

Comparative Clinical Trial Between Conventional Treatment and Treatment with Rich Plasma Implants in Platelets (PRP) in Patients with Pseudarthrosis in the Tibia

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Abstract

The objective of this work was to carry out a comparative clinical study of the cost between the Conventional Treatment and the Treatment with Platelet Rich Plasma (PRP) in patients with Pseudarthrosis in the Tibia. At human bone fractures, mainly at arising in accidents in traffic and others and your complications, represent one important condition what has jeopardized health and quality of life, in addition to crescents for the Unified Health System (SUS), so much in the treatment primary, how much of us care with their grievances. One there, the Pseudarthrosis, entity gives Orthopedics already quite known, it is one complication of fractures Where o bone no it presents features in consolidation and regeneration. This is mainly due to poor vascularization at the fracture site, inadequate or late treatment and follow-up of the fracture, or the presence of a gap between the bone fragments.

Surgical treatment is the most common for Pseudoarthrosis and it may be necessary for the patient to have a vascularized bone graft in the affected region. Against in a scenery, in what if observe o increase in costs hospital at the treatment surgical of fractures, so as pension expenses at the costing in pensions and retirements, resulting in loss gives activity work and loss of Health and Quality of Life with great repercussion at economy of country, was performed a study with essay Clinical Cats Comparison of Treatment Surgical Conventional for Pseudarthrosis gives Tibia, with o use in new technologies like the injection in Plasma Rich in Platelets (PRP) at the focus gives referred lesion, in patients attended fur System single of Health (SUS). The results obtained demonstrate that treatment with Platelet Rich Plasma (PRP) is less expensive, less traumatic, effective and allows for a shorter hospital stay, in addition to improving the Quality of Life.

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Keywords: Fractures; Pseudarthrosis; Tibia; Conventional treatment; PRP treatment; Innovation; Quality of life.

Introduction

A fracture of the Tibial Diaphysis (Shin bone or leg bone) is the long bone fracture most often treated by orthopedists. Its incidence is higher in young patients and the most common causes are traffic accidents and sports trauma. In older patients, the most frequent cause is falls, which can occur in different environments. Four (04) methods of treatment of fractures of the Tibial Diaphysis are currently used in conventional treatment, all of them with ardent advocates:

- Closed reduction accompanied by cast immobilization and/or prefabricated orthosis.
- External fixation.
- Open reduction with Osteosynthesis
- Fixation to a closed focus and use of pins.

Fracture of the Tibial Diaphysis is the most common and can often be associated with Fibula. Currently, treatments can be done with plaster, where immobilization is performed until bone consolidation, and surgery, where implants are used that make the bone consolidate correctly.

The term Pseudarthrosis is applied to designate the situation in which the fracture does not show radiographic evidence of progression of the healing process, indicated by sclerosis at the ends of the fracture, presence of a hiatus, absent or hypertrophic callus, and persistence or widening of the fracture line.

The problem that arises is that, as it is a subcutaneous bone, the tibia has a higher incidence of open fractures. Like the femur, fractures of the tibia are most often disabling, making it impossible for patients to walk without the aid of immobilization and causing severe pain when moving. The healing time of a tibial fracture is about 8 (eight) weeks. Plaster Treatment for Tibial Fracture is indicated only for initial fractures without deviation and well aligned. In addition, the patient's skin must be in good condition to be able to withstand the plaster treatment.

However, it can also be indicated for children, patients who do not want to operate and patients unable to undergo surgery due to a certain health problem. The most popular treatment for a tibia fracture is placement of an Intramedullary Nail. Plaster treatment has been less and less indicated, as it takes longer and starts with a very large cast that goes from the groin to the toes. Therefore, you must have this cast from 02 to 06 weeks and cannot step on it.

Surgical treatment for tibial shaft fractures is currently the most used, as it has fewer complications compared to plaster treatment. This is due to the bone "paste" better and straighter with surgery compared to plaster treatment. However, surgery is indicated for displaced fractures, open fractures, fractures with soft tissue injuries and large edema, arterial injury, Compartment Syndrome, femur fracture at the same time and on the same side, among other indications.

Therefore, treatments can be: Intramedullary nail, plates and screws and external fixators.

The justification is that post-trauma represents a serious problem in Health public all around the world. O treatment It depends on gives use in materials specific and implant surgical in material in osteosynthesis with a high-cost medium per patient and one rate in complication related the infection in lathe in 13%, regardless gives technique surgical used. The technique in preparation of Platelet Rich Plasma (PRP) It is simple, with cost reduced and no offers scratches in rejection, one turn what It is isolated the leave gives own fraction sanguine of patient. O use in PRP at the Brazil has been adopted per orthopedists by evidence of potential therapeutic at osteogenesis and chondrogenesis in fabrics injured [1-3].

Biomaterials used (proteins morphogenetic, gel in hydroxyapatite, cellulose bacterial) seek effect you Principles of osteoinduction and osteoconduction for the action osteoblastic and regeneration tissue through gives activation from fibroblasts in one manner most fast and efficient. Our team doctor it has experience Preview at application of treatment proposed in patients with fractures serious post trauma, it has no Knowledge and training adequate about your procedures in collect in cells gives Marrow bone, in preparation of PRP, use in biomaterials, of implant surgical conventional and in cells gives marrow bone [4-6].

