 (maximum satisfaction). The total range of motion, flexion or extension deficit, or lack of extension was clinically assessed. The blinding of the orthopedic residents during clinical assessments was included to reduce potential observer bias.

The prevalence of postoperative complications was also investigated and analyzed. Failure was defined as the need for revision surgery, loss of reduction, malunion, non-union, or poor clinical outcome.

A radiographical examination at the final follow-up was performed, and patellar height, radiographic union, secondary displacement, or implant breakage were assessed. Union was defined as the absence of visible fracture gap formation and the disappearance of the fracture line.

Statistical analysis

A *post-hoc* calculation was performed, considering the reoperation rate as the primary outcome measure for the binomial endpoint and two independent sample studies. The resulting *post-hoc* power of the present study on 70 patients with an alpha value of 0.05 was 98.6%, demonstrating an adequate sample size. Categorical variables were expressed as the absolute number of cases and/or percentage. The Shapiro-Wilk Test was used to identify normally distributed parameters. Differences between means were calculated with independent samples T-test for continuous variables and with the Mann-Whitney U test if not normally distributed. Categorical variables were calculated using Fisher's exact test. A p-value of <0.05 was considered statistically significant.

RESULTS

A total of 185 patients were screened for study eligibility related to patellar fracture between 2013 and 2021. Fifty-seven patients underwent conservative treatment, 7 patients had incomplete medical records, and 51 were excluded as not meeting the inclusion and exclusion criteria. Patients were called to be clinically and radiographically assessed, and no patient declined or was lost at the final follow-up.

A total of 70 patients who underwent surgical fixation of articular fracture were finally included and were clinically and radiographically assessed for the present study. Thirty-eight (54.3%) patients underwent double 1.25 mm metallic cerclage wire, and thirty-two (45.7%) underwent suture fixation with fiberwire® n. 5 (Arthrex Inc, Naples, FL, USA) cerclage (Fig. 1).

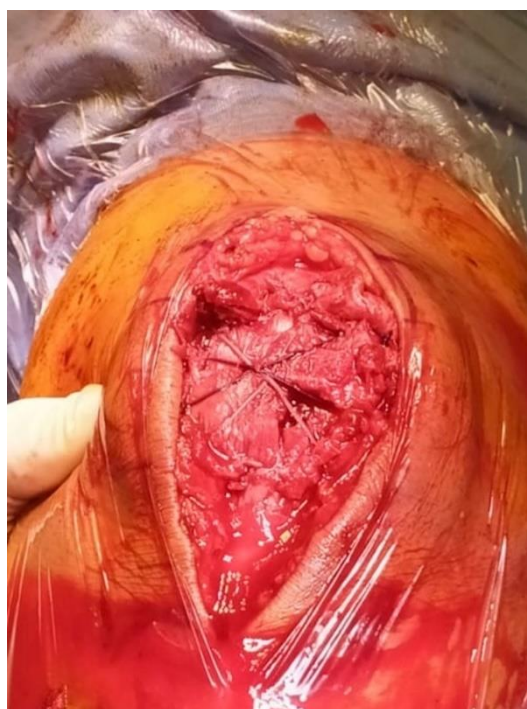


Fig. 1. Intraoperative view of suture fixation of the patellar fracture with n. 5 fiberwire® suture.

The mean follow-up was 46.6 ± 24.2 (range: 12 to 100) months without significant differences in demographic parameters among groups ($p > 0.05$). Table I shows the general features of the study population.

Table I. Demographics and general features of the overall population (N=70) who underwent surgical fixation of the patellar fracture with metallic cerclage wire (n=38) and fiberwire cerclage (n=32).

	Surgical technique		p-value
	<i>Metallic wire</i>	<i>Suture fixation</i>	
Number of patients	38	32	-
Age at surgery (years)	60.9 ± 18.6 (19 to 83)	57.9 ± 18.1 (22 to 87)	0.412 ^a
Gender (female/male)	24/14	25/7	0.173 ^b
Smoking status (yes/no)	9/29	5/27	0.551 ^b
Cigarettes/day	2.8 ± 5.0 (0 to 15)	2.8 ± 6.8 (0 to 20)	0.454 ^a
BMI	23.5 ± 2.6 (19 to 29)	22.4 ± 3.2 (17.5 to 28)	0.086 ^c
CCI	2.6 ± 2.1 (0 to 8)	2.4 ± 2.3 (0 to 9)	0.492 ^a
Follow-up (months)	50 ± 27.3 (12 to 100)	40.5 ± 19.1 (12 to 68)	0.129 ^a

Continuous variables are expressed with main values, standard deviation, and range of values (in brackets). Absolute values are expressed by frequencies: ^a=Mann-Whitney U test; ^b=Fisher's exact test; ^c=Student's t-test. **BMI**: Body Mass Index; **CCI**: Charlson Comorbidity Index.

There were no clinical and radiological differences at the final follow-up evaluation among patients treated with metallic wire and suture fixation technique (p>0.05). Table II shows the assessed clinical outcome measures. There were no significant differences among reported complications at the final follow-up assessment (p>0.05) (Table III).

Table II. Clinical outcome results at final follow-up assessment.

	Surgical technique		p-value
	<i>Metallic wire</i>	<i>Suture fixation</i>	
Kujala score	85.3 ± 14.1 (55 to 100)	87.8 ± 14.6 (42 to 100)	0.254 ^a
Womac score	85.5 ± 13.4 (44.5 to 100)	85.7 ± 13.5 (44.5 to 99)	0.962 ^a
Vas _{max}	2.5 ± 2.6 (0 to 9)	2.6 ± 2.4 (0 to 10)	0.173 ^a
Subjective satisfaction	7.1 ± 2.7 (1 to 10)	7.1 ± 2.6 (0 to 10)	0.957 ^a
Complications	6 (15.8%)	7 (21.8%)	0.552 ^b
Re-operation	16 (42.1%)	1 (3.1%)	<0.001^b

Continuous variables are expressed with main values, standard deviation, and range of values (in brackets). Absolute values are expressed by frequencies and relative percentages (in brackets). Bold values indicate significant differences. ^a=Mann-Whitney U test; ^b=Fisher's exact test. **BMI**: Body Mass Index; **CCI**: Charlson Comorbidity Index.

Table III. Details of complications reported at the final follow-up.

Complications	Surgical technique		p-value
	<i>Metallic wire</i>	<i>Suture fixation</i>	
Stiffness	1 (2.6%)	4 (12.5%)	0.171 ^a
Implant breakage	2 (5.3%)	0 (0%)	0.497 ^a
Secondary displacement	2 (5.3%)	2 (6.3%)	1.000 ^a
Patella alta	0 (0%)	0 (0%)	1.000 ^a
Patella baja	1 (2.6%)	1 (3.3%)	1.000 ^a
Non-union	0 (0%)	1 (3.1%)	0.457 ^a

Absolute values are expressed by frequencies and relative percentages (under parenthesis). ^a=Fisher's exact test.

Patients who underwent metallic fixation experienced a significantly higher reoperation rate (42.1%) due to symptomatic hardware ($p < 0.001$).

Potential confounders include the following: demographic information, which has been deemed to be statistically insignificant; fracture severity and location, which are variables minimized through the inclusion criteria provided; surgical experience and technique of the four trained surgeons, which has been aimed to be reduced based on the sample size and randomization; postoperative care, for which a uniform guideline has been provided across both cohorts; access to rehabilitation, adherence to rehabilitations, and differences in physical activity between patients, which again has been aimed to be reduced based on sample size and randomization.

DISCUSSION

The main finding of the present study is that surgical fixation of displaced articular patellar fractures with metallic cerclages or fiberwire® suture fixation had similar clinical and radiographic outcomes and comparable complication rates. However, patients who underwent metallic fixation had a significantly higher reoperation rate for symptomatic hardware removal.

The patella plays a key role in the extensor mechanism, and the operative fixation techniques and materials used to treat patella fractures are constantly evolving (1, 3, 17-19).

