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Original Research Article

EFFICACY OF PROPHYLACTIC AUTOLOGOUS PLATELET RICH PLASMA IN CESAREAN WOUND HEALING

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ABSTRACT

Background: This study aims to assess the effectiveness of platelet-rich plasma in caesarean wound healing. It enables us to assess how platelet-rich plasma, when given during caesarean wound closure, can improve wound quality and avoid SSI.

Materials and Methods: This was a RCT which incorporated 44 women who were divided into two groups after following the inclusion and exclusion criteria. The patients in the case group were administered subcutaneous injection of autologous PRP during caesarean which was prepared in our lab. Whereas, the patients in the control group were managed by the existing hospital protocol. The patients were then assessed on day 3, day 8/10 and on day 42 using the REEDA scale.

Results: The proportion of patients with SSI was significantly lower in the case group (4.55%) compared to control group (31.82%) with a p value of 0.046.The mean REEDA on day 8/10 was 1.77 ± 0.61 for case group which was significantly lower than the control group (3.27 ± 2.1) with a p value of 0.009.Similarly mean REEDA on day 42 was found to be 0.55 ± 0.51 and 1.41 ± 1.01 for case and control respectively, the difference of which was statistically significant. There was no statistically significant difference in terms of length of hospital stay. Most of the infections were of superficial nature.

Conclusion: Prophylactic administration of Autologous PRP during caesarean wound closure was found to significantly improve wound quality and reduce the development of SSI in the post-op period. Therefore, our study recommends the use of autologous PRP for a seamless postoperative experience of the patient.

Keywords: PRP, SSI, REEDA score

INTRODUCTION

Caesarean births in India increased 4.3 percentage points over five years to 21.5% (NFHS-5) from 17.2% (NFHS-4, 2015-16). Nearly half the total Caesarean births (49.3%) took place at health facilities in urban areas.[1] In case of lower segment caesarean section, surgical site infection complicates 2 to 15% of caesarean delivery according to global estimates.[2] While the global estimates of overall surgical site infection (SSI) have varied from 0.5% to 15%, studies in India have consistently shown higher rates ranging from 23% to 38%.[3]

Infection, hematoma, seroma, dehiscence, and pain are the common surgical site complications which might occur in the postpartum period.[4] As per unpublished data of our hospital, the overall incidence of surgical site infection was found to be 20% which further highlights the burden of SSI in our setup.

PRP is a biological product defined as a portion of the plasma fraction of autologous blood with a platelet concentration above the baseline (before centrifugation).[5] As such, PRP contains not only a high level of platelets but also the full complement of clotting factors and growth factors. The most

important growth factors released by platelets are vascular endothelial GF, fibroblast GF (FGF), platelet-derived GF, epidermal GF, hepatocyte GF, insulin-like GF 1, 2 (IGF-1, IGF-2), matrix metalloproteinases 2, 9, and interleukin-8.[6]

There are many studies proving the effectiveness of PRP in orthopaedic surgeries and dermatological conditions. Furthermore there have been prospective trials of autologous platelet graft in gynaecological surgeries.[7]

FDA also considers PRP as a safe biological product as long as it is autologous and minimally manipulated by the addition of by any other external chemical agents.[8,9] Hence, PRP is a safe biological product with strong regenerative potential.

MATERIALS AND METHODS

Study Design: Ethics committee approval (IECHR-2023-59-97-R1) was obtained from the IEC. Clinical trial registry for the study was done at Clinical Trial Registry India (CTRI). Patients who were scheduled to undergo caesarean section with gestational age more than 28 weeks were included in the study while those with infections like HIV, HCV, HBV, syphilis, fever and anaemia and thrombocytopenia were excluded from the trial. The patients were randomised into 2 groups by block randomisation, 22 in each group: Group A, Autologous Platelet Rich Plasma group and group B, Control group. Patients were fully counselled about the procedure .An informed consent was recorded in the vernacular language. The history, examination and lab investigations were duly recorded in a Performa.

PRP preparation: The patient's blood was drawn in a sterile 10 ml syringe followed by immediate transfer into Acid Citrate Dextrose vials.

The sample was then carried to the Department of Biochemistry at room temperature wherein platelet rich plasma (PRP) was extracted by the following method following standard aseptic precautions [Figure 1].

- The blood was centrifuged at 1,200 rpm for 12 minutes in a cold centrifuge.
- The blood separates into three layers: an upper layer that contains platelets and white blood cells, an intermediate thin layer (the buffy coat) that is rich in white blood cells, and a bottom layer that contains red blood cells.
- The upper two-third which are rich in platelet and leucocytes was then transferred to an empty sterile tube. Then this plasma was centrifuged again at 3,300 rpm for 7 minutes to help with the formation of soft pellets at the bottom of the tube;
- The upper two-thirds of the plasma was discarded because it is platelet-poor plasma.
- Pellets are homogenized in the lower third of the plasma to create the platelet rich plasma; the platelet rich plasma which was ready for injection. Approximately 10 mL of venous blood yielded 1.5-2mL of platelet rich plasma.
- The prepared platelet rich plasma solution was transferred within sterile syringe from the laboratory to the OT at room temperature.
- This was then injected subcutaneously at 6 points along the suture line that is at both the edges approximately 2cm from each end of the wound and 2 points in the middle of the wound at a depth of 4-5mm in subcutaneous plane with a sterile insulin syringe for better calibration. Each of these points received approximately 0.3 ml of platelet rich plasma.