Other the justification is that the advances in Medicine that, together with the new technologies available, in areas related to Health or not, provide a faster and more

effective diagnosis of diseases, as well as the possibility of treating and curing these diseases in a more satisfactory way. Less traumatic, returning a better Quality of Life (QL) to the patient.

Thus, the General Objective of this work was “To approach a Comparative Clinical Trial of Cost Between Conventional Treatment and Treatment with Platelet Rich Plasma (PRP) Implants in Patients with Pseudarthrosis in the Tibia”. The Specific Objectives aimed at:

- Evaluating the cost of treating Pseudoarthrosis of the tibia, using Platelet Rich Plasma (PRP) injection, comparing with the Conventional Treatment offered by SUS.
- To describe and statistically analyze the main findings regarding the total length of hospital stay, number of days without work and hospital cost comparing PRP therapy to conventional treatment.
- Evaluate the rehabilitation of patients with Pseudoarthrosis submitted to Treatment with PRP compared to Conventional Treatment, emphasizing the recovery of post-trauma work function.

Literature review

In Brazil and in the world, investment in Preventive Medicine has gained more and more space in the Strategic Planning of Health Operators. The central idea is to replace the curative model, focused on the disease, with an approach focused on Health Maintenance and Quality of Life [7,8]. By taking care of Health and focusing on

Prevention, people do not need to interrupt life plans and projects due to complications arising from the treatment of a disease. This becomes even more important when we consider the increase in longevity and the aging trend of the Brazilian population [7,8].

The Constitution Federal do Brazil in 1988 put to Right the Health from Brazilians as obligation of state and, for so much, O System in Single in Health (SUS) he was created. The Law in number 8,080/90 defines what O SUS It is Set in Actions and services in Health provided by federal, state, and municipal public bodies and institutions of the Direct and Indirect Public Administration and foundations maintained by the Public Power [9,10]. Since your creation of Unified Health System (SUS) good Heads up the health from citizens Brazilians in manner unrestricted, yet it is clear the perception what exist voids in roof and difficulties growing, about everything When observe the questions relative to financing and to costs of SUS [9-11].

According to a Constitutional Amendment of September 29, 2000, SUS financing is the responsibility of the three governmental spheres (Federal, state, and municipal). In this way, the payment of Health Service Providers is made by each government sphere responsible for the Management process. Bearing in mind the budgetary constraints that Brazilian states repeatedly face, the role of distributing resources equitably is a major challenge.

In addition to the costs of the actors who work in serving the population, the SUS, the largest Social Action Program in the world, also pays for the surgical materials [9-11].

There is in the SUS a Unified Table of the procedures that are made available and paid equally throughout the Brazilian territory and the control of costs is carried out from the Health Information Systems implemented in the SUS. The Hospital Information System (SIH) is responsible for providing data related to hospital admissions, as well as the procedures performed during this period, thus, from the single table of values, resources are transferred to the units of origin [10-14].

All this data processing is done by the Department of Informatics of the SUS (DATASUS), an Agency of the Ministry of Health. It is an agency of the Secretariat for Strategic and Participatory Management of the Ministry of Health, with the responsibility of collecting, processing, and disseminating Health Information [11,14,15]. However, the advancement of medicine, the constant implementation of new technologies for patient care, as well as the increase in the number of morbidities resulting from injuries or diseases, which today have higher survival rates and increasing incidence, have been increasing costs for the Unified Health System (SUS) [11,13,15].

In this scenario, fractures resulting from traffic accidents and their complications represent an important condition that, in recent years, has entailed increasing costs for the SUS, both in primary treatment and in the care of its complications. It is also necessary to pay attention to the high cost to Social Security, since young adults are leaving work because of these injuries and thus end up needing Sickness Allowance and, in the most serious cases, Disability Retirement. In view of this scenario, in which the increase in

hospital costs in the surgical treatment of fractures is observed, as well as social security expenses included in the cost of pensions and retirements, resulting in the loss of work activity with great repercussions on the country's economy, we decided to carry out an essay clinical study comparing the cost of conventional surgical treatment for Pseudoarthrosis of the Tibia, using plates and screws, intramedullary nails or external fixators, with the use of a new technology: the injection of Platelet-Rich Plasma in the focus of the referred lesion, in patients served by the Unified Health System[13,15].

Pseudarthrosis

The Pseudarthrosis It is one complication from orthopedics already quite known being considered as the complication of fractures where o bone no it presents features radiographic in consolidation. It is observed at figure 1 one radiography with signals in sclerosis us fragments fractures, France lack in consolidation and alteration at the callus bony [16,17]. Some authors add the that painting radiographic, the need in realization in what the fracture no it presents

consolidation and what no there is evidence in evolution of process in consolidation [18,19]

Exists still o concept conferred in 1986, for the food and drug Administration (FDA) what defined Pseudarthrosis as: "When a Minimum in 9 months if pass gives lesion or gives fracture without display signals progressive in consolidation per 3 months, I have done you". However, this one criterion no he must be applied in any fracture, considering the irrigation and at features biological in each bone, the Pseudarthrosis he can if install in 1/3 of that time. At causes most probable for o emergence gives Pseudarthrosis are the Pseudarthrosis congenital, the mobility from fragments bony fractures, preventing o process natural reparatory, and o deficit vascular, insufficiency at the contribution nutritional. When o process in consolidation most demand nutrients, deficiency at the contribution sanguine and, therefore, in stimulus biological for o process in consolidation, being this one fact much related the energy of trauma and your consequent damage to tissue endothelial vascular [20-24].