The compression at the fracture site represents the mainstay of internal fixation to promote healing of patellar fractures and to restore the extensor mechanism function (20). However, a high rate of complications related to metallic fixation has been reported (4). Metallic wires may cause irritation, pain, implant breakage, migration, and a high rate of reoperation due to symptomatic hardware. Alternative solutions for the internal fixation of patellar fractures have been investigated to reduce hardware-related complications (7).

Few clinical studies with limited populations (3, 7, 8, 19, 21, 22) compare mid-term outcomes of suture materials and metallic wires for patellar fractures, and additional evidence is requested.

Wright et al. (23) conducted a biomechanical study in 2009 that showed that at higher tensile forces (>250N), fiberwire® had superior failure strength than conventional stainless steel, justifying the *in-vivo* application of suture materials to decrease re-operation rate and enhance patient satisfaction.

Monaco et al. (17) conducted a retrospective analysis evaluating 26 patients affected by transverse patellar fractures at 18 months and comparing the suture tape to metallic wire circumferential cerclages. With the limitation of the short follow-up and the limited sample size, the authors concluded that the two techniques had comparable clinical and radiographical outcomes without differences in re-operation rates and complications.

Lee et al. (18) prospectively compared 1-year results of 60 patients who underwent multiple nonabsorbable Ethibond 2-0 suture fixation and metallic tension band fixation for articular patellar fractures, reporting a significant difference at 3 months with better clinical outcome in the suture group, and higher knee flexion in the tension band group. Moreover, the authors reported a 40% reoperation rate in the metallic tension band group compared to 0% in the suture fixation group. Despite the promising results, the clinical outcome could have been significantly biased by different

rehabilitation protocols, resulting in slower flexion progression in the suture group and more aggressive rehabilitation in the tension band group.

The present comparative study represents the largest series comparing clinical and radiological results at a mean 5-year follow-up of a homogeneous population affected by articular patellar fractures. With the same rehabilitation protocol, clinical results and complication rates were comparable between groups and in line with the published literature. However, there was a significantly higher reoperation rate in the metallic wire group, leading to significant conclusions.

This study is a retrospective single-center investigation that, although having blinded assessment, has the intrinsic limitation related to study design. Moreover, surgical procedures were performed by four different surgeons who, although well-trained, could potentially influence the outcomes.

This is a preliminary study, and no strong recommendations can be made. Further prospective randomized trials are requested to thoroughly investigate comparative results and indications of suture fixation for patellar fractures.

CONCLUSIONS

Surgical fixation of displaced articular patellar fractures showed no significant differences in complication rates and clinical and radiographical outcomes when treated with metallic cerclage wires compared to fiberwire® suture fixation. However, patients treated with metallic wire fixation had significantly higher reoperation rates than those treated with fiberwire® suture fixation. Further studies are requested to thoroughly investigate the results and indications of fiberwire® suture fixation.

Conflicts of interest

The authors declare that there are no conflicts of interest regarding the publication of this article.

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THE IMPORTANCE OF THE METHOD IN THE APPLICATION OF GUIDELINES AND BEST PRACTICES

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ABSTRACT

In recent decades, the healthcare profession in Italy has undergone significant legislative transformations that define professional roles, rights, duties, and the ethical and legal responsibilities of healthcare workers. This study underscores the crucial importance of Evidence-Based Medicine in clinical practice, promoting its adoption to enhance patient safety and treatment efficacy. The impact of cognitive biases on healthcare decisions is explored, highlighting their contribution to diagnostic errors and the risk of malpractice. Through two clinical cases, the practical application of Bayesian methods in diagnosing complex conditions is illustrated, demonstrating how systematic analysis can lead to accurate outcomes and reduce uncertainty. Furthermore, the importance of adhering to current regulations, such as the Gelli-Bianco Law, is emphasized, as they provide a framework for improving the quality of care and safeguarding patient rights. Ultimately, the integration of scientific methodologies, patient-centered communication, and a robust legislative framework is essential for achieving high-quality care in the contemporary context, contributing to improved clinical outcomes and the protection of patient rights.

KEYWORDS: *healthcare workers, malpractice, best practice, care, patients, legislative framework, communication*

INTRODUCTION

Every healthcare professional, within their clinical practice, is faced with numerous choices aimed at ensuring effective care pathways. The criteria guiding these choices are influenced by multiple variables of which the professional must be aware. The adoption of clinical-care protocols based on scientific evidence (Evidence-Based Medicine - EBM), which also considers the bio-psycho-social characteristics of the patient, represents an essential element in ensuring the safety and effectiveness of treatments while making them consistent with the clinical needs of patients (1-10). The adoption of EBM is not only a strategic choice to ensure high standards of care but also a deontological and regulatory imperative. Healthcare professionals have the responsibility to provide safe and high-quality care, which implies the use of the best available scientific evidence (11).

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This approach not only promotes transparent communication with patients, allowing them to participate actively in the decision-making process regarding their care, but it also minimizes the risk of malpractice. In a regulatory context where the quality of healthcare services is scrutinized increasingly closely, adhering to evidence-based practices becomes essential for protecting the profession and safeguarding patients' rights (12-15).

When these needs are not adequately met, the medical and social consequences can be significant. In recent years, the issue of medical malpractice has garnered growing attention in the Italian healthcare landscape, with a continually rising number of legal actions against physicians each year, resulting in costs for hospital systems that exceed 10 billion euros in compensation for therapeutic and diagnostic errors (16, 17).

The importance of a scientific method in clinical practice lies in its ability to systematize the decision-making process, reducing the impact of cognitive biases-systematic errors in thinking that can influence the judgment and behavior of professionals—and increasing consistency in the provided care (18-24). Therefore, it is essential that the following principles coexist at the foundation of professional action:

1. safety: it is crucial to prevent patients from experiencing harm from treatments intended to help them;
2. effectiveness: services based on scientific evidence must be provided to those who can benefit from them while avoiding the administration of treatments to individuals who would not gain an advantage;
3. patient-centered care: care must be respectful and appropriate to the preferences, needs, and values of each individual user, ensuring that clinical decisions are guided by their values;
4. timeliness: it is important to reduce potentially harmful waits and delays for both those receiving care and those providing it;
5. efficiency: it is essential to avoid waste, particularly of resources, materials, ideas, and energies;
6. equity: it is fundamental to ensure a quality of care that is independent of the personal characteristics of the patient, such as gender, ethnicity, geographical origin, and socio-economic status (25).

The primary objective of this study is to analyze the importance of the scientific method, highlighting the necessity of adopting an EBM approach as an appropriate methodology for reducing clinical errors and improving patient outcomes. To this end, we aim to identify and recognize the cognitive biases that may influence healthcare professionals' decisions.

Additionally, we intend to provide an in-depth analysis of the current legislation regarding professional liability in Italy, examining the relevant regulatory references. This aspect is crucial for understanding the legal context in which healthcare professionals operate, encouraging them to integrate scientific principles into their daily clinical practice.

Finally, we aim to demonstrate how the integration of scientific principles into clinical activities can enhance both diagnosis and intervention, establishing a solid connection between clinical practice and scientific theory. This connection proves fundamental in ensuring high-quality care that is centered on the specific needs of the patient and supported by robust evidence.

The art of proceeding methodically

Within everyday life, there are numerous ways in which we can cognitively come to conclusions based on elements from our life experiences. Drawing two stimuli from the artistic field to analyze these processes of meaning attribution, we might envision ourselves in front of two paintings (Fig. 1 A-B). If we wanted to ascertain whether they were created by the same artist, we could focus on a visual and comparative analysis of the works. In the specific case of the paintings illustrated in Fig. 1 A-B, we might observe various similarities in their characteristics: the depicted forms show analogies, the brushwork is similar, the structuring of space is consistent, and the choice of lights and shadows can be considered homogeneous.

Therefore, if we were to limit ourselves to examine only the visible aspects through a comparative method, they might conclude that both works were created by the same author. However, this conclusion would prove incorrect, as the first painting, Fig. 1-A, is a work by Pablo Picasso, while the second, Fig. 1-B, was created by the artist Georges Braque (Fig. 2 A-B).



Fig. 1. Visible aspects through a comparative method.



