Research Article
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Comparative study to evaluate the efficacy of treatment with platelet rich plasma and non-steroidal anti-inflammatory drugs in gonarthrosis grade I-II

Summary

Background: Worldwide, the incidence of degenerative diseases has increased, mainly gonarthrosis. The World Health Organization estimates that 40% of the population over 70 years of age has gonarthrosis, which may increase in the following decade,[1] generating 10%-25% of consultations.[2] Treatment with intra-articular Platelet Rich Plasma is an effective therapy.[3] Methodology: A cross-sectional, prospective, quasi-experimental, non-randomized study was carried out comparing the evolution of the symptoms of grade I and II gonarthrosis in 140 patients, half treated with non-steroidal anti-inflammatory drugs (NSAIDs) and the other half treated with Platelet Rich Plasma (PRP), at the Specialty Clinic N.3, Cuauhtémoc Health Jurisdiction, 2020. Descriptive statistics were analyzed by calculating the mean and standard deviation, inferential statistics through Chi-square.

Results: The most affected age group was from 60 to 69 years old with 43.5%, with a female sex prevailing with 33.5%. Most patients were overweight and obese with 39% and 53% respectively. Pain improved in 92% of patients treated with PRP and in 25.7% of patients treated with NSAIDs. The functional capacity of the knee recovered in 97% of the patients treated with PRP and in 35.7% of those treated with NSAIDs.

Conclusions: treatment of grade I and II gonarthrosis with intra-articular PRP is more effective than treatment with NSAIDs.

Keywords: Platelet rich plasma, non-steroidal anti-inflammatory drugs, gonarthrosis, intra articular, pain, functional

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Introduction

Research question

Is the application of Platelet Rich Plasma in the knee joint a more effective alternative to NSAID treatment for the remission of symptoms of GI and II Gonarthrosis? Each year there is a significant number of patients who come to the first level of care for Gonarthrosis for which the treatment options are limited to the prescription of non-steroidal anti-inflammatory drugs (NSAIDs), generally ending in referrals to the second level, a level of care that today presents a saturation that causes long-term appointments, making it impossible to provide timely care for patients with joint pain due to degenerative processes mainly located in the knee joint. So far, there is no experience with the application of Platelet Rich Plasma at the first level of care. Parallel to the high prevalence and incidence of patients with gonarthrosis, new treatments have been developed, ranging from oral medications such as non-steroidal and steroidal anti-inflammatory drugs, supplements such as chondroitin sulfate and glucosamine, intra- articular procedures such as visco-supplementation, the use of ozone, the use of platelet- rich plasma and even surgical procedures (partial or total arthroplasty). All with the fundamental objective of improving the patient's symptomatology and with this the quality of life of the patient and the disability that can produce even in working ages.[3]

The present work will focus on evaluating the application in the first level of health (Specialty Clinic No.3) of one of the variants of intra-articular treatment of knee osteoarthritis, the infiltration of the affected joint with Platelet Rich Plasma, a fraction of centrifuged blood that concentrates growth factor of great benefit to mitigate the inflammation of the synovium and improve the regeneration of cartilage, commented in previous works such as the one performed at the Manuel Ascunce Domenech Hospital in Cuba4 and the one documented in the Scientific Journal World of Research and Knowledge.[5] We consider it important to mention that this procedure has been practiced since the 1990s with increasingly encouraging results. It is a harmless product generated from the patient's own blood, easily obtained in any conventional laboratory.[6] Osteoarthrosis is a chronic degenerative arthropathy, produced mainly by alterations in the regulation of the degradation and synthesis of the extracellular matrix of cartilage and fibrocartilage, resulting in a series of changes in the characteristics of the articular parts such as synovial thickening due to chronic synovitis, loss of the cartilaginous surface, loss of articular spaces, formation of marginal osteophytes, secondary muscular atrophy and disuse of the joint due to rest.[7]

All this causes a series of symptoms ranging from joint pain and increased pressure within the joint to functional limitation. Many people with knee pain have limitations in function or restrictions of range of motion flexion-extension, which prevent them from participating in their usual activities such as walking, dressing and crossing their legs, as well as climbing stairs, getting up from a chair and walking long distances, causing a deterioration of lifestyle and disability.[8] Functional disability would appear in more advanced stages of the disease, where joint deformity, muscle atrophy and subluxations, joint blockage, presence of intra-articular free bodies,

constant swelling and popliteal effusion or cysts can be found.[9] As a complement for the diagnosis of this disease it is essential to have diagnostic tools such as knee radiography, which not only helps us to confirm, but also allows us to classify the disease according to degrees of evolution for an adequate treatment of the patient and prognosis. One of the most used classifications in our environment is that of Kellgren and Lawrence, proposing a scale in degrees from 0 to 4.[10]