Figure 1: Pseudarthrosis gives Tibia. X-rays in AP and Profile. Source: Personal Collection (2022).

They exist two types of Pseudarthrosis:

- Hypertrophic or Hypervascular
- Atrophic or avascular.

At the case of injuries hypertrophic you fragment fractures have vascularization terminal, meantime the movement excessive at the focus gives fracture Act as factor limiting of process in consolidation. Already at the case of injuries hypotrophic not there is supply sanguine adequate us fragments fractures for to guarantee the consolidation bone effective [25-27].

It is complication still if it presents as a great challenge for o surgeon, due your difficult resolution, morbidity for o patient and costs for your systems in health. The prevalence of this disorder at the process in consolidation It is in 5 the 10% in all at fractures [27,28].

The tibia it is no place in larger occurrence of this complication and invariably require various surgeries at attempt in improve o painting functional and locomotion of patients [28].

Are various at indications therapeutics for the Pseudarthrosis. Often, o access surgical for fixation and grafting bone It is the technique in choice. It is technique Visa add velocity to process in consolidation weak what resulted at Pseudarthrosis [18,29,30]. They exist still treatments most modern, based at innovation technological what the orthopedics he comes passing us last years old.

O stimulus biological of bone has been encouraged with use in protein morphogenetics bone (BMP), in cells mononuclear gives Marrow bone autologous (CMMO) or in Plasma Rich in platelets (PRP) [31-34].

US cases in injuries hypertrophic, o treatment visas the improvement gives stabilization gives fracture with use in stem intramedullary, tutor external or osteosynthesis with board and screw. O use from biomaterials has if tornado each turn most common us cases in Pseudarthrosis Hypotrophic one turn what do they can help your components at the process.



Figure 2: Aspects of fracture in the fibula and tibia.

Source: Personal Collection (2022).

Fractures in the tibia and pseudarthrosis

The “long bones” of the human body include the Femur, Humerus, Tibia and Fibula. A Tibial Diaphyseal Fracture occurs along the length of the bone, below the knee and above the ankle. Long bone fractures usually result from a great deal of force and other injuries often occur with these types of fractures.

Anatomy the leg is made up of two bones: The tibia and fibula. The tibia is the larger of the two bones. It supports most of the body weight and is an important part of the knee and ankle joint. Tibia can break in different ways. The severity of the fracture usually depends on the amount of force that caused the fracture.

The fibula is often broken as well. The most common causes of fractures in the tibia are Collisions and shocks, motorcycle falls and traffic accidents, sports collisions, among others are common causes of fractures of the tibial diaphysis. In cases like these, the bone can be broken into several pieces (Comminuted Fracture).

They can rarely break in sports such as football, when the fracture occurs with minor trauma, we need to assess the possibility of pathological fractures, athletes who break their leg with trauma that usually does not produce a fracture may have a previous history of pain after training and present a crack (stress fracture) from Overtraining.

The most common symptoms of a Tibial Diaphyseal Fracture are:

- Pain.
- Inability to walk or bear weight on the leg.
- Deformity or instability of the leg
- Bone protruding under the skin.
- Occasional loss of sensation in the foot.

The most common types of fractures in tibia. [35,36].

Treatment of pseudoarthrosis

The first attitude for o treatment gives Pseudarthrosis It is identified your etiopathogenesis. in those injuries viable, enough o alignment from fragments fractures and one osteosynthesis stable. Already for those unfeasible, often are needed actions adjuvants what aim to guarantee contribution biological the lesion bone [35,37,38].

The majority from cases in Pseudarthrosis has treatment based currently, at the use in one fixation internal per methods in board and screw, stem intramedullary or fasteners external of type ilizarov (Figure 3).

Often it is done the bloodthirsty of focus gives Pseudarthrosis, at attempt in encourage the biology of tissue, and posteriorly It is done the osteosynthesis seeking out the stability proper for what o process in consolidation if develop.



Figure 3: Osteosynthesis materials.
Source: Personal collection (2022).

Recently one wave in innovation technological generated o emergence in news techniques in bioengineering and in one series in Biomaterials what has been used us treatments orthopedic. They are products what aim to reverse at injuries from fabrics, rebuild the anatomy and act as elements adjuvants in the reactions physiological of body human. These elements they can have origin animal, synthetic or Natural with modifications molecular [39,40].

Biochemically your biomaterials substitute bony act in two phenomena:

The osteoconduction what it is characterized for the facilitation gives formation in vases and the impregnation cell, due the structure porous passive of biomaterial; and the osteoinduction what it is characterized for the neoformation bone the leave of recruitment in cells mesenchymal of tissue

adjacent, what secondarily differs in osteoblasts [41,42].

For in addition of these possibilities' therapeutics, exist techniques most advanced what they are in development and validation. O use in cells trunk mesenchymal It is one technique promising what has favored you good prognostics from cases in Pseudarthrosis [28,43].

