

RESEARCH ARTICLE

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Quality standards and thromboelastography in platelet pools at the Hospital de Especialidades Centro Medico Nacional Siglo XXI: Instituto Mexicano del Seguro Social

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ABSTRACT

Aims: Faced with uncertainty about why pooling platelet products for an adequate therapeutic dose is uncommon, the National Medical Center Siglo XXI assessed the quality of blood components from whole blood. To determine their effectiveness, platelets (PLTs) suspended in an additive solution were evaluated for functionality using thromboelastography (TEG).

Methods: Six hundred whole blood samples were centrifuged and separated to obtain red blood cells (RBC), plasma (PL), and buffy coat (BC). The RBCs were immediately filtered in-line to obtain pre-storage leukodepleted red blood cell concentrate (LRBC). The BCs, after an overnight hold, were pooled with an additive solution. Subsequently, the BC pools were centrifuged and separated to obtain pre-storage leukodepleted platelet concentrate (LDPC).

Results: Leukodepleted red blood cell concentrate unit volume was 253 ± 17.8 mL, compliance of 99.3%, resulting in hematocrit (HTC) of $54.8 \pm 2.84\%$ and

hemoglobin values of 44.5 ± 5.69 g/Unit. Plasma units resulted in a volume of 236.25 ± 51.15 with 70.27 ± 6.95 g/L of total proteins and $145.30 \pm 79.25\%$ of Factor VIIIc. Leukodepleted platelet concentrate units yield $2.72 \pm 0.41 \times 10^{11}$ with $0.23 \pm 0.26 \times 10^6$ residual leukocytes, with a volume of 342 ± 24.67 mL, pH 7 ± 0.08 , and all TEG maximum amplitude (MA) values resulted between 75 and 80 mm.

Conclusion: The findings confirm the quality and consistency of blood component collection and processing, with low variability and regulatory compliance. Thromboelastography analysis showed high coagulation capacity in pooled PLTs, highlighting the benefits of standardized pooling for transfusion medicine and healthcare sustainability in Latin America.

Keywords: Buffy coat, Leukodepletion, PAS, Platelet, Thromboelastography

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INTRODUCTION

The Blood Bank of the National Medical Center (Centro Medico Nacional – CMN) Siglo XXI of the Mexican Social Security Institute (Instituto Mexicano del Seguro Social – IMSS) is characterized by innovative technology and processes to guarantee the safety of its donors and patients. Currently, its platelet concentrates are produced from apheresis and single platelet units from whole blood systems. However, for the CMN, the demand for this component is increasing as it is a reference center, with great coverage and care in Mexico City. This forces the CMN to evaluate new methodologies that optimize the blood donation resource to achieve greater recovery of components and demonstrate the quality and safety of the blood products obtained to benefit more patients.

The buffy coat (BC) method has been successfully used for several decades to obtain single platelets. However, the practice in European, Canadian, and Asian countries is to prepare platelets (PLTs) by pooling BC to improve platelet recovery. This process allows obtaining PLT concentrates equivalent to a therapeutic dose of PLTs or one unit per apheresis, helping to improve PLT yield and meet PLT requirements.

In many Latin American countries, preparing PLT pools using BC is an uncommon practice, highlighting the need to standardize procedures in Latin America [1]. The CMN, led by their blood bank, evaluated the BC pool procedure for obtaining leukodepleted platelet concentrates (LDPC), pre-storage, and suspended in platelet additive solution (PAS), against Mexican and European quality standards (EDQM). Additionally, this study used thromboelastography (TEG) tests to evaluate platelet functionality and to provide evidence-based data on the efficacy of platelet concentrates obtained from this new method.

One common misconception is that these PLTs lose their functionality after processing, leading healthcare professionals to rely on other methods. The Hospital Siglo XXI of the Mexican Social Security Institute developed research in which pools of BC of PLTs were established. Thromboelastography (TEG) was used in this study to evaluate whether PLT function prophylactically is necessary and to supply evidence-based data concerning the effectiveness of the three reagents/methods.