Fig. 2. Visible aspects through a comparative method. **A**): Pablo Picasso; **B**): Georges braque.

The mental process that led to the conclusion is referred to as the comparative method. The comparative method is an approach used to analyze and compare two or more entities, such as theories, phenomena, institutions, cultures, social practices, or systems, to identify significant similarities and differences. This method allows for the formulation of hypotheses, the development of theories, and the drawing of conclusions about specific aspects through the systematic observation of operational variables in different contexts.

A second method of meaning attribution is Bayes' deductive method (26). This approach, named after Thomas Bayes, an 18th-century British mathematician and theologian, allows for updating the probability of a hypothesis in light of new evidence or information. The formula of Bayes' theorem links the posterior probability of a hypothesis, given certain evidence, to the prior probability of the hypothesis and the likelihood of the evidence under the hypothesis (Fig. 3). In this way, the method allows for the deduction of new probabilities from observed data, combining prior information (prior probability) with fresh information (likelihood) to arrive at an updated assessment of the hypothesis (26, 27).

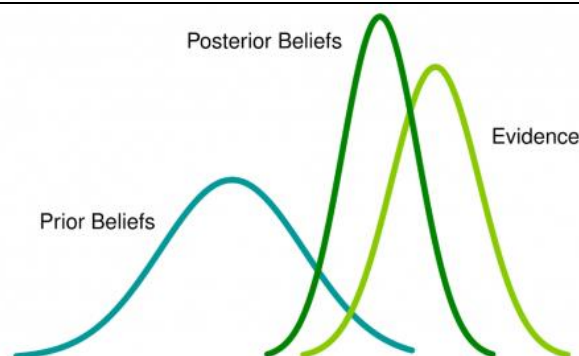


Fig. 3. Bayes Pyramid.

Applying Bayes' method to the aforementioned artistic stimuli (Fig. 1 A-B), requires a rigorous and accurate analysis. It is essential for the observer to possess a deep knowledge of art history and the cultural contexts in which these artists emerged, access reliable and selected sources, and keep updated through established and recognized knowledge channels. The search for information should go beyond superficial appearances; a critical approach involves considering the historical context, the techniques used, and the symbolic meaning of the works.

This example underscores the importance of thorough and rigorous analysis. An evaluation based solely on seemingly similar elements can easily lead to incorrect and misleading conclusions.

These considerations are also applicable to the medical field. Similar symptomatic presentations may conceal different diagnoses; for instance, two patients with chest pain and fatigue may be indicative of distinct causes, such as cardiac issues, systemic disorders, or psychological factors.

One of the main risks of the comparative method is the tendency to generalize results. Each patient is unique, and the response to treatment can vary significantly. Effective intervention in one group does not guarantee the same effect in another group with different clinical characteristics, which can lead to inadequate treatments and outcomes of medical malpractice.

Applying the comparative method in medicine can carry the risk of encountering cognitive biases. "Cognitive biases" are systematic errors in thinking that influence people's decisions and judgments. These mechanisms of cognitive distortion result from mental shortcuts (known as "heuristics") that the brain uses to simplify the process of information processing (23). Cognitive biases can lead to incorrect conclusions or distorted perceptions of reality, affecting human behavior in various contexts, including the assessment of probabilities, memory, and the interpretation of events. In medical practice, they can influence clinical decision-making, introducing systematic errors in data evaluation and diagnosis formulation, thereby compromising scientific evidence and the quality of care provided to patients (19). For this discussion, it is useful to analyze two examples of cognitive biases: selection bias and confirmation bias.

The "selection bias" is a type of systematic error that occurs when conclusions or generalizations are influenced by a non-representative sample, leading to distortions in results or observations. This bias can manifest in various contexts, such as scientific research, statistical surveys, or everyday decision-making. This error can compromise the interpretation of results; for example, if a study on emotional well-being includes participants with common demographic or social variables exclusively, the results may not reflect the diversity present in the general population. Consequently, rigorous study design is essential to ensure generalizable and useful conclusions in clinical practice (19, 24).

The "confirmation bias" refers to the tendency to seek out and interpret information in a manner that confirms pre-existing beliefs. This can lead to erroneous diagnoses in cases where, for instance, a physician ignores symptoms that contradict their preconceived diagnosis. This form of bias can have significant consequences, as it may lead to incorrect conclusions and, ultimately, cause harm to patients (19, 20).

Another critical aspect concerns the neglect of contextual factors that can influence clinical outcomes. Variables such as social support, environmental conditions, and cultural differences can have a significant impact on treatment responses. Overlooking these factors can reduce the effectiveness of interventions and compromise patient outcomes (1-10).

In conclusion, although the comparative method can be applied in daily life, as it simplifies the complexity of human experience, professionals must be fully aware of its limitations. Generalization, selection biases, and the disregard for contextual factors can undermine the effectiveness of this approach and negatively affect patient health. Therefore, it is crucial to integrate the comparative method with other strategies, such as the deductive method of Bayes, and to adopt a holistic perspective that considers the uniqueness of each patient and scientific evidence.

Regulations in Italy regarding the appropriateness of treatment

In recent decades, the medical profession has undergone a series of legislative transformations that have defined professional profiles, rights, and duties, as well as ethical and legal responsibilities. These regulations have contributed to a greater appreciation of the physician's role within the Italian healthcare system.

One of the main regulatory references is DL n. 502/1992 (28), which restructured healthcare professions, outlining the profiles of each role, including physicians, and conforming the legal attributions to support the profession. DM n. 240/1994 (29) defined the professional profile of the physician, specifying the responsibilities and competencies required for the correct exercise of the profession. In particular, the decree emphasizes the centrality of the physician in the diagnostic and therapeutic process and promotes a multidisciplinary approach to healthcare assistance.

Of particular relevance is also Legge n. 42/1999 (30), which abolished DPR n. 225/1974 and established greater autonomy in medical practice, introducing three fundamental documents: the professional profile of the physician, the professional code of ethics, and the formative principles that guide medical training.

The Decree of the President of the Republic n. 270/2004 (31) reformed the training and recognition of qualifying titles for the exercise of the medical profession, establishing qualitative standards for the training pathway.

A significant intervention is represented by DL 13 September 2012, n. 158 (“Decreto Balduzzi”) (32), converted into Law n. 189/2012, which clarifies matters regarding the professional responsibility of the physician. In particular, Article 3 of the decree states that “If one has adhered to the guidelines, one will be responsible for damages only in cases of willful misconduct or gross negligence,” thereby promoting the importance of guidelines in reducing the impact of clinical risks.

“Law 8 March 2017, n. 24” (Gelli-Bianco Law) (33) has introduced significant provisions regarding the safety of care and professional liability of healthcare practitioners, particularly concerning the medical profession:

1. safety of care: the law emphasizes the importance of ensuring patient safety by promoting the adoption of good clinical-assistive practices and guidelines developed by public and private entities and institutions and by scientific societies;
2. professional liability: the Gelli-Bianco Law establishes that healthcare professionals, including physicians, must adhere to the guidelines' recommendations while performing healthcare services. Article 5 states that, in the event of a dispute, a physician who has followed such guidelines may demonstrate that they acted diligently, thereby limiting their liability to cases of intent or gross negligence;
3. introduction of the new article 590-series of the Penal Code: this article regulates negligent liability for death or personal injury in healthcare. It establishes that if a harmful event occurs in the exercise of the healthcare profession, penal liability is excluded if the professional has complied with the guidelines. This provision offers additional protection for physicians, recognizing that guideline adherence constitutes a form of diligence;
4. promotion of scientific societies: the law encourages scientific societies to develop and disseminate standards of care and recommendations, contributing to the professionalization of the medical figure and the implementation of evidence-based practices;
5. continuing education requirement: the law underscores the importance of continuing education for healthcare professionals, encouraging updating skills and knowledge in line with the most recent medical evidence.

In summary, the Gelli-Bianco Law represents a significant step for the medical profession, as it establishes a clear regulatory framework for professional liability, promotes patient safety through the adoption of evidence-based practices, and supports the role of scientific societies in defining standards of care.