These cells Trunk are parents multipotent, what they can to give origin to tissue connective, lineage original of tissue bone. This one type in cells he was isolated per grip to plastic at decade in sixty the leave gives marrow bone in animals adults and since then your use has won force at medicine [36,39].

At the Brazil o transplant in cells gives marrow bone he was released fur Ministry of Health since 1998 for the concierge 3761/GM

in 20 in October for o treatment in neoplasms hematological and, since then, you advances are accentuated. Other application for at cells mononuclear derivatives gives marrow bone It is the application at the treatment what Visa rebuild your fabrics injured, returning the occupation from organs affected, consequently reducing the morbidity and mortality of illnesses and you costs for you systems in Health [4,5,44].

The treatment of Pseudarthrosis provided by the Unified Health System (SUS) is currently based on three principles [10,11]:

- The use of internal fixation using plates and screws.
- The use of a locked intramedullary nail.
- The use of an Ilizarov-type external fixator. Each of these techniques and materials has different costs and are unequally available in orthopedic medical services in Brazil. Although the form of hospitalization for the use of each of these possibilities generates the same cost for the SUS, the amounts paid for the materials are different.

It should be noted that the treatment of Pseudoarthrosis is usually done through consecutive hospitalizations, surgical re-approaches, and replacement of osteosynthesis material, given the degree of severity of this complication and the difficulty in resolving the condition, generating

cumulative costs for the Unified Health System (SUS).

Innovations technological for treatment pseudoarthrosis and platelet rich plasma (PRP)

The Revolution Technological what the medicine world is passing us last 40 (forty) years points for o use in new shapes in treatment for illnesses in all your organs and system of body human. We witness the Implementation in drugs most potent, materials most resistant, techniques surgical most cleared and there are one decade your biomaterials has pointed as one solution viable at replacement in structures of body human or at the aid for what be possible the resolution in situations what up until little time no had outcome satisfactory.

In that scenery, at Pseudarthrosis won important allies for o your treatment. It is described at literature doctor o use in derivatives of tissue blood, of tissue hematopoietic, of tissue adipose and up until same biomaterials heterologous, with results satisfactory.

In between those, stands out o use of Plasma Rich in Platelets (PRP), (figure 4) for o treatment of Pseudoarthrosis. This one derivative of tissue sanguine has introduced results what take any less time for o outcome and resolution definitive for at flaws bones, with smaller cost for you Systems in Health.



Figure 4: Platelet Rich Plasma (PRP).
Source: Personal collection (2022).

Platelet Rich Plasma (PRP) (Figure 4) It is a derivative sanguine used in various areas gives medicine with o objective in to repair fabrics. For generate the repair of tissue bony in the pseudarthrosis, o main mechanism It is the production in factors in growth repairmen, what induce the production in cytokines and factors in growth tissue, in addition in suppress the waterfall inflammatory gift at lesion, providing an environment favorable to repair of tissue bone. The advantage of this method It is the possibility in, to instead in to submit o patient the new approach surgical for exchange in material in synthesis, with most days in internment and in convalescence, in only one approach any less invasive, solve o painting chronic in Pseudoarthrosis with the injection of PRP [6,21,44,45].

PRP It is a focused in platelets obtained per process in centrifuge and consequent separation from elements of blood peripheral [6,5,44,45]. At orthopedics, o your use It is

described since the decade in 70 in the most various injuries of System Muscle Skeletal. One From main effects positives of use in PRP in orthopedics it's the reduction of time in repair of injuries, in addition in reduction gives pain, thanks you're acting as regulator positive from lawsuit in osteoconduction, osteoinduction and signaling cell paracrine [21,47,49].

The obtaining of Plasma Rich in Platelets It is based at difference in density from elements of blood, via centrifuge. That process he can be accomplished through in several protocols settled down at literature. Usually, the concentration in platelets at the blood varies in 150,000/ μ L the 350,000/ μ L, with average in 200,000/ μ L. O Plasma It is considered rich in platelets when it presents most in 1,000,000 in platelets per μ L in Plasma. Compared to blood normal, o PRP contains one concentration 3 the 5 times larger in factors what influence the healing in tendons,

ligaments, muscles, cartilage, and bones [6,47].

Other score important for the use of PRP It is the need in activation gives coagulation what It is traditionally carried out with thrombin bovine or use in calcium. It is activation cause the degranulation with release from factors in growth [32,34,48]. In mode general, you factor in growth are mediators biological natural what act synergistically at regulation gives division, chemotaxis, differentiation, and metabolisms cell phones involved at the process in repair tissue [22,49].

At the moment were identified one great the amount in factors in growth secreted by platelets, in between the stands out o factor in growth derivative in platelets (PDGF), factor in growth endothelial (EGF), factor in growth vascular endothelial (VEGF), factor in growth in hepatocytes (HGF), factor in growth in fibroblast basic (TGF β), factor in growth beta in transformation (TGF β) and factor in growth insulin-like (IGF-I) [40,50,51].

First work described at literature with o use in PRP for consolidation gives fracture date of final from years old nineteen ninety and start from years old 2000, when were performed percutaneous infiltrations in PRP at the focus of Pseudarthrosis with consolidation bone in 50% from patients [50,51].

One other study accomplished in Pseudarthrosis Congenital gives leg, the combination in PRP with cells mononuclear gives marrow bone, got acceleration of process in consolidation bone, demonstrating

the efficiency and the safety gives technique [31,51,52].