The study has implications for several reasons. In the first instance, it clears up myths that have been circulated for years, potentially breeding best practice for plate transfusion use. Second, it offers a potential for resource-poor sites. Finally, the information can contribute toward improved standards and care and healthcare for the region of Mexico and for Latin America and bring into the foreground evidence-based clinical practice [2].

The local trend against the application of BC pool systems was developed due to a widespread misconception that recovered PLTs from the approach are inefficient. The misconception served as a barrier to a practice that

is widely accepted and applied in several other countries. Efforts toward reversing this barrier are essential for the progress of clinical practice in the region [3].

The provision for health service for Latin America translates into scarce resources, and hence cost-effective and efficient measures become a necessity [4]. Buffy coat-based PLT pools that are leukocyte reduced are a suitable option. It is against such assumptions that the study for the Siglo XXI Hospital was conducted since it reveals their efficacy according to the test on TGE [5].

Advantages of the PLTs produced under BCs.

The BC technique: A cost-effective method for preparation of pools of PLTs. It allows preparation of a sufficient number of PLTs for transfusion with a single donation, thereby sidestepping apheresis donations. This is of special advantage in areas with scarce donors [6]. The BC method allows for a greater quantity of PLTs to be prepared at one time, requiring fewer donor exposures. In patients who need multiple transfusions, this is important as susceptibility to the development of both alloimmunization and alloantibodies is reduced. Platelet concentrates obtained using the BC method have been demonstrated to have good functionality and quality. Several robust clinical trials in Europe and elsewhere have shown the clinical benefit of these PLTs, so the evidence base is good [7].

Importance of Leukoreduction

Leukodepletion is an essential step in the manufacturing process of PLTs and has several advantages. Leukocyte reduction from PLT components reduces the incidence of febrile non-hemolytic transfusion reactions, alloimmunization, and transmission of leukocyte-associated pathogens. It contributes to patient safety and makes the transfusion experience better [8, 9].

Leukoreduction maintains PLT function by reducing the extent of inflammatory and immune effects caused by residual leukocytes. This way, a superior product is provided to patients, and there is improved therapeutic effect [9]. Leukoreduction is standard procedure in many countries, especially in Europe and North America. Adopting this practice in Latin America would bring regional health systems closer to globally accepted standards for safer and more effective transfusions [10].

Thromboelastography as a Test to Measure Platelet Efficacy

Thromboelastography, which is a kinetic test, measures the hemostatic abilities of blood in terms of clot formation, clot maintenance, and clot dissolution. It enables assessment of PLT function, fibrinogen contribution, and global coagulation state in real-time. It has a significant clinical advantage because it allows real-time determination of platelet function and coagulation kinetics, resulting in immediate and more complete information that standard coagulation tests may not provide. It can, due to thoroughly reflecting the

coagulation process, identify even minor coagulation abnormalities. This real-time recognition of platelet dysfunction is essential for management decisions, which is key for transfusion decisions such as in patients undergoing surgery [11].

Benefits for Latin America and Mexico

Optimization of platelet transfusion strategy may potentially result in improved patient outcomes and less platelet transfusion-related complications. Bone up on BC techniques allows healthcare providers to provide better care to more patients. The cost savings of the BC approach are especially beneficial in low-resource settings. Hospitals can optimize resource utilization and provide a practical overall care delivery approach, by decreasing dependence on expensive apheresis treatments [12]. Reorienting practices to evidence, as well as improving best practices within a global operating context. Reorienting clinical practice according to evidence can help raise standards and align with best international practice [13].

The Siglo XXI Hospital trial endeavors to test the functional efficacy of PLT pools from BCs, according to TEG testing. With the work, it will be confirmed that such plates meet the clinical standard for performance and shatter prevailing myths concerning their lack of efficacy. The conduct of the study could set the basis for future evidence-based transfusion guidelines and policies. Through BC preparation methods for PLTs adopted across routine practices, regional health systems can build the safety, effectiveness, and affordability of PLT transfusion.