Today there is an important range of treatments for gonarthrosis ranging from drug treatment to relieve pain, inflammation, dietary supplements to knee arthroplasty. Among these are the intra-articular treatments with Ozone, Sodium Hyaluronate, Fibroquel, Platelet Rich Plasma and Stem Cells, treatments that nowadays enjoy popularity due to their low aggressiveness and the great results obtained when properly applied, considering the patient's age, weight, degree of evolution of the disease and causes.[11] In this work we will focus on treatment with Platelet Rich Plasma (PRP), as it is one of the treatments that has offered the best results in early stages of the disease, as we can see in previous studies, where PRP is applied in more than 90% of the patients treated.[12,13] PRP contains not only a high level of platelets, but also of the growth factors that are actively secreted by platelets. In addition, PRP is also rich in proteins that act at the level of cell adhesion (fibrin, fibronectin), thus providing the structural support necessary for cell migration, and for the proliferation and three-dimensional growth of the tissues on which it acts. PRP has effects not only directly on the target cells for growth factors, but also as an extracellular matrix for the stimulation of tissue repair and/or regeneration in a global way.[14]

When anticoagulated blood is centrifuged, 3 layers are formed according to density: the lower layer (density 1.09), composed of red blood cells; the middle layer (density 1.06), composed of white blood cells and platelets; and the upper layer (density 1.03), composed of plasma. The plasma phase, in turn, can be subdivided into 3 fractions depending on the amount of platelets present, which from top to bottom are: a platelet-poor fraction, the intermediate fraction with a medium concentration of platelets, and the platelet-rich fraction. Centrifugation is the basic procedure for obtaining PRP, with a yield of approximately 10% of the blood collected. Fragmentation of platelets during the process should be avoided, as this would result in their early activation, and with it, some secretory proteins would acquire their definitive tertiary bioactive structure. Undue release by fragmentation of high levels of proteins could compromise the bioactivity of the proteins.

Platelet membrane integrity can be maintained by using dextrose acid citrate as an anticoagulant (citrate sequesters calcium and blocks the coagulation cascade, and dextrose provides the nutrients that make platelets viable), and slow centrifugation speeds (standard centrifugation parameters are 1400 to 2500 RPM for 8 to 10 minutes). Although other parameters can be used according to the protocol for obtaining Platelet Rich Plasma.[14] After centrifugation, this platelet concentrate can be activated with thrombin, calcium chloride, calcium gluconate, among others, so that the platelets release their contents, a mixture of peptides and intercellular signaling proteins or growth factors (GF), cytokines and other molecules with biological activity. Once activated, the PRP can be injected in its liquid form, or after 10 minutes it will form a hydrogel, which can be applied directly to the damaged tissue, or it can be used in conjunction with cells.[15] Different authors propose different methods of PRP activation. Some mix the components a priori: from the simple mixture of calcium chloride and thrombin with PRP, to the quantified mixture of PRP, calcium chloride/thrombin, air and variable agitation times. Some authors propose that the mixture of PRP and activating solution be produced in situ on the wound. For this purpose, they use a device that combines 2 syringes with different plunger sizes, one with PRP and the other with the activating solution. Activation occurs when both solutions are mixed immediately before dispensing them on the wound, i.e. the platelets are already activated.

Whichever method is used for PRP activation, the activated mixture should be applied within 10 minutes to prevent the clot from retracting and sequestering secretory proteins on its surface.[14] Platelets begin actively secreting these substances 10 minutes after clot formation and release more than 95% of the pre-synthesized growth factors within one hour. After the massive and slower protein release thrombocytes synthesize and secrete proteins five to 10 days later. When the platelet influence begins to subside the macrophages that have reached the focus through vascular growth take over the regulation of tissue repair by secreting their own factors. Outside the bloodstream platelets are activated and release proliferative and morphogenic proteins.[15] It is worth mentioning that in our study we did not use any external activator of Platelet Rich Plasma, but we appealed to the endogenous or in situ activation already discussed in other works.[16]