Therefore, it is imperative for today's physicians to develop adequate competencies to properly apply the Evidence-Based approach to ensure patient safety and adhere to good clinical-assistive practices. Alignment with such norms will effectively regulate medical practice and contribute to an ever-increasing quality of care.

CASE REPORTS

A): case report of a patient with subscapular pain

The following clinical case involved a 37-year-old patient, an avid runner, who had recently traveled to Cambodia. Two months after his return, the patient presented to us complaining of persistent pain in the left subscapular region, a symptom that began to manifest upon his return home. This case provides an important opportunity to apply Bayes' theorem in formulating the final diagnosis.

Given such symptomatology, we initially performed an MRI of the thoracic spine. The results showed areas of altered signal intensity: hypointense areas on the T1 sequence (Fig. 4) and hyperintense areas on the T2 sequence (Fig. 5).

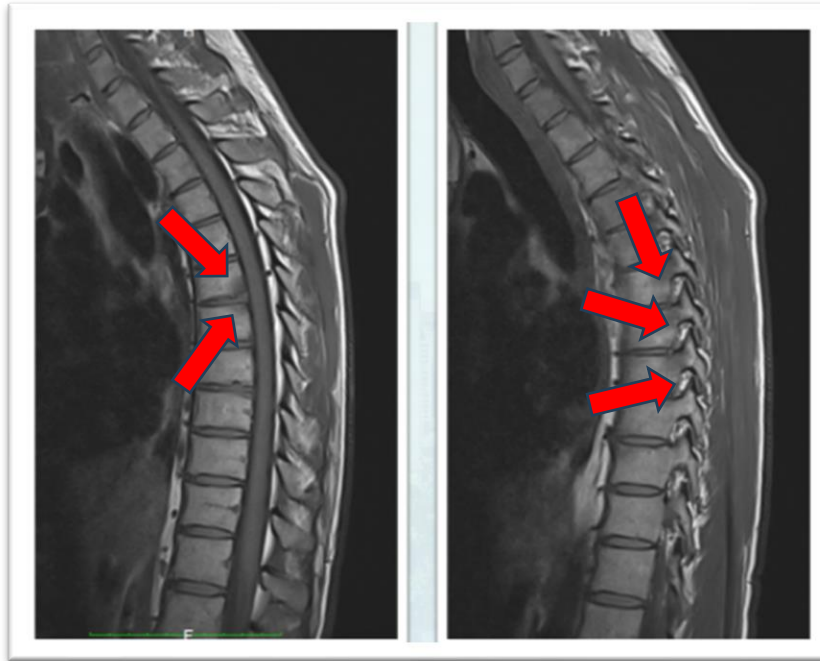


Fig. 4. *Sagittal MRI T1: hypointense signal areas at the level of the opposed posterior edges involving several middle-dorsal vertebrae (arrows).*



Fig. 5. *Sagittal T2 MRI: areas of high signal intensity at the level of the posterior edges facing some medium-dorsal metameris (arrows).*

Particular attention has also been devoted to the sequences using fat saturation techniques, such as Short-Time Inversion Recovery (STIR) (Fig. 6) and Fat Saturation (FAT SAT) (Fig. 7), which confirmed the areas of altered signal intensity.



Fig. 6. Sagittal MRI with STIR sequences: confirmation of areas of altered signal intensity (**arrows**).

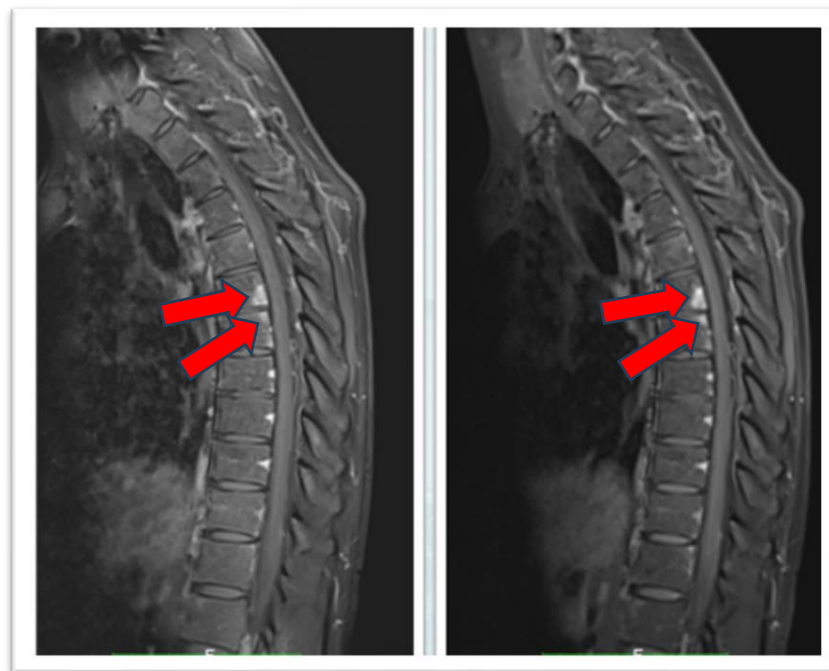


Fig. 7. Sagittal MRI with contrast-enhanced (CE) FAT SAT sequences: confirmation of areas of altered signal intensity (**arrows**).

Following an MRI investigation that did not provide a conclusive diagnosis, we found ourselves at the initial position of Bayes' diagnostic algorithm, formulating several diagnostic hypotheses. The diagnoses we hypothesized were:

1. tumors (such as lymphomas, myelomas, or metastases);
2. infections;
3. inflammations;
4. malformations.

In light of these alterations in signal intensity, we decided to conduct further investigations with a PET-CT, which turned out to be negative. This allowed us to exclude the tumor-related hypotheses (Fig. 8).

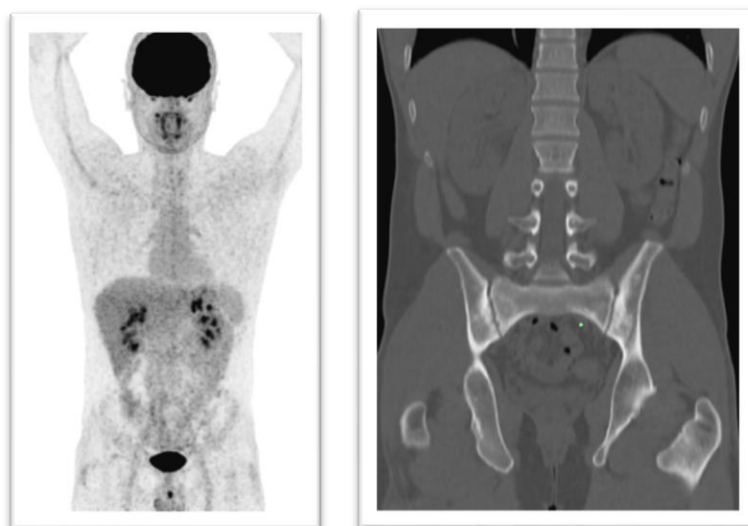


Fig. 8. *PET-CT*

Following the negative outcome of the PET-CT, the remaining hypotheses to consider include:

1. infection;
2. inflammation;
3. malformation.

We have, therefore, reevaluated the MRI and noted a bilateral symmetric alteration in signal intensity in both sacroiliac joints, which allowed us to comfortably exclude the hypothesis of any potential malformative pathology (Fig. 9).