MATERIALS AND METHODS

The study was approved by the Local Research Committee (CLEI) and the Research Ethics Committee (CEI) at UMAE Specialty Hospital, National Medical Center Siglo XXI. A total of 600 whole blood (WB) (450 mL $\pm$ 10%) was collected in quintuple CPD (Citrate Phosphate Dextrose Anticoagulant Solution), SAGM (Red Blood Cell Additive Solution : Saline, Adenine, Glucose and Mannitol) T&B (Top & Bottom System) bags with leukodepletion filter in line (LPT6285LS, Macopharma, France) in the Blood Bank Center, Siglo XXI. On day 0, the WB was centrifuged at 3500 rpm $\times$ 9 minutes (Presvac DP-2065 12 B). The separation was conducted in the Macopress Smart (MPS) device (Macopharma, France) to obtain red blood cells (RBC), plasma (PL), and buffy coat (BC). The RBCs were immediately filtered in line to obtain leukodepleted red blood cell concentrate in line pre-storage (LRBC).

The BCs on day 1, after an overnight resting time (18 hours) at 20 $\pm$ 2°C, 4 BCs (ABO compatible) were pooled with 1 unit of PLT additive solution (PAS) (SSP+, Macopharma), using the BC pooling system in-line filter (TRV806U, Macopharma) and sterile connector

(Maconnect, Macopharma France), the PAS allows an adequate recovery of PLTs from the BC bags by simple washes. Subsequently, the BC pools were centrifuged at 1400 rpm $\times$ 5 minutes and separated with the MPS to obtain pre-storage leukodepleted PLT concentrate suspended in PLT additive solution (PAS) (n=150).

As a quality control on day 0, it was evaluated for LRBC: Final Volume (digital balance 310 g/0.01 Ceslab), hemoglobin (Hb), hematocrit (HTC), residual leukocytes (WBC) (Celltac ES MEK-7300), and microbiological control (BD BACTEC FX). And for the PL, it was evaluated: Visual Appearance, Final Volume (digital balance 310 g/0.01 Ceslab), total Proteins (ABBE, ZWAJ), factor VIIIc (ACL Elite Pro, Werfen), and residual cells (Celltac ES MEK-7300). On day 2, the leukodepleted platelet concentrate (LDPC) was evaluated to: final volume (digital balance 310 g/0.01 Ceslab), PLT count (Elltac ES MEK-7300), pH (pHmeter ORP 920), residual leukocytes, microbiological control (BD BACTEC FX), and platelet functionality by thromboelastography (TEG, Haemonetics).

RESULTS

The measurement of whole blood volume before processing and fractionation revealed that among the 600 units collected, the mean $\pm$ SD was 452 $\pm$ 10.5 mL. Of these, 99.7% had volumes within 450 $\pm$ 45 mL, confirming process and equipment standardization for whole blood collection. The measurements of all units were taken within 12 min after donation, confirming the suitability for the processing procedure. After 1–2 h periods of relaxing, fractions of the units were done. Interestingly, some outliers below 405 mL (minimum 389 mL, N = 2) were found, although most samples fell into the expected range, thereby indicating low variability of the collection (Table 1).

The average ($\pm$ SD) volume of leukodepleted red blood cell concentrate (LRBC), processed following the separation of whole blood, was 253 mL ($\pm$ 17.8) in a total of 99.3% of cases. Mean hematocrit (HCT) concentration was 54.8 $\pm$ 2.84% and mean Hb was 44.5 $\pm$ 5.69 g/unit, indicating adequate levels for transfusion. The average residual leukocyte content in the leukoreduced RBCs was 0.18 $\pm$ 0.17 $\times$ 10⁶ demonstrating effective reduction of leukocytes. Moreover, all tested units were devoid of bacterial contamination, which was indicative of sterility (Table 2). Post-fractionation from pooled BCs, the quality of the PL was within acceptable limits. All samples were within the reference values, indicating similar PL composition (Table 3). Leukoreduced platelet concentrates (LPPC) showed mean PLT increment of 2.72 $\pm$ 0.41 $\times$ 10¹¹, which was higher than the British and European minimum acceptable product amount (>2.0 $\times$ 10¹¹) [14, 15]. Very little white blood cell contamination (0–23 $\pm$ 0–26 $\times$ 10⁶) was observed, far below reported limits [16]. The mean volume of PLT units was 342 $\pm$ 24.67

mL. Addition of PLT additive solution (PAS) decreased PL usage by 60% and conditioned the material effectively possessing a mean pH value of 7 ± 0.08 (Table 4).