It is essential to understand that as far as is known, there is no conservative treatment for knee osteoarthritis that has been shown to halt or slow the progression of its progression. There are a number of interventions that have been postulated as effective for symptom reduction and functional improvement and that present solid evidence of their usefulness in weight loss and low-impact activity in water and floor associated with joint physiotherapy, joint range exercises and open chain strengthening. The consumption of drugs is extremely frequent in the population, there is a great variety of schemes and, over all conditions, self-medication is a common practice. It is worth noting the active imprint that natural and traditional medicine offers as a therapeutic alternative.[17] One of the problems common to all treatments is their limited long-term effect; according to the studies reviewed, there are no studies of effectiveness for more than six months, unlike the treatment with Platelet Rich Plasma where after six months remissions of the symptoms of Gonarthrosis continue to be observed.[18]

There are several methods and questionnaires for the measurement of the evolution of symptoms in Gonarthrosis in our work we will use the WOMAC questionnaire (Western Ontario and Mcmaster Universities Osteoarthritis Index) for the effectiveness shown for the evaluation of pain, joint stiffness and functional capacity proven in previous works.[19] Null Hypothesis: Patients with GI and GII gonarthrosis treated with Platelet Rich Plasma, do not evolve better than those treated with NSAIDs. Alternate Hypothesis: Treatment of GI and GII gonarthrosis with Platelet Rich Plasma is more effective than treatment with NSAIDs.

Research methodology

Type of study

A cross-sectional, prospective, quasi-experimental, non-randomized study was carried out to compare the behavior of gonarthrosis in two groups of patients, the first group treated with NSAIDs and the second group treated with intra-articular infiltration with Platelet Rich Plasma. The same was carried out at the Specialties Clinic N.3 of the Cuauhtémoc Sanitary Jurisdiction during the year 2020, prior authorization and registration N. 101-110- 19-19 of the research ethics committee of the Secretary of Health of Mexico City with registration CONBIOETICA-09-CEI-004-20180213.

Study population

Male and female patients diagnosed with gonarthrosis grade I, II according to Lawrence and Kellgrem radiological classification in the orthopedic office of the Specialty Clinic N.3 during the first, second and third quarter of 2020.

Sample

The study was carried out on 140 knees of patients aged between 40 and 80 years of both sexes. Separated into two groups of 70 knees, group 1 treated with NSAIDs and group 2 treated with intra-articular injection with Platelet Rich Plasma. The same was obtained by applying the formula for a known population of 300 patients. Where, N = population size Z = confidence level, P = probability of success, or expected proportion Q = probability of failure D = precision (Maximum admissible error in terms of proportion). Sampling was deterministic.

Inclusion criteria

I. Patients between 40 and 80 years of age of both sexes.

II. Patients with clinical radiological diagnosis of gonarthrosis grade I and II. 3- Patients who accept PRP treatment.

Exclusion criteria

I. Patients who do not accept the indicated treatment.

II. Patients with other knee diseases such as gouty arthritis, rheumatoid arthritis, congenital malformations, valgus or varus angulations, recent fractures

Elimination criteria

I. Patients who drop out of treatment.

II. Patients who suffer any type of trauma to the knee during treatment.

Procedure

The study was carried out in the aforementioned population, the first group was diagnosed in consultation with radiological studies and immediately started treatment with NSAIDs and relative rest for 10 days, the second group was diagnosed in the same way prescribing treatment with Platelet Rich Plasma at a weekly dose for 6 weeks, for which the patient was summoned between 7:00 and 7:30 in the morning in the laboratory for extraction of 5 ml of blood in blue cap tubes with calcium citrate as anticoagulant, the plasma was obtained by closed technique. After the extraction, the tubes were introduced into a SOLBAT J-40 centrifuge; the blood was centrifuged immediately after extraction and without being refrigerated; the centrifuge was balanced and the blood was spun by setting the parameters (speed and time) 2500 RPM for 10 minutes; obtaining the appropriate fractions as indicated and, finally, PRP was extracted following the norms (suspend platelets and extract PRP with the appropriate syringe), obtaining approximately 0.5 ml of PRP. No external activator was used. All handling of the devices was performed aseptically, to minimize the chances of contaminating the plasma fractions obtained. An adequate laminar flow cabinet was used in the fractionation and activation processes, reducing the risk of microbiological contamination. The waste was disposed of in accordance with general hygiene guidelines and legal regulations governing the appropriate disposal of infectious material. Subsequently, 3 ml syringes were placed intra-particularly in the affected knee of the patient in a period not exceeding 10 minutes; this procedure was performed with the same patient weekly for 6 weeks. For both groups the evolution was evaluated using the WOMAC 24- item questionnaire (Western Ontario and Mc Master Universities Arthritis Index) applied at the beginning of the treatment and once the treatment was completed in both study groups.