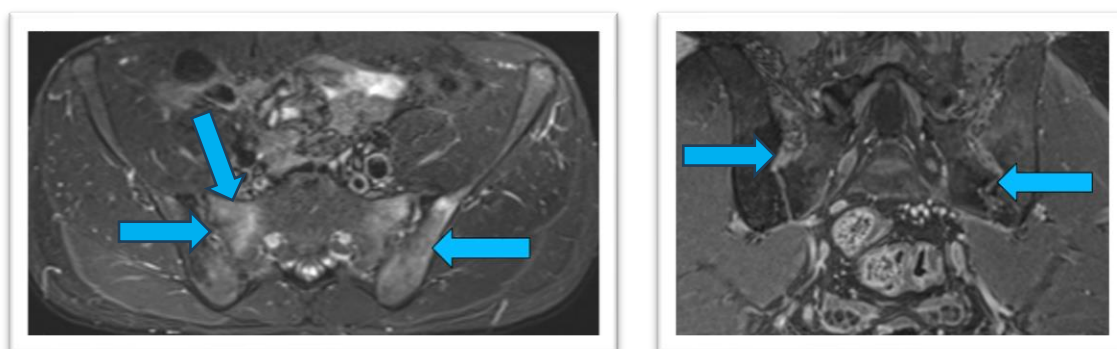


Fig. 9. *MRI signal alteration on both sacroiliac joints (arrows).*

The hypotheses remaining to be considered at this point in the diagnostic process include:

1. infection;
2. inflammation.

Continuing with the diagnostic process, blood tests were performed using serological and rheumatic tests. The results showed a negative rheumatoid factor, the Waaler-Rose test was negative, and there was a weak positivity for C-reactive protein. A serological analysis was subsequently conducted to exclude specific infections. Tests for Bartonella, Toxocara canis, Brucella, Schistosoma, fungi, Coxiella, tuberculosis, HIV, and Strongyloides revealed negative results.

With all potential infections excluded, only the hypothesis of inflammation remains. However, it is necessary to define the specific nature of this inflammation. To explore this aspect further, a fundamental diagnostic test must be performed: the HLA-B27 antigen assay. The result of this examination is positive, guiding us towards a diagnostic conclusion.

Through a rigorous application of Bayes' theorem, we have reached the pinnacle of our diagnostic pyramid. The patient was diagnosed with ankylosing spondylitis, an inflammatory condition that justifies the symptoms and the alterations observed in the various tests. This case demonstrates how a systematic and evidence-based approach, such as

that provided by Bayes' theorem, can guide clinical practice through the complexity of the diagnostic process, allowing not only for the confirmation of a specific diagnosis but also for the exclusion of other potential pathological conditions.

B): case report of a patient with left lumboischialgia

The following clinical case involved a 61-year-old man who presented with a left lumbosciatica, characterized by pain radiating along the course of the L5 nerve root. The patient also reported localized pain in the lower lumbar region, accompanied by paresthesia in the lower limbs. For this reason, the patient underwent a lumbar-sacral MRI, which was reported as follows: "Maintained metameric alignment of the posterior wall. Dimensions of the spinal canal are within normal limits. No evident disc herniations are recognizable; the L4-L5 disc slightly protrudes from the bony profiles in the posterolateral region, on the left side. Marginal spondylotic changes with associated Schmorl's nodules at the upper endplate of L5, where adjacent edema of the cancellous bone is also noted. The conus medullaris appears normal in morphology, dimensions, and signal intensity. Additionally, small hemangiomas of the L2 and L3 vertebral bodies are reported incidentally" (Fig. 10 A-B).

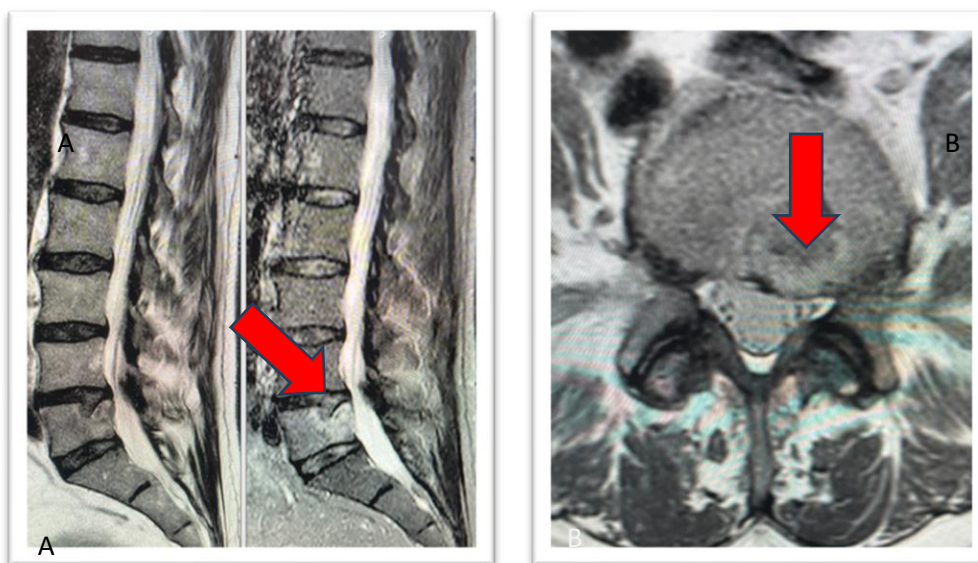


Fig. 10. A-B: sagittal and axial MRI of the lumbosacral spine: an area of altered signal intensity involves the left hemibody of L5 (arrows).

Since there is no diagnostic correlation between the radiological report and the symptoms reported by the patient, it has been decided to further investigate with a computed tomography (CT) scan to better characterize what is described concerning the vertebral body of L5.

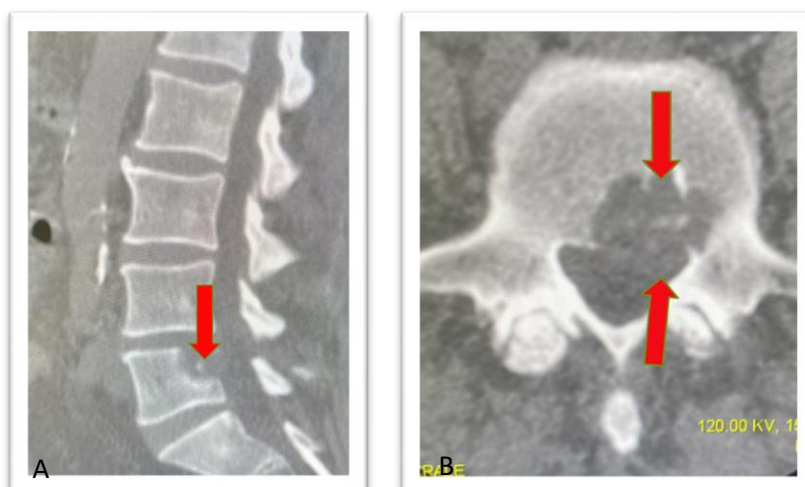


Fig. 11. CT investigation with algorithms for bone: A: sagittal reconstructions; B: axial scan: osteolytic area with interruption of the posterior wall affecting the left hemibody of L5 (arrows).

The results of the CT scan revealed that the area previously interpreted on the MRI as edema was, in fact, an osteolytic lesion (Fig. 11 A-B). The CT investigation, further complemented by reconstructions in three planes of space, allowed for the identification of an additional lesion of similar significance affecting the left hip joint, a finding not reported in the MRI examination (Fig. 12 A-B). This new information prompted a reevaluation of the patient's clinical condition, suggesting the need for further investigation with a Staging CT scan to search for a possible primary lesion responsible for the metastatic presentation.

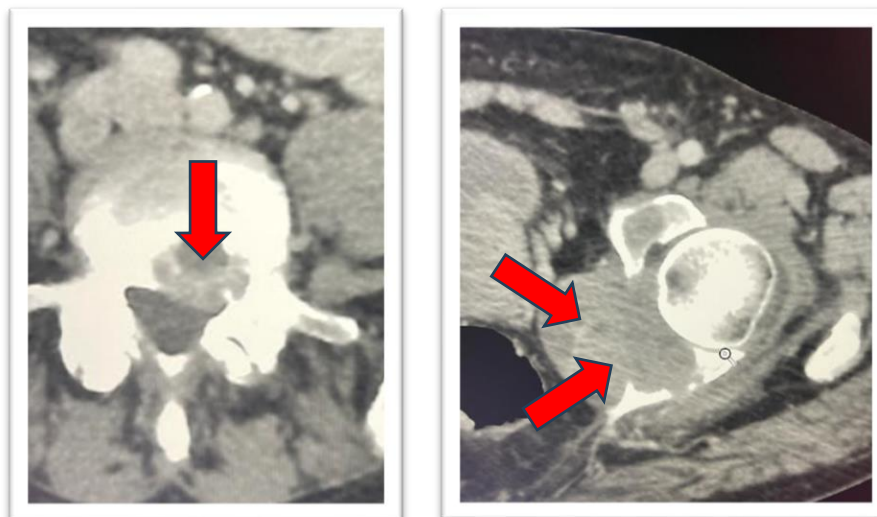


Fig. 12. Lumbar-sacral-pelvic CT. **A:** osteolytic lesion at L5 (arrows); **B:** recurrent lesion at the left hip joint (arrows).