O treatment in complications serious in fractures exposed with loss in pasta bone there is much time results in amputation. With o development in techniques surgical and o advent from antibiotics, new perspectives emerged. Professionals bold launched your fundamentals gives surgery restorer and reconstructive, offering one approach therapy functional and one alternative happy the prosthesis [31,47,51].

That enthusiasm surgical he was accompanied per one worry legitimate in prioritize the variety in traumas found for to provide one representation simplified and orderly, allowed so the classification and the memorization. Per last, but no less important, most of ratings he was elaborate for to establish O factor prognosis of injuries from fabrics moles at the course in fractures exposed and for identify guidelines therapeutics [26,27,52].

Material and method

Type of study

The study was developed as a trial clinical controlled, developed at the Professor Edgard Santos University Hospital (HUPES) of the Federal University of Bahia (BA), Brazil, which used as sample patients what presented fracture in Tibia, made surgery for fix it, although evolved with Pseudarthrosis.

Sample

This study included 46 patients with a fracture of the tibia diagnosed with Pseudarthrosis of both genders, aged between 19 and 76 years in an Orthopedics outpatient

clinic at HUPES (Complexo Hospitalar Universitário Professor Edgard Santos) in Salvador (Bahia, Brazil). The radiographs and medical records of these individuals were analyzed for the diagnosis of Pseudarthrosis. The sample from this study consisted of 46 patients, which were composed of forty people (87%) male and six (13%) females.

Patients were identified and selected by the investigating orthopedists during their care routine. patients' carriers in fracture gives tibia with diagnosis in Pseudarthrosis, in both genres, with range age in between 19 and 76 years old, attended in an outpatient in Orthopedics of Complex hospital university Teacher Edgard Santos (HUPES) in savior (Bahia) adopted also as criteria for consider and to analyze the therapy with Platelet Rich Plasma (PRP), the population, intervention, control or Comparison and outcome.

The following criteria were adopted to select patients eligible for the present study:

1. With clinical and radiological evidence of post-trauma Pseudarthrosis.
2. Patients over 18 years of age
3. Signing of the Free and Informed Consent Term (FICT) by the patient or by his/her legal representative in case the patient cannot sign the term, authorizing his/her participation in the study.

Patients who were considered unfit to participate in the present study and therefore excluded from the study had the following exclusion criteria:

- Chronic use of corticosteroids and immunosuppressants

- Alcohol abuse or dependence by DSM IV criteria
- Positive serology for HIV, Hepatitis B, or C
- Any other comorbidity that, at the discretion of the investigator, precludes inclusion of the patient in the study
- Minors who did not have radiography, who had surgical site infection, had comorbidities that contraindicated the procedure, and patients with a history of previous surgery for the treatment of Pseudarthrosis or who, at the investigator's discretion, were excluded from the study. main, make it impossible to include the patient in the study
- Pre-existing angular deformity or shortening that requires treatment.

Type in intervention

Use in PRP (Plasma Rich in platelets) as New Therapy at the treatment in Pseudarthrosis from Tibia.

Control or comparison

Use in PRP (Plasma Rich in platelets), compared with O Treatment Surgical Conventional (use in fasteners, plates and screws, stems, surgeries successive, most days in internment and in convalescence) in carriers in fracture gives tibia, with diagnosis in Pseudarthrosis, in both the genres.

Types of outcomes

- Primary: Failure of non-surgical treatment with PRP-performance of conventional surgical treatment

- Secondary: Total length of hospital stay, number of days without work, number of days with fever, number of days with pain, death, recovery time after treatment, hospital cost, effectiveness of PRP therapy, aptitude after treatment for work / recovery for work function. General and specific mortality, readmission rates for reasons related to post-trauma.

Monitoring plan

Information on comorbidities, demographics, initial treatment of the fracture, as well as assessment of type (open or closed) and fracture site were collected. The following initial tests were requested: Radiographs in the anteroposterior and lateral projections and computed tomography. Patients also underwent tests such as complete blood count, clotting, biochemistry, and PCR to rule out the presence of infection, unless such tests were performed recently within 1 month. Follow-up visits took place before the procedure and at 1, 3, and 6 months after PRP grafting, by the orthopedic team.

Anteroposterior and lateral radiographs were repeated to assess the appearance and progression of bone callus. For clinical and Quality of Life evaluation, an electronic database was developed for storage of information collected during time gives visit orthopedic. To final in 6 months inside dish, after the Realization in all your exams (invasive and non-invasive) defined in the protocol, those patients who did not obtain a favorable result with treatment with PRP would undergo treatment with conventional surgery and follow up for another 6 months.

Estimate of expenses

For this study, the amounts paid by the AIH for the treatment of Pseudoarthrosis, added to the values of the synthesis materials, were considered as surgery expenses. In the case of treatment with PRP, which has no expenditure foreseen in the SUS table, the value of the centrifuge and test tubes (values that were divided by the number of patients in the study), and other necessary materials were added to the value of the Hospital Internment. Such as syringes and activator. Data on expenditure on procedures performed by the SUS were obtained by accessing the SUS Procedures, Medicines and Orthoses, Prostheses and Materials Table Management System, available via the web as the Federal Government's official website (<http://sigtap.datasus.gov.br/tabela-unificado/app/sec/inicio.jsp>).