Thromboelastography (TEG) (Figure 1) demonstrated MA values predominantly of 75–80 mm, consistent with robust and uniform coagulability. Clot strength can be represented by MA which is a prospector value that demonstrates how strongly the clot is formed [5]. Figure 1 represents box plot of MA values of the pooled PLT sample by TEG. The average MA was nearly in the middle of distribution interquartile range (IQR) and held the scale of variability to a minimum with little spreading. The IQR ranges from about 72 to 79 mm, and the whiskers from about 66 to 82 mm, showing the entire observed range. These results indicate a relatively uniform clotting response from the pooled samples with no major outliers or skewness.

Scatter plot data (Figure 2) reinforced these findings, with minimal variability and most samples clustering tightly, confirming robust clot formation capacity in pooled PLT samples. The plotted points appear as a converged clump, with most settling between 70 and 80 mm. This dispersion pattern is supported by the summary statistics of Figure 1, which strengthens the evidence for low intra-sample variation. The lack of substantial outliers or extremes also underlines the homogenous functional capacity of the pooled PLTs with respect to clot firmness.

DISCUSSION

Batch screened WB units depicted in Table 1 reflect high uniformity with an average volume of 452 mL, in accordance with the Mexican Reference Value. This

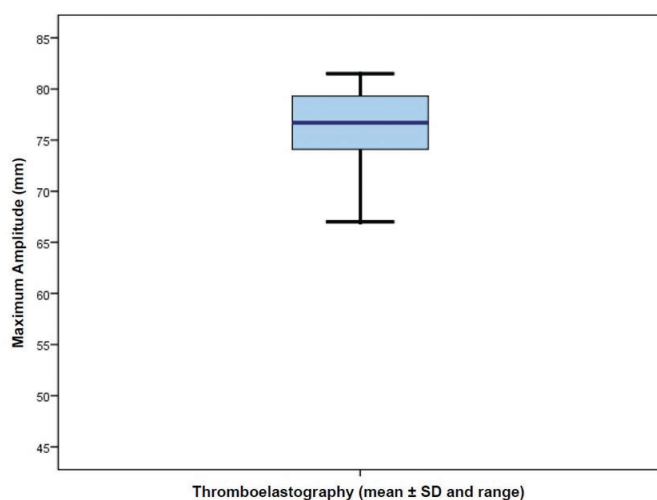


Figure 1: Maximum clot strength (MA) in functional pooled platelets: thromboelastography results. *Abbreviations:* MA: Maximum amplitude (a measure of clot strength in thromboelastography); mm: Millimeters; SD: Standard Deviation.

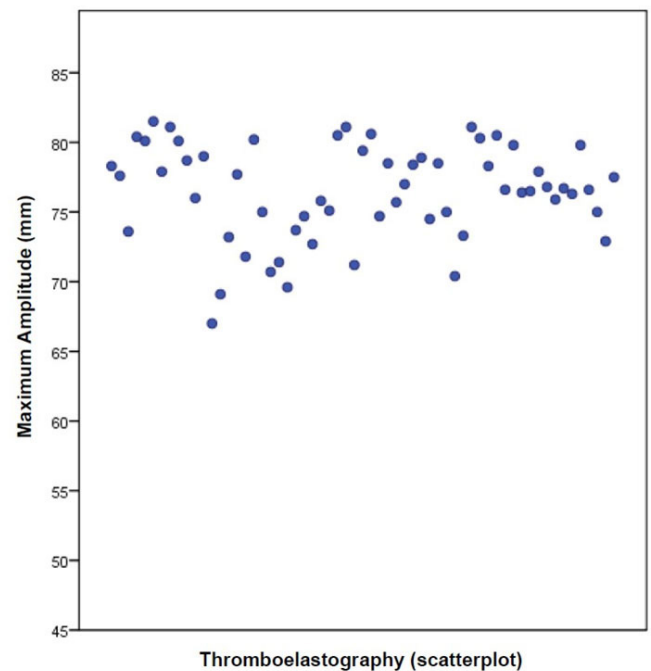


Figure 2: Sample-wise clot strength (MA) distribution in pooled platelets. *Abbreviations:* MA: Maximum amplitude (a measure of clot strength in thromboelastography). mm: Millimeters; Thromboelastography (a viscoelastic assay used to assess clot formation and strength in whole blood or platelet products) [20].