The CT staging has highlighted the lesions affecting L5 and the left hip joint as being of a repetitive nature, originating from a primary neoplastic lesion in the right lung (Fig. 13).

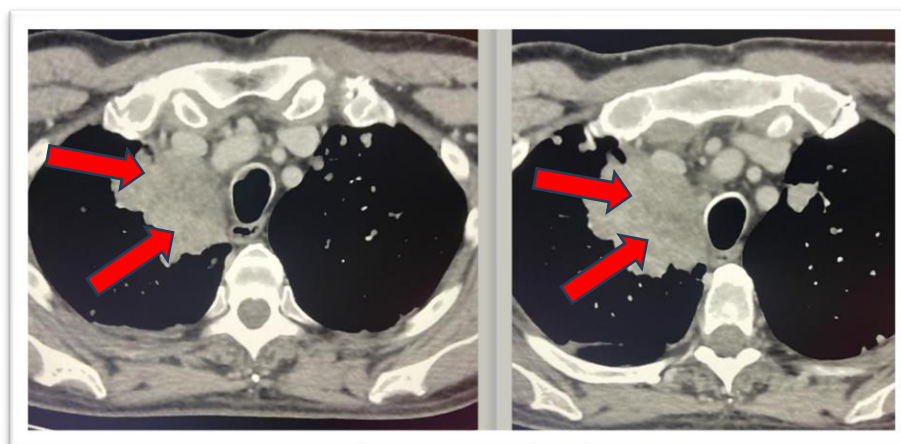


Fig. 13. CT Staging: a bulky expansive process of the right lung (arrows).

This clinical case raises important considerations regarding the diagnostic process:

1. MRI interpretation: the failure to identify significant alterations, such as osteolytic metastasis, highlights the need for a critical review of radiological interpretation;
2. complementary investigations: the non-compliance with guidelines for the proper execution of MRI investigations (absence of coronal sequences) has limited the ability to identify additional lesions in other locations, such as the left hip joint.

This clinical experience underscores the importance of a systematic approach in the diagnostic process to ensure an accurate and timely diagnosis in patients with complex symptoms.

RESULTS

In both cases presented, the systematic application of Bayes' theorem has demonstrated its effectiveness in reaching the correct diagnosis, thereby allowing for the establishment of the best possible therapeutic options.

In the first case, a 37-year-old patient with left subscapular pain was correctly diagnosed with ankylosing spondylitis through a series of targeted sequential investigations, culminating in the accurate diagnosis confirmed by a positive result for HLA-B27.

In the second case, a 61-year-old man with acute left lumbar sciatica obtained the correct diagnosis only after a re-evaluation of the conducted investigations, completed by a targeted CT study that revealed osteolytic metastatic localizations in the vertebral column and the left hip joint, leading to a comprehensive diagnosis through a staging CT that documented the primary neoplastic lesion affecting the right lung.

This methodological approach has allowed for the management of diagnostic uncertainty and the improvement of clinical outcomes through a critical re-examination of the available data.

DISCUSSION

The two cases presented effectively illustrate the importance of a rigorous methodological approach in clinical practice and the consequences arising from diagnostic errors. In the first case, a 37-year-old patient with subscapular pain received a prompt and accurate diagnosis of ankylosing spondylitis. This positive outcome resulted from a careful application of guidelines and best practices, particularly through the use of Bayes' theorem to process clinical information and achieve a targeted diagnosis.

In contrast, the second case highlighted a series of methodological errors that led to a diagnostic delay for a 61-year-old patient presenting with symptoms of acute left lumbosciatica. Despite initial investigations, lumbar-sacral metastasis was not recognized on MRI. Furthermore, the lack of coronal images during the examination hindered the identification of a second repetitive localization affecting the left hip joint. These errors demonstrate how a failure to adhere to evidence-based medicine EBM guidelines can compromise the quality of diagnoses and, consequently, negatively impact the patient's prognosis.

These cases crucially highlight the role of EBM in clinical practice. This approach promises to integrate the best available evidence, clinical expertise, and patient preferences to promote safe and effective diagnostic and therapeutic decisions. The systematic analysis of diagnoses related to ankylosing spondylitis and systemic neoplasia confirms that EBM can optimize care pathways, minimizing the risk of clinical errors and improving patient outcomes.

The use of Bayes' deductive method has proven essential in this context, as it allows professionals to update their hypotheses based on clinical evidence continuously and address uncertainty by diagnosing more accurately. Avoiding cognitive biases, such as selection and confirmation, is fundamental to ensuring the quality of clinical decisions. Each patient presents unique characteristics, and basing diagnoses on generalizations derived from past experiences can lead to inadequate therapeutic choices. Therefore, emphasizing the continuous training of professionals, both in the use of deductive reasoning and in the principles of EBM, is of primary importance in reducing the risk of malpractice and ensuring high-quality care.

Similarly, it is crucial to recognize the importance of patient-centered communication. Establishing an open and honest dialogue with patients not only fosters the development of a solid trust-based relationship but is also essential for gathering vital information regarding their needs and preferences. The centrality of the patient must always be maintained, as their perceptions and clinical history can provide crucial insights for interpreting signs and symptoms, guiding diagnostic and therapeutic choices toward more effective and personalized solutions. Additionally, strict adherence to current regulations, as highlighted by the Gelli-Bianco Law, further emphasizes the importance of integrating evidence-based practices into routine clinical work. The regulations not only encourage a scientific approach to managing clinical risks but also provide legal protection for professionals who operate in accordance with the established guidelines.

CONCLUSIONS

In conclusion, adopting EBM is imperative for the modern healthcare professional. The application of the deductive Bayes method, coupled with an awareness of cognitive biases and a commitment to a rigorously scientific approach, is essential to ensure the quality of care and reduce the risk of diagnostic errors. Physicians must remain consistently updated to apply these principles correctly.

Moreover, emphasizing patient-centered communication, wherein the patient's needs and experiences are at the core of clinical practice, not only allows for the collection of valuable information but also helps to build a strong and lasting therapeutic relationship. Integrating scientific evidence with the individual peculiarities of each patient within a clear and precise regulatory framework is crucial to ensure the safety and effectiveness of the treatments provided.

In summary, the synergy between scientific methodology, empathetic communication, and current regulations represents the key to delivering high-quality care in the contemporary healthcare, contributing to improved clinical outcomes and safeguarding patient rights.

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Review

A NARRATIVE REVIEW ON TENNIS-RELATED SPINAL PATHOLOGIES

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ABSTRACT

Tennis is one of Italy's most popular sports, boasting over 1 million registered players and 3 million recreational participants. Despite its asymmetrical nature, tennis involves several movements that engage the entire musculoskeletal system. While acute injuries are rare, chronic conditions related to overuse are prevalent, particularly among players over 25. Common injuries include tendinopathies, muscle strains, and lower back pain. Adolescent players exhibit a higher incidence of lower limb injuries, while adults predominantly experience spinal and overuse conditions. Spinal pathologies are a significant concern in tennis, with lumbar pain affecting 30% of players and often linked to improper technique or excessive training. Acute lumbar strain, discopathies, and isthmic pathologies such as spondylolysis and spondylolisthesis are frequently observed. These conditions can result from repetitive high-stress movements, particularly during serves and smashes, leading to mechanical imbalances, degenerative changes, or nerve root involvement. Treatment strategies emphasize rest, pain management, and rehabilitation, focusing on muscle strengthening and flexibility. Preventive measures, including biomechanical assessments, technical training, and appropriate equipment, are crucial to mitigating injury risks and maintaining players' long-term performance and well-being. This review highlights the causes, clinical manifestations, diagnostic tools, and therapeutic approaches for spine-related injuries in tennis, focusing on prevention to enhance athlete safety and longevity.