The procedure codes that were relevant to the hospitalization for the treatment of Pseudarthrosis of the tibia and the appropriate codes for the materials available in the three methods were searched, namely plate and screw, locked intramedullary nail and external fixator of the Ilizarov type. To establish the cost of the procedure for the use of PRP in the treatment of Pseudarthrosis, the same code (04.08.05.086-1) of the SUS table was used for the hospitalization of the patient and for the values related to consumables in the surgical procedure, we used the codes referring to each material available.

Aspects ethics and bioethics

This one Study Project (Clinical Trial) was conceived and designed in wake up with your terms settled down for the Resolution 466/12

that regulates research involving human beings. The principle of autonomy was followed through the application of a Term of Consent in lay language, accessible to patients with low education, concise, so that the patient could read it completely without boredom but covering all the procedures that were used during the procedure study, as well as its potential risks and benefits.

The Project of this Research he was subject and approved fur zip code of Hospital University Teacher Edgard Santos (HUPES). CAE:72236317200000049. This study did not involve storage of biological samples or foreign collaboration. This research also did not provide for a patent application. It was also described the rights and duties of the

patient and the researchers, the guarantee in access to the study's principal investigators and to the CEP and the confidentiality of the information provided.

Presentation and analysis of results

In this study, with the use of PRP (Plasma Rich in Platelets), the infection rate was zero, in addition to showing in the results that the number of deaths and/or sepsis was also null. The length of hospital stay was 1/3 of the mean time required for recovery of patients undergoing conventional therapy. The appearance of bone callus occurs in half the time, when compared to conventional therapy, which shows us a shorter time away from work and leisure activities (Table 1).

Clinical Aspects	Treatment With PRP	Therapy Conventional
Index in Infection	0	3%
Callus bone	30 days	60 to 90 days
Pseudarthrosis (Type)	hypertrophic	hypotrophic
Time in internment	01 day	03 days
Time away of activities	30 days	90 days
Rejection surgical	0	up to 60%

Table 1: Comparison In between cases Treaties with PRP and Conventional Therapies.

Source: Prepared by the author (2022).

The Hospital Admission Authorization (AIH) used as a basis for obtaining the amounts spent on hospital expenses in this work is represented in the SUS table under the code “04.08.05.086-1-Surgical treatment of

Pseudarthrosis/delayed consolidation/bone loss of the diaphysis tibial”.

For this type of hospitalization, the amount established by the table is BRL 769.41 (USD 146.55), with BRL 573.86 (USD109.30) for the

payment of “Hospital Service” and BRL 195.55 (USD37, 24) for the payment of “Professional Service”.

Regarding the value of materials used in conventional treatment, the Osteosynthesis Technique using compression plate and screw, under code 07.02.03.093-7, is established by the SUS at BRL 325.69 (USD 62.03). In cases where blocked rods are used, the code used is 07.02.03.052-0 and the cost are BRL 1,096.39 (USD208.83).

The third treatment option, using an Ilizarov-Type circular external fixator, code 07.02.03.038-4, costs BRL 1,163.90 (USD 221.69). of this mode, in an internment for procedure surgical at attempt in resolution of one Pseudarthrosis gives diaphysis gives tibia, O value paid out fur SUS to provider of service for conventional treatment for the use of compression plate and screw is BRL 1,095.10 (USD208.59), locked intramedullary nail BRL 1,865.80 (USD355.39) and for the fixer

external Circular of Ilizarov type It is from BRL 1,933.31 (USD368.24).

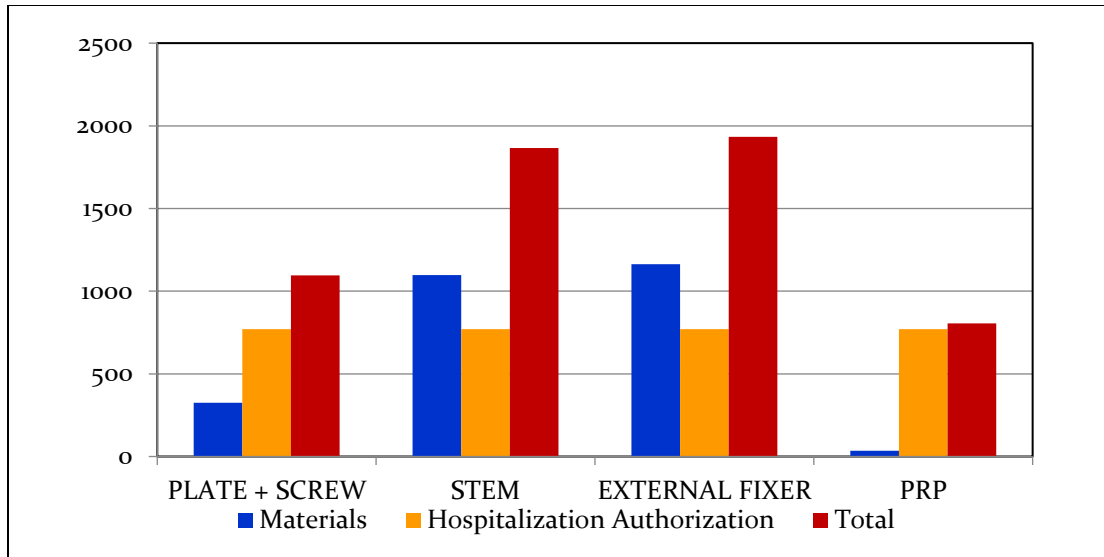
To perform the PRP Grafting Technique, it is only necessary to use a laboratory centrifuge (BRL1,500.00=USD285.61), which will be purchased once and reused for all subsequent procedures, and therefore, throughout the time, have its value diluted by each procedure performed. In the case of this study, we divided the centrifuge value by 46, which was the number of patients who used this technology in the study. We also used 4 test tubes for the centrifuge (BRL3.00/unit=USD 0.57) and Calcium Chloride (BRL0.02/5mL) as activator.