Assessment and Follow up

On postoperative Day 3, dressing was removed and wound healing was assessed using the REEDA score.[10] If the wound was healthy, no further dressing was done and caesarean site was left open as such, and if unhealthy, then appropriate management of the SSI was done as per hospital protocol. At Day 8 during suture removal, REEDA score was re-assessed. Any SSI if diagnosed during this procedure was classified as per CDC criteria. Follow up after discharge was done telephonically and the patient was explained to report if she had fever, pain, wound discharge or any other complaints. During a routine PNC visit after 42 days, the patient was re-evaluated for wound healing by REEDA score. In presence of signs and symptoms of inflammation/ infection, pus swab was collected using aseptic technique and Anti-microbial susceptibility testing (AST) was performed for isolated pathogenic bacteria by Modified Kirby-Bauer Disk Diffusion Test using the latest Clinical and Laboratory Standard Institutes (CLSI M100) guidelines.[11]

Outcome measures

Primary Outcome Measure

Comparison of wound healing by Mean REEDA (Redness Ecchymosis Edema Ecchymosis Discharge Approximation) score in both groups on days 3, 8 (Primary Caesarean) or 10 (Repeat Caesarean) and 42.

Secondary Outcome Measures

- Total number of superficial and deep surgical site infection in both group
- Comparison of length of hospital stay due to wound related complications in both groups
- Determine the organisms associated with caesarean surgical site infection in both groups

Statistical Analysis

All the data was entered in MS Excel. The scores of wound healing by REEDA score was compared in both groups by unpaired t test (Mann Whitney test). Incidence rate of surgical site infection and other parameters between the two groups were compared by Chi-square test. P-value <0.05 was taken as significant.

RESULTS

Demographic parameters: Mean age of cases and controls was comparable (27.36 ± 5.09 years vs 27.18 ± 5.05years, p=0.906). There was no significant

difference in the mean BMI of both the groups (22.88 ± 1.98 kg/m2 in case group vs 23.03 ± 2.22 kg/m2, p = 0.82). Case and control group had a comparable distribution of socio-economic status: upper (9.09%in cases vs. 0% in controls), upper middle (72.73% vs. 95.45%), lower middle (18.18% vs.4.55%) (p = 0.11). Most of the patients in our study are booked (59.09% in case and 81.82% in control, p=0.185). Case and control group was also similar in the distribution of gestational age with majority of the patients being at term (68.18%in cases, 86.36% in controls) (p=0.317). Parity was also comparable between both the groups with no statistically significant difference between them (p=1.0). [Table 1]

Preoperative and Intraoperative parameters

The mean of platelet count (in lakhs/mm³) was similar in case and control group (2.2 ± 0.65 vs 2.18 ± 0.7 lakhs/mm³, p = 0.915). Similarly the preoperative haemoglobin (in gm/dl) was also found to be similar with no statistically significant difference between them (12.24±0.84 in case vs 12.2±0.72 in control, p=0.863). The case and control groups were statistically similar in terms of indication of caesarean section (p value = 0.763). About 45.45% sections were done for maternal indications in case group compared to 40.91% in control group. Fetal indications contributed to 54.55% of the caesareans done in case group compared to 59.09% in control group.

The maternal indications for emergency caesarean included 2nd stage arrest (10%in case vs 11.11% in controls), Placenta previa with APH (10% vs 11.11%), previous caesarean with impending scar dehiscence (70%vs66.67%) and Uncontrolled Hypertension (10%vs11.11%). The fetal indications included Cord prolapse (8.3% in case vs 7.69%in controls), failed induction (16.67% vs 15.38%), FGR with AEDF (8.33%vs7.69%), Malpresentation at term (25%vs 23.08%) and MSL with fetal distress (41.67% vs 46.15%). Both the groups were also similar as far as intraoperative blood loss was concerned with mean blood loss of 565.68 ± 100.31 mL and 564.09 ± 98.19 mL in case and control group respectively, (p = 0.958). [Table 1]

Outcome measures

Case group had a significantly lower proportion of patients with SSI (4.55% vs. 31.82% in control). However the incidence of inpatient infection and readmission rates were similar in both the groups. Most of the infections were superficial SSI (100% in case vs 71.43% in controls, p =1.0) [Table 2]. The mean REEDA score in Case group ranges from 1 to 3 whereas for control group it ranged from 1-4. No significant difference was seen in REEDA score at day 3 (2.36 ± 0.58 in Case and 2.77 ± 0.81 in control, p value=0.071).