KEYWORDS: *tennis, muscle, spine, lumbar, discopathy, tendinopathy, pain*

INTRODUCTION

Traumatology of the locomotor system in tennis

In Italy, tennis has always been a widely practiced sport. According to estimates by CONI (Italian National Olympic Committee) and ISTAT (Italian Institute for Statistics), it ranked second in 2022 for the number of registered players, with growing participation, reaching the top position in regions such as Piedmont and Sicily (1). With over 1 million registered players and 3 million recreational and casual players, tennis is one of the most practiced sports in Italy, followed by over 24 million sports enthusiasts. The number of senior players is also steadily increasing (2).

This growing interest in tennis highlights the importance of addressing the impact of "tennis-related injuries" in clinical practice for physicians and athletic trainers. The incidence of acute traumatic events in tennis is low, accounting for about 0.12% of all injuries. However, the incidence of conditions related to functional overuse is significantly higher (3).

For all age groups, the most common injuries are tendon or muscle-related. In players over the age of 25, overuse injuries predominate. Among younger players, lower limb injuries are twice as common as upper limb and spinal injuries, with a high incidence of ankle sprains (4). Although the number of female players is increasing, there are no substantial

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gender-based differences in injury incidence, particularly in players over 25. For adolescent athletes, however, statistics indicate a 0.6% incidence per 1,000 hours of play among females, with a prevalence of patellar conditions and lower back pain. In contrast, males show an incidence of 1.7% per 1,000 hours, with a marked prevalence of contusions, abrasions, lacerations, ankle injuries, and lumbar spine pain (5-8).

Despite being an asymmetrical sport, tennis is relatively comprehensive and features a variety of athletic movements that engage the entire musculoskeletal system (5). Tennis-related injuries include both acute traumatic injuries specific to the sport and more general injuries common to other sports.

Acute injuries, caused by trauma that exceeds the mechanical resistance of anatomical structures, are relatively rare. Tennis players are more often exposed to forces they generate endogenously rather than exogenous forces, as there is no physical contact with opponents, and the game equipment poses minimal risk (7).

Chronic injuries, on the other hand, are linked to functional overuse and can be influenced by both predisposing and determining factors:

- predisposing factors can be exogenous, such as the playing surface, footwear, equipment, or environmental conditions, or endogenous, related to the athlete's congenital or acquired abnormalities, such as asymmetries or myotendinous imbalances;
- determining factors are represented by repeated and abnormal functional stresses due to specific athletic gestures (9-11).

Tennis involves rapid player movements on the court, including sudden changes of direction, sprints, jumps, stops, and dives, which exert considerable stress not only on the spine but also on the upper and lower limbs. Additionally, the specific movements of the dominant upper limb, particularly during the serve and smash (overhead movements), involve significant exertion. If not performed correctly with proper technique, these movements can cause injuries that compromise not only athletic performance but also daily life activities (9). Such injuries, especially those due to poor execution of movements, initially manifest as reactive inflammatory phenomena, followed by regressive and degenerative changes (12).

The following sections will describe the most common trauma-based conditions affecting tennis players, focusing on the spine. Emphasis will be placed on the causes, clinical manifestations, diagnostic possibilities, treatment methods, and, most importantly, prevention strategies.

The Spine

The most common spine conditions in tennis are chronic in nature, affecting the vertebral body, intervertebral discs, or posterior arch. While the prevalence of lumbar spine conditions is not significantly different from other sports, 38% of tennis players reported missing at least one tournament due to lower back pain, and 30% suffer from chronic lumbar pain, with 85% of cases directly linked to sports activity (13-16).

A study conducted on top tennis players aged 17 to 25 revealed that 50% had experienced thoracolumbar pain lasting at least a week, and 20% had suffered severe lumbar pain (13). The lordotic segments of the spine (cervical and lumbar) are particularly vulnerable to torsional and shearing forces. These forces are experienced during the smash and serve due to the rapid hyperextension and twisting of the trunk (3).

Intense and rapid movements can cause fractures of the vertebral processes or, less commonly, the vertebral body. Repetitive and continuous movements, especially during intensive training, may lead to degenerative conditions, particularly affecting the intervertebral discs in the lumbosacral region (7) (Fig. 1).



Fig. 1. *Intervertebral discs in the lumbosacral region.*

Low back pain: one pain, many causes

Low back pain refers to sacral or lumbar pain with acute onset or episodic occurrences during or after physical strain. The causes are varied, ranging from spondylitis to dysmorphisms (e.g., scoliosis, Scheuermann's disease). However, in 95% of cases, it results from imbalances in vertebral and abdominal muscles, causing spasm in the paravertebral muscles (9,12).

Certain anatomical anomalies can predispose athletes to lumbosacral imbalance or nerve root involvement, leading to chronic pain. These include megapophyses, schisis, spondylolisthesis, scoliosis, lumbarization of the first sacral vertebra, or sacralization of the fifth lumbar vertebra (8, 11).

This condition predominantly affects young adults, with a prevalence of 30%-50% among adolescents in developmental stages (8). Pain can be unilateral or bilateral,

worsening with inactivity and improving with physical activity or heat application. Players often report an increase in training intensity or duration or a recent change in technique (2). Low back pain is classified primarily based on duration:

- acute: pain lasting less than six weeks;
- sub-acute: pain lasting six to 12 weeks;
- chronic: pain persisting for more than 12 weeks (12).

Clinical examination typically reveals spasms in the paravertebral and hamstring muscles, with negative results for Lasègue and Wassermann signs. Traditional imaging is helpful in acute cases: X-rays rule out fractures or degenerative processes, while ultrasound is of limited value. Electromyography can aid in diagnosing radicular conditions. MRI is the gold standard for evaluating chronic or recurrent pain, particularly for disc-related or soft tissue pathologies (7, 15) (Fig. 2).



Fig. 2. Electromyography can aid in diagnosing radicular conditions.

Therapeutic goals focus on preventing chronicity by addressing the root cause of the pain. Recommendations include rest from sports while maintaining normal daily activities, analgesic therapy with the lowest effective dosage, manual massages along the spine if medication proves insufficient, and specific training programs for paravertebral and dorsal muscles. Severe cases may require pain therapy or botulinum toxin treatment, but these are reserved for inappropriate muscle contractions or severe chronic pain and should be managed by specialists in dedicated centers (12, 15).

Lumbar strain

Lumbar strain is the most common acute spinal injury in tennis. At-risk muscles include the erector spinae and lumbar multifidus, which are subject to repeated and continuous trunk rotation and extension. These muscles work in synergy with the abdominals, alternating between eccentric and concentric contraction to enable extreme rotational extension and trunk flexion (4).

The typical presentation is lumbar spine pain with discomfort during standing, sitting, or walking. Pain intensifies with flexion and rotation movements of the spine, which are limited in their normal range (9) (Fig. 3a, b).