standardization is important since changes in whole blood volume may strongly influence yields of the components and their clinical efficacy. The few units below 405 mL (minimum 389 mL) indicate the necessity for continued evaluation of quality, although the overall chain is still safe (Table 1). Although infrequent, such variations should trigger rigorously in donor selection or collection management with a view to maintain the consistency of the components. The effect of blood volume on RBC concentrate quality is of special importance [17].

The quality of leukodepleted red cell units demonstrates robust adherence to national and European Directorate for the Quality of Medicines and HealthCare (EDQM) standards. High HTC and Hb concentrations, low residual leucocytes, and complete sterility confirm the efficacy of the leukoreduction methods. These effects decrease the potential for immune responses and febrile reactions and enhance their clinical feasibility. Thus, the strong agreement found (Table 2) further supports the trustworthiness of the treatment schemes.

In addition, the plasma quality after fractionation and separation of pooled BCs showed high level of stability and low level of variance among the parameters, further indicating the standardization of procedures and effective separation of components.

These results (Table 3) offer confidence in PL consistency for transfusion purposes and may serve as a baseline for continuous quality assessments [14].

The analysis of LDPC revealed high platelet yield and minimal leukocyte contamination, demonstrating not only procedural efficiency but also compliance with stringent quality metrics (Table 4) [14–16]. The decrease in plasma content as a consequence of PAS use is striking, and as a result allergic and transfusion-related reactions are decreased with continued pH stability. These factors lead to lower PLT activation during storage and limitation of the loss of biological function. Thromboelastography demonstrates that pooled PLT concentrates can increase clot strength (MA > 70 mm) that might be an advantage in some clinical situations when hemostasis is urgent (Figure 1). However, this increased MA may also indicate hypercoagulability, leading to increased thrombotic

risks in some patients [18–27]. Although useful in acute bleeding predicaments, the individual patient risk profile should be considered when aiming to maximize the effects of treatment.

The scatter plot in Figure 2 confirms the hypothesis that the plates are consistently functional across samples. The observed consistency supports the reliability of the BC pooling procedure applied in the National Medical Center Siglo XXI Blood Bank. Lack of bacterial growth in the platelet samples also adds to product safety. Taken together, these results demonstrate the utility of the LDPC preparation procedure that is consistent with national and international guidelines (Table 4).

Table 1: Pre-processing quality assessment of whole blood units for component fractionation

Parameter	Volume
EDQM Reference Value (21st Edition 2023) [16]	To define the system used
Mexican Reference Value [15]	450 mL ± 10%
N (number of units)	600
Mean ± SD	452 ± 10.5 mL
Lowest value	389 (N=2)
Highest value	491

Abbreviations: EDQM: European Directorate for the Quality of Medicines and HealthCare; mL: Milliliters; N: Number of units; SD: Standard Deviation.

Table 2: Quality assessment of leukodepleted red blood cell concentrate (LRBC) derived from whole blood processing

Parameter	EDQM Reference Value (21st Edition 2023) [16]	Mexican Reference Value [15]	No. (number of units)	Mean ± SD
Hematocrit	50–70%	50–70%	50	55.05 ± 5.72
Hb content (g per unit)	≥40	≥40 g per unit	50	45.10 ± 12.52
Residual leukocytes content per final unit	<1.0 × 10 ⁶	<1.0 × 10 ⁶	44	0.18 ± 0.2
Bacteriological control	NR	NR	50	NR
Volume	Defined by the system used	>215	600	266.94 ± 58.33

Abbreviations: EDQM: European Directorate for the Quality of Medicines and HealthCare; Hb: Hemoglobin; g: Gram; mL: Milliliter; NR: No growth; SD: Standard Deviation.