Description of the medications used in the group treated with NSAIDs. They were indicated indistinctly according to availability in the pharmacy and taking into account the patient's allergy history Table 1.

Drug	Presentations	Dose
Ibuprofen	400 mg	1 tablet every 8 hours for 7 days
Indomethacin	25 mg	1 tablet every 8 hours for 7 days
Celeocib	200 mg	1 capsule every 24 hours for 10 days

Table 1 Behavior of grade I and II gonarthrosis according to age and sex

Age group	Male	%	Female	%	Total	%
40- 49	8	5.7	21	15	29	21
50- 59	6	4	17	12	23	16
60- 69	14	10	47	33.5	61	43.5
70- 80	3	2	24	17	27	19
Total	31	22	109	78	140	100

Source: Medical records of patients seen in the orthopedic consultation of the N3 Specialty Clinic, selected for research.

The information obtained from the questionnaires was stored in digital support in a WINDOWS 10 environment and the statistical package EPI-INFO7 was used for the analysis of the results obtained (TABULATION SCHEMES AND GRAPHICS). The descriptive statistics were analyzed from the elaboration of a table of frequencies that allowed us to calculate the mean and standard deviation, as well as the inferential statistics were analyzed through the Chi-square test Table 2–5.

Table 2 Relationship of Body Mass Index and Grade I and II Gonarthrosis

BMI	GI Gonarthrosis	GII Gonarthrosis	Total	%
Normal weight	9	2	11	8
Overweight	42	13	55	39
Obese	35	39	74	53
Total	86	54	140	100

Source: Medical records of patients seen in the orthopedic consultation of the N3 Specialty Clinic, selected for research.

Ethical considerations

The Cuauhtémoc Health Jurisdiction of Mexico City was asked in writing for authorization to carry out this research and, subsequently, the Ministry of Health was asked for the consent of the specialists who contributed to the collection of information. The benefits that can be obtained at the first level of health referred to in this research were explained. Consent was requested from the patients who were included in the study, to whom the purpose of the study was explained, the benefits that could be obtained from it and their right to refuse to participate in the research, making it clear that refusal would not affect the patient-physician relationship, nor would it have a negative influence on their treatment. The present work was considered of minimal risk in accordance with the Regulations of the General Health Law on Health Research.

Table 3 Pain Behavior in Patients Treated with NSAIDs and PRPs

	Treatment	With	NSAIDs	Treatment	with	PRP
Pain	**Beginning**	**Improvement at the end of treatment**	**%**	**Beginning**	**Improvement at the end of treatment**	**%**
None	0	0	0	0	0	0
Little	22	1	4.5	26	24	92
Moderate	48	17	35.4	41	39	95
A lot	0	0	0	3	2	66
Total	70	18	25.7	70	65	92

Source: WOMAC questionnaire.

Table 4 Behavior of functional capacity in patients treated with NSAIDs and PRP

	Treatment	with	NSAIDs	Treatment	with	PRP
Functional capacity	**Beginning**	**Improvement at the end of treatment**	**%**	**Beginning**	**Improvement at the end of treatment**	**%**
No difficulty	0	0	0	0	0	0
With difficulty	41	7	17	34	33	97
With great difficulty	14	3	21.4	5	4	80
Total	70	25	35.7	70	68	97

Source: WOMAC questionnaire.

Table 5 Behavior of patients treated with NSAIDs and PRP according to the average reduction of points according to the WOMAC scale in terms of pain and functional capacity and assessment of unwanted effects

Outcomes	Final Effect NSAIDs	Final Effect PRP
Pain	2	6
Functional Capacity	5.5	17
Gastritis	10	0

Source: WOMAC questionnaire. Medical Records of the patients attended.

Resource needed

As we commented at the beginning of the work, the research that was carried out demands a minimum value of resources or support with existing resources. For the same we rely on a conventional centrifuge that reaches 2500 RPM, the activator of the Platelet Rich Plasma (dextrose acid citrate) and laboratory material for blood extraction and intra-articular treatment for 70 patients during 6 sessions each.