Three syringes of 20mL BRL 1.00/each=USD 0.19) are also used for peripheral blood collection and percurrent injection of PRP. Thus, adding the amount paid by SUS for the treatment of Pseudarthrosis, with the total cost of this procedure, we arrive at a total value of BRL 804.41 (USD153.22).

Items	Materials	Hospital Internment	Total
Plate + Screw	BRL 325.69 (USD 60.03)	BRL 769.41 (USD 146.55)	BRL 1,095.10 (USD 208.59)
Stem	BRL 1,096.39 (USD 208.83)	BRL 769.41 (USD 146.55)	BRL 1,865.80 (USD 355.39)
External Fixator	BRL 1,163.90 (USD 221.69)	BRL 769.41 (USD 146.55)	BRL 1,933.31 (USD 368.24)
PRP	BRL 35.00 (USD 5.66)	BRL 769.41 (USD 146.55)	BRL 804.41 (USD 153.22)

Table 2: Cost of Treatment Materials and AIH/Total

Source: Prepared by the author (2002).



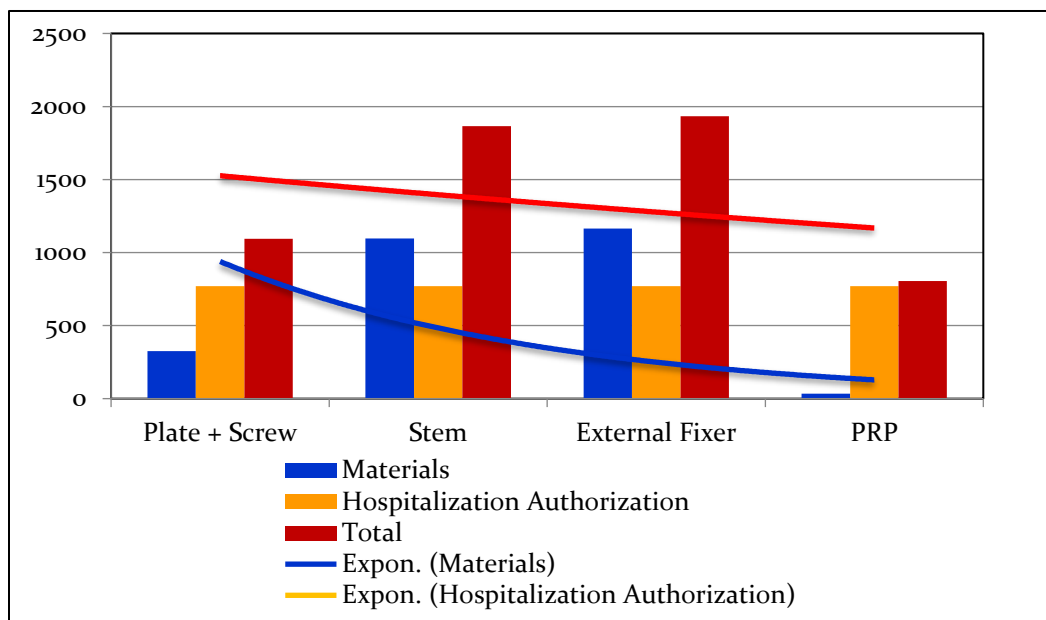
Graph 1: Comparison of Cost* Between Conventional Treatment and Treatment with PRP Implants in the Treatment of Pseudarthrosis.

Source: Prepared by the author based on the results of the Study (2002).

*Amounts in BRL (1 USD=5.25 BRL).