Table 3: Quality assessment of plasma post-separation and buffy coat fractionation from whole blood samples

Parameter	EDQM Reference Value (21st Edition 2023) [16]	Mexican Reference Value [15]	No. (number of units)	Mean ± SD	Lowest Value
Visual inspection	Fulfill	Fulfill	50	Fulfill	Fulfill
Total proteins (g/L)	>50 g/L	>50 g/L	50	70.27 ± 6.95	62
Factor VIIIc (%)	≥70 IU/100 mL	≥70 IU/100 mL	50	145.30 ± 79.25	55.1
ERI/L	<6.0 × 10 ⁹ /L	<6.0 × 10 ⁹ /L	50	1.67 ± 1.70	0
LEU/L	<0.1 × 10 ⁹ /L	<0.1 × 10 ⁹ /L	50	0.0007 ± 0.0009	0
PLA/L	<50 × 10 ⁹ /L	<50 × 10 ⁹ /L	50	0.0095 ± 0.0063	0.0003
Volume	–	–	50	236.25 ± 51.15	174.64

Abbreviations: EDQM: European Directorate for the Quality of Medicines and HealthCare; g/L: Grams per liter; IU: International units; mL: Milliliters; ERI/L: Erythrocytes per liter. LEU/L: Leukocytes per liter; PLA/L: Platelets per liter; SD: Standard Deviation.

Table 4: Quality assessment of leukodepleted platelet concentrate (LDPC) derived from buffy coat pools

Parameter	EDQM Reference Value [16]	Mexican Reference Value [15]	Number of samples	Mean ± SD
Volume (mL)	—	—	150	342 ± 24.67
Platelet content per final unit	$\geq 2 \times 10^{11}$	$\geq 2 \times 10^{11}$	150	2.72 ± 0.41
pH	6.2–7.4	6.2–7.4	150	7 ± 0.08
Residual leukocyte content per unit	$<1 \times 10^6$	$<1 \times 10^6$	67	0.23 ± 0.26
Bacteriological control	No growth	No growth	84	No growth
Inspection	Fulfill	Fulfill	150	Fulfill

Abbreviations: EDQM: European Directorate for the Quality of Medicines and HealthCare; mL: Milliliters; pH: Potential of hydrogen (measure of acidity/alkalinity); SD: Standard Deviation.

CONCLUSION

The results of our study at Siglo XXI Hospital confirms the effectiveness, safety, and standardizability of BC pooling-derived PLT concentrates validated with a thromboelastographic analysis. These findings offer strong evidence that wherever stringent quality control for the production of PC is practiced, a pool of PC could have efficacy at least equivalent to, and perhaps greater than, one donor's apheresis PLT in defined clinical situations. These challenges preconceived ideas and dispels some of the myths that have arisen around the so-called inferiority of PLT pooling techniques. It is also proven that in Mexico, the PLT pools obtained by BC are not inferior but equivalent to international and national standards used for the quality of PLTs as well as for the transfusional safety.

These findings have important implications for health services in other Latin American countries and in other low- and middle-income countries (LMICs), where the cost and limited availability of apheresis technologies and single donor PLT products are prohibitive. In these circumstances underuse of pooling of PLTs, possibly due to out-dated beliefs and lack of evidence-based guidance, may also mean that an opportunity to increase the availability of blood components and improve transfusion care is overlooked. Buffy coat pooled platelets (BCPP) have multiple clinical and operational advantages including a lower cost per transfusable unit, efficient donor utilization, and the blood bank flexibility of batch bacterial testing and inventory management.

In addition, the demand for PLTs is increasing globally reflecting the rising use of oncologic therapies, complex surgery and hematologic diseases that require frequent transfusion. However, in most jurisdictions expensive imports are used or transfusion access constrained by insufficient local supplies. The results of this study promote for a paradigm change those countries with low used BC to PLT yield ratio for a scalable and cost-effective approach of BC pooling program; for optimization of PLT availability with preserved therapeutic quality and selected safety.