Results

In our study there was a higher incidence of gonarthrosis in patients aged between 60 and 69 years with 43.5% of the total patients studied, being the female sex the most affected with 33.5 %, coinciding with results of previous studies such as the one published by Doctor Filardo in 2015 in the Knee Surg Sports Traumatol Arthrosc,[20] and Doctor Sanchez in 2016 where they comment a prevalence of 3 to 1 (female-male) for this disease.[21]

The highest concentration of the patients studied was in the obese group with a total of 74 patients for 53% of the total. The standard deviation was 13, a value located below the mean which is 30, so it groups the highest concentration of patients within the obese group. Coinciding with previous studies.[22] The advantage of PRP treatment over conventional treatment with NSAIDs for pain relief in patients with G I-II gonarthrosis is evident, only 25.7% of the patients treated with NSAIDs improved their pain, but this was not the case in the group treated with PRP where there was an improvement in 92% of the patients. The calculated value of the chi-square was 65.4, well above the critical value (19.7), so the null hypothesis is rejected. In the group of patients treated with NSAIDs only 35.7% of the patients experienced improvement in terms of recovery of functional capacity in contrast to those treated with PRP where 97% of the patients recovered knee function. The calculated chi-square was 58 and as in the previous table, it is above the critical value, so the null hypothesis is rejected.

Discussion

We consider that the study carried out had several limitations: the sample size was not desired because we were limited to patients who came to the orthopedic clinic for knee pain. We did not have works to compare because our literature search with similar studies did not yield many results, so continuing to delve deeper into the topic is undoubtedly an opportunity for new research. From the population studied we see that the greatest affectation or presence of gonarthrosis is in ages above 60 years, coinciding with the characteristic evolution of this disease, where we know that the degenerative process of the joints is more evident, pointing out that, due to the characteristics, habits and economic needs of the population of the clinic's environment, at these ages moderate and high impact work is still performed. Likewise, most of the affected patients presented a body mass index that placed them in the obese category, coinciding with previous studies,[22,23] given that, and appealing a little to physics, the greater the weight, the greater the load on the knees and other joints, increasing the intra-articular pressure and with this the deterioration of the joint.

In our study we detected that on average, patients treated with NSAIDs at the end of treatment had a 2-point decrease in pain and a 5.5-point improvement in functional capacity compared to the initial score according to the WOMAC questionnaire applied at the beginning and end of treatment, unlike those treated with PRP in which we observed an average improvement of 6 points in pain reduction and 17 points of improvement in functional capacity. We cannot fail to mention that the group of patients treated with NSAIDs presented comorbidities during treatment, such as gastritis, due to the use and abuse of anti-inflammatory drugs. The previous results are similar to other studies such as the one carried out by Dr. Diego Ubilla.[24,25] The standard deviation calculated in the group of patients treated with NSAIDs according to evolution towards improvement was 5, a value very close to the mean (5.25), interpreting from the above that most of the patients had an unfavorable evolution. This was not the case in the group of patients treated with PRP where standard deviation values of 55 were obtained, very far from the mean (7), so the data were very scattered, but most of them evolved towards pain relief and recovery of functional capacity. In both cases they represented the expected values. Our study, unlike previous works reviewed, had a particularity, since we did not use external activators of platelet-rich plasma, but we bet on the endogenous or in situ activation of the same, in spite of this, there were no great differences in the results obtained with respect to the previously mentioned works. It should be noted that we will continue to follow up these patients treated with Platelet Rich Plasma to monitor the time that mediates the reappearance or not of the symptoms and the radiological evolution of the disease.

Conclusion

Our study showed that Gonarthrosis is a disease that has a higher incidence in patients considered as older adults, above 60 years of age. We demonstrated that body weight has a negative influence on the articular degenerative process since most of the patients had a body mass index that placed them as obese. Pain evolved towards a considerable improvement in most of the patients treated with platelet-rich plasma (PRP), but not in the group treated with non-steroidal anti-inflammatory drugs (NSAIDs). The functional capacity of the knee joint recovered in patients treated with PRP and in a very small group of those treated with NSAIDs. We conclude that treatment with intra-articular PRP for the treatment of grade I and II gonarthrosis is more effective than treatment with NSAIDs, thus corroborating the alternative hypothesis put forward at the beginning of the study.

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None.

Conflicts of interest

The author has no conflicts of interest of any kind.

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