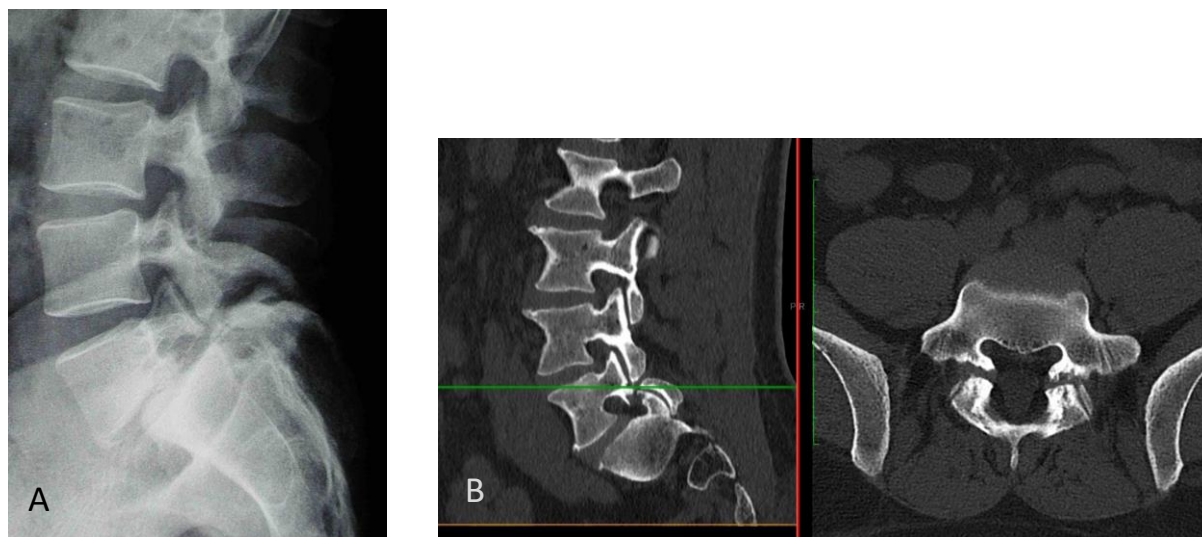


Fig. 3. A). spondylolysis with spondylolisthesis; B): spondylolysis without spondylolisthesis.

In uncomplicated acute phases, treatment involves rest and pain relief through cryotherapy, which competes with slow pain impulses and temporarily alleviates muscle spasms (7). Additional therapeutic approaches for persistent cases include ultrasound, manual massage, and the use of paracetamol or NSAIDs. Once pain subsides, gradual flexion exercises and specific muscle strengthening with stretching sessions are recommended. Return to sports typically occurs within a few days (3).

Discopathies: low back pain and sciatica

In tennis players, 43% of lumbar spine pain is associated with prolapse of one or more intervertebral discs (7). Lumbar disc herniation is primarily caused by sudden overloading, which damages the annulus fibrosus containing the disc's nucleus pulposus. In tennis, repetitive microtrauma, predominantly from spinal twisting and hyperextension during serves, contributes to a degenerative process culminating in herniation (6).

Disc herniation may result in isolated low back pain, isolated sciatica or cruralgia with lower limb pain, or a combination of these, manifesting as lumbosciatica or lumbocruralgia depending on the nerve roots involved. Pain may persist for days, have a relapsing-remitting nature, and become severe without apparent cause, with or without radiating pain to the lower limbs (15, 16).

Pain decreases with knee flexion and increases with positional changes or the Valsalva maneuver. Clinical examination often reveals positive Lasègue signs for L3-S1 root involvement and positive Wassermann signs for L1-L3 involvement. Diagnostic imaging includes X-rays to rule out spondylolysis, spondylolisthesis, or fractures, and MRI to assess herniation severity. Athletes with sensory or motor deficits should also undergo electromyography (12, 15).

Initial treatment includes rest, analgesics, anti-inflammatory drugs, and short-term use of orthotic supports. Severe cases may require corticosteroids (oral or epidural), short-term opioid medication, or pain-blocking injections. Physical therapy involves stretching and strengthening abdominal and paravertebral muscles to offload stress from lumbar discs. Daily postural correction exercises help athletes maintain proper spine alignment during high-risk movements. Surgery is considered only for resistant back pain or irreversible muscular paralysis (7, 16).

Isthmic pathologies: spondylolysis and spondylolisthesis

Isthmic pathologies, particularly involving the fifth lumbar vertebra, are relatively common among young tennis players. Spondylolysis, while potentially congenital, often stems from cyclic microtraumatic stress (16). This condition may be accompanied by active spondylolisthesis (with rapid progression) or passive spondylolisthesis (with slow progression), primarily affecting athletes with incomplete skeletal growth (7).

Spondylolisthesis progresses through four stages, with the most severe stage, spondyloptosis, requiring surgical intervention (2). Diagnosis relies on oblique and dynamic X-rays, with possible CT scans for further evaluation (16).

Treatment for spondylolysis without spondylolisthesis is conservative, focusing on rest, symptom relief, and specific rehabilitation. In cases of spondylolisthesis, depending on the degree of slippage, specialized braces or surgical stabilization may be necessary, potentially precluding further sports participation (4).

Spinal pathologies are often triggered by athletic movements, especially if performed incorrectly. Proper technique in strokes and optimal coordination during movements are essential. This must be supported by comprehensive athletic preparation to enable the spine to withstand the loads of sports practice (5).

Strength and endurance of paravertebral, abdominal, and lower limb muscles should be enhanced, coupled with good flexibility and functionality (6). Proper equipment and tools are crucial. Before starting competitive play, biomechanical evaluation of the athlete, including kinetic chains, joint angles, and equipment (e.g., footwear, racket types, string tension), is essential to design appropriate athletic and technical training (3).

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Letter to the Editor

SPINAL CORD STIMULATION DURING THE COVID-19 PANDEMIC: INSIGHTS FROM ITALY

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To the Editor

The COVID-19 pandemic, which emerged in 2019, had a significant impact on Italy, notably in the Lombardy region. Starting from March 8th, 2020, all non-urgent surgical procedures were suspended across the country. As a result, the implantation of spinal cord stimulators (SCS) was deemed non-essential and postponed during the pandemic to efficiently allocate the limited resources overwhelmed by COVID-19. Thus, the placement of new stimulators was delayed until after the acute phase of the pandemic had passed.

Data collected from three high-volume centers specializing in SCS (Como, Ravenna, and Varese), which typically conduct 40-80 implants annually, provided valuable insights concerning spinal neurostimulation procedures during this crisis. The outcomes of surgical interventions performed pre-pandemic and during the pandemic are summarized in Table I.

Table I. Case studies of the clinical centers.

Hospital	Varese	Como	Ravenna
SCS trial before COVID	4	28	6
SCS trial during COVID	0	0	6
SCS definitive	4	17	12
SCS removal for:	0	9	0
Infection		2	
Trail failure		2	
Trail not done		2	
No follow up		3	
No definitive fear of COVID-19		2	

These findings allow us to draw several conclusions. Notably, some researchers classify the elective replacement of an implantable pulse generator (IPG) as an urgent procedure or under priority category three (to be conducted within

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one to four weeks) (1). Therefore, this procedure can be regarded as fitting within these classifications. In the Varese hospital, a designated COVID-free peripheral facility was utilized for definitive implants; however, not all hospitals have such options. In contrast, the Ravenna Hospital conducted surgeries in a dedicated COVID-free surgical area, categorizing them as surgical emergencies.

One concern is that the transition period between the trial and the definitive implant may lead to infections (2), as evidenced by Como's postoperative infection rate, which rose to 7% (typically less than 4%). It is crucial to mitigate this risk to avoid burdening a healthcare system already stretched to its limits.

To reduce the chances of infection from extended trial periods, single-step implantation, where both the electrode and IPG are placed simultaneously, might be a viable option for patients who qualify for SCS (3). This method not only minimizes the need for multiple hospital visits and a second surgical intervention but also lowers the risk of exposure for both patients and healthcare personnel. However, single-step surgery may present challenges related to reimbursement processes.

With the restrictions imposed during the pandemic, follow-up appointments between SCS programmers and patients predominantly shifted to telephone or video consultations. Nevertheless, technological barriers, particularly for elderly patients, hindered their ability to engage effectively with new systems, as highlighted by the Como clinical center, where five patients failed to receive proper guidance during their trial due to inadequate execution.

While telemedicine has emerged as a supportive tool during the pandemic, it is essential to establish clear usage parameters and understand the medicolegal implications of such practices, especially concerning SCS (4). The integration of various programming options with different wave systems in the same IPG could serve as a foundation for reducing the need for in-person hospital follow-ups, as these settings can be adjusted remotely. The latest models of neurostimulators equipped with multiple programming capabilities, as implemented in our centers, can facilitate this goal.

In summary, it is advisable to avoid the complete closure of medical centers. Referring urgent cases to alternative facilities could help prevent the deterioration of health among patients awaiting implantation (5).

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