In addition, this study stresses the necessity of having defined blood collection volumes and quality assurance methods to guarantee reproducibility, safety, and regulatory approval in transfusion facilities. These medically sound practices should be highlighted by national policies and international initiatives to advance patient safety, decrease the risk of transfusion-transmitted infections, and strengthen the sustainability of blood programs in resource-constrained environments.

Areas for future research that would have the most impact are long-term clinical outcomes, cost-benefit analysis, and potential solutions for harmonizing pooling methods across heterogeneous healthcare settings. Widespread publication and institutional implementation of these results have the potential to advance the field of transfusion medicine to the optimization of platelet therapy quality to become available to more patients of all types around the world.

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Author Contributions

Gamaliel Benítez Arvizu – Conception of the work, Design of the work, Analysis of data, Interpretation of data, Revising the work critically for important intellectual content, Final approval of the version to be published, Agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved

Isabel Castillo Mercado – Conception of the work, Analysis of data, Interpretation of data, Drafting the work, Revising the work critically for important intellectual content, Final approval of the version to be published, Agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved

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All relevant data are within the paper and its Supporting Information files.

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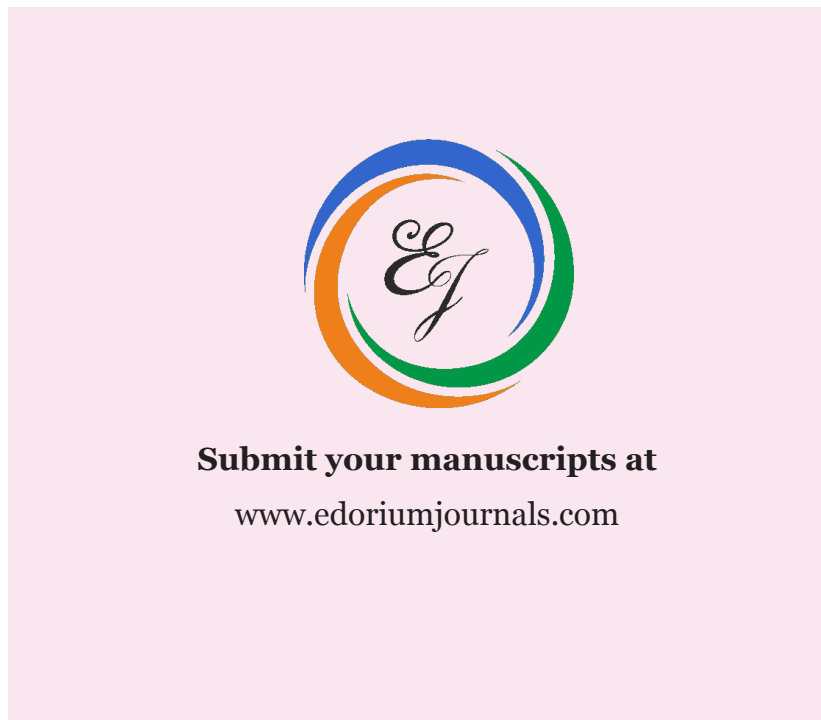
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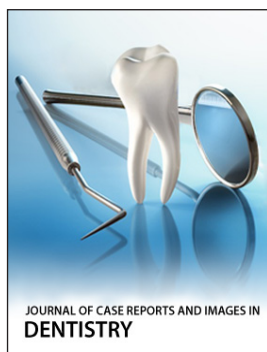
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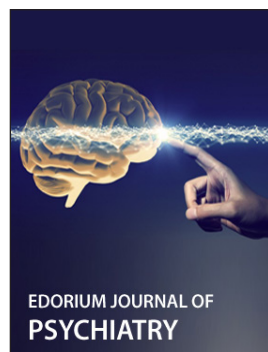
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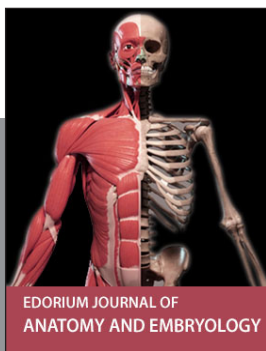
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