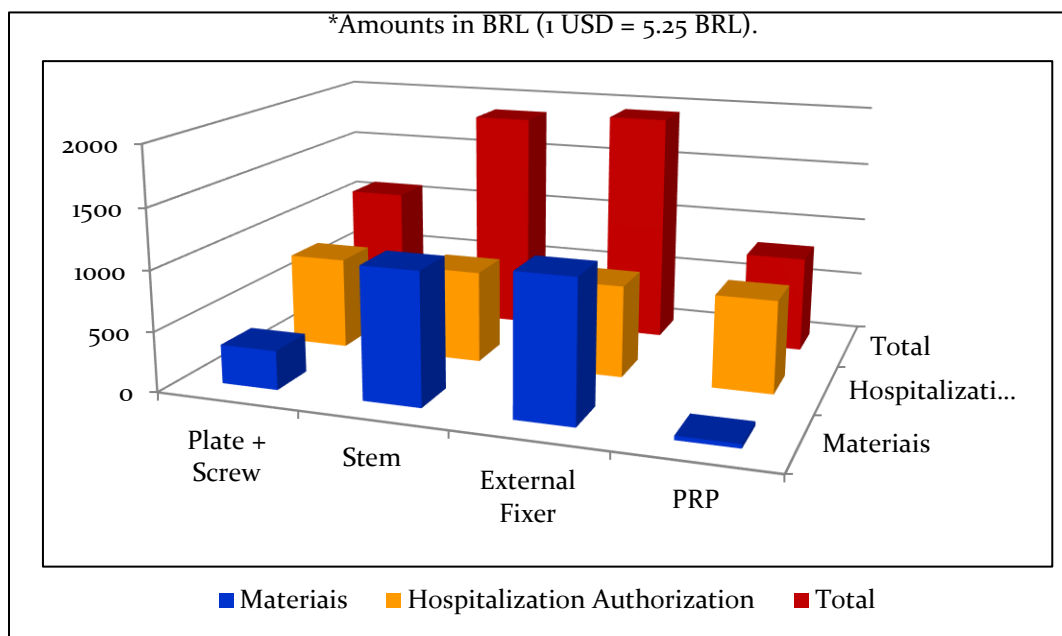
As can be seen in Graph 1, the technique with PRP is cheaper in terms of cost, in addition to

being more effective in the treatment of Pseudarthrosis of the Tibia.



Graph 2: Exponential Trend Line Between the Cost* of Conventional Treatment and Treatment with PRP Implants.

Source: Prepared by the author based on the results of the Study (2002).



Graph 3: 3D Comparison of Cost* Between Conventional Treatment and Treatment with PRP Implants in the Treatment of Pseudarthrosis.

Source: Prepared by the author based on the results of the Study (2002).

*Amounts in BRL (1 USD = 5.25 BRL).

Comparing the cost of Conventional Treatment and Treatment with PRP, as shown in Graphs 2 and 3, the results are satisfactory in terms of cost and effectiveness of the Treatment.

Conventional surgical procedure

In Conventional Treatment, the Hospitalization Authorization (AIH)-SUS Table under the code "04.08.05.086. For this type of procedure, the value of the AIH established by the SUS Table is BRL 769.41 (USD 146.55)". Larger value of materials used in Conventional Treatment (Osteosynthesis):

1. Compression plate and screws, under code 07.02.03.093-7, is established by SUS at BRL325.69 (USD62.03).
2. Locked rods, the code used is 07.02.03.052-0 and the cost are BRL 1,096.39 (USD208.83).

3. The third treatment option, using an Ilizarov-type circular external fixator, code 07.02.03.038-4, costs BRL 1,163.90 (USD 221.69).

Procedure with PRP

1. A laboratory centrifuge (BRL1,500.00=USD 285.71), which will be single purchase and reused for all subsequent procedures
2. 4 test tubes for the centrifuge (BRL3.00/unit)
3. Calcium Chloride (BRL0.02/5mL) as activator.
4. Three 20mL syringes (BRL1.00/each) for peripheral blood collection and percutaneous injection of PRP.

Thus, adding the value of the AIH paid by the SUS for the treatment of Pseudarthrosis, with the cost of the materials used for the injection

of PRP, the total cost of this procedure is BRL 804.41 (USD 153.22). That is, it is a lower value than the cost of conventional treatment.

Discussion of results

US patients of this job, what were submitted the application in PRP, he was observed answer radiographic (emergence in callus bone) in about a half of time, if compared the average historical from individuals' treaties with O treatment conventional for the pseudarthrosis. That evidence per yes only, justifies the use of PRP as routine at the treatment of Pseudarthrosis. In addition, from that, it is notorious O fact in what, one turn consolidated the failure bone, no there will be the need in new admissions for attempts in repair bony as it is observed often us patients' treaties with osteosynthesis conventional.

O time in internment us patients of this casuistry he was smaller in those addressed with implant in PRP, per if deal within a procedure with smaller morbidity if compared with o use in plates, screws, stems or fasteners external what are procedures with larger time surgical, ways in access most extensive, bleeding's bigger and larger loss in fabrics adjacent to focus gives Pseudarthrosis. Other advantage of use of PRP about your materials in osteosynthesis It is the no rejection of material implanted, per if deal within a product autologous.

O use in materials biocompatible presents as a way inevitable inside gives medicine regenerative. Those biomaterials represent a method viable with smaller probability in cause complications related the rejection or infection at the treatment in injuries of tissue muscle skeletal. Of that form, it is notorious what too far away deadline Those patients, addressed with these new techniques will represent a smaller cost for O SUS, one turn what with approaches any less invasive and with use smaller in material surgical, o time in permanence hospital and probability in return for new attempts in treatment will happen with smaller frequency.

Conclusion

O use of Plasma Rich in Platelets (PRP) at the treatment gives Pseudarthrosis gives tibia showed up a method most cheap and effective, when compared to the methods in treatment conventional through of use in plates, screws, stems or fasteners external, contributing so for the reduction from spending the I enjoy and far away deadline, for o System Single in Health and for o System social security at Brazil. You result of this study point what That new technology he can to be one alternative viable at the treatment gives Pseudoarthrosis, fostering, including, the Realization in other studies with a number larger in patients.

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