However, significant difference was seen in REEDA score at day 8/10. The mean REEDA score was found to be 1.77 ± 0.61 for the Case group whereas it was found to be 3.27 ± 2.1 for the control group (p=0.009). [Table 3]

Similarly, the mean REEDA showed statistically significant difference on day 42. The Case group had a mean REEDA of 0.55 ± 0.51 whereas Control group had a 1.41 ± 1.01.(p=0.001)

The average REEDA score of Case group was found to be 1.56 ± 0.42 and that of the control group was found to be 2.48 ± 1.11. This difference was statistically significant with a p value of 0.002. [Table 3, Figure 2]

Distribution of organisms isolated was also comparable (p=1.0) with Acinetobacter baumannii being the most common organism isolated from the infected wounds. [Table 2]. There was no statistically significant difference in the mean duration of hospital stay (8.09 ± 9.04 days in case vs 6 ± 4.41 days in control, p value=0.891). Indication for prolonged hospital stay for majority of the patients was NICU admission of the baby.

Table 1: Comparison of baseline parameters between case and control

Parameters	Case	Control	P value
Age (years)	27.36 ± 5.09	27.18 ± 5.05	0.906
Socioeconomic class • Upper • Upper Middle • Lower Middle	 2 (9.09%) 16 (72.73%) 4 (18.18%)	 0 (0%) 21 (95.45%) 1 (4.55%)	0.11
Education • Illiterate • Primary • Middle School • High School • Intermediate • Graduate	 6 (27.27%) 2 (9.09%) 3 (13.64%) 5 (22.73%) 2 (9.09%) 4 (18.18%)	 4 (18.18%) 4 (18.18%) 2 (9.09%) 5 (22.73%) 4 (18.18%) 3 (13.64%)	0.776
Gestational age	38.12 ± 3.22	37.96 ± 2.59	0.855
Parity • Primigravidae • Multigravidae	 11 (50%) 11 (50%)	 11 (50%) 11 (50%)	1.0
BMI(kg/m2)	22.88 ± 1.98	23.03 ± 2.22	0.82
Preop Hemoglobin (gm/dl)	12.24 ± 0.84	12.2 ± 0.72	0.863
Preop Platelet Count (lakhs/mm3)	2.21 ± 0.65	2.18 ± 0.7	0.915
Duration of surgery(hrs)	1.39 ± 0.41	1.36 ± 0.24	0.736
Blood Loss(ml)	565.68 ± 100.31	564.09 ± 98.19	0.958
Duration of hospital stay (in days)	8.09 ± 9.04	6 ± 4.41	0.891

Table 2: Comparison of SSI between Case and control

SSI	Case(n=22)	Control(n=22)	Total	P value
No SSI	21 (95.45%)	15 (68.18%)	36 (81.82%)	0.046*
SSI present	1 (4.55%)	7 (31.82%)	8 (18.18%)	
Total	22 (100%)	22 (100%)	44 (100%)	
Class of SSI				
Deep	0 (0%)	2 (28.57%)	2 (25%)	1*
Superficial	1 (100%)	5 (71.43%)	6 (75%)	
Total	1 (100%)	7 (100%)	8 (100%)	
Organism Isolated				
Acinetobacter baumnnii	1 (100%)	2 (28.57%)	3 (37.50%)	1.0*
E coli	0 (0%)	1 (14.29%)	1 (12.50%)	
Enterococcus faecalis	0 (0%)	2 (28.57%)	2 (25%)	
MRSA	0 (0%)	1 (14.29%)	1 (12.50%)	
Pseudomonas aeruginosa	0 (0%)	1 (14.29%)	1 (12.50%)	
Total	1 (100%)	7 (100%)	8 (100%)	

* Fisher's exact test

Table 3: Comparison of average REEDA score between Case and control

Average REEDA score	Case(n=22)	Control(n=22)	Total	P value
Mean ± SD	1.56 ± 0.42	2.48 ± 1.11	2.02 ± 0.95	0.002§
Median (25th-75th percentile)	1.5(1.333-1.917)	2.17(1.75-3.167)	1.83(1.333-2.333)	
Range	1-2.33	0.67-4.67	0.67-4.67	
REEDA score				
At day 3				
Mean ± SD	2.36 ± 0.58	2.77 ± 0.81	2.57 ± 0.73	0.071§
Median(25th-75th percentile)	2(2-3)	3(2-3)	3(2-3)	
Range	1-3	1-4	1-4	
At day 8/10				
Mean ± SD	1.77 ± 0.61	3.27 ± 2.1	2.52 ± 1.7	0.009§
Median(25th-75th percentile)	2(1-2)	2.5(2-4.75)	2(1.75-3)	
Range	1-3	1-7	1-7	
At day 42				
Mean ± SD	0.55 ± 0.51	1.41 ± 1.01	0.98 ± 0.9	0.001§
Median(25th-75th percentile)	1(0-1)	1(1-2)	1(0-1)	
Range	0-1	0-4	0-4	

§ Mann Whitney test

Figure 1: (A) ACD vials and counterbalance placed in the centrifuge, (B) After first cycle of centrifugation at 1200 rpm for 12 minutes, (C) After second cycle of centrifugation at 3300 rpm for 7 minutes, (D) freshly prepared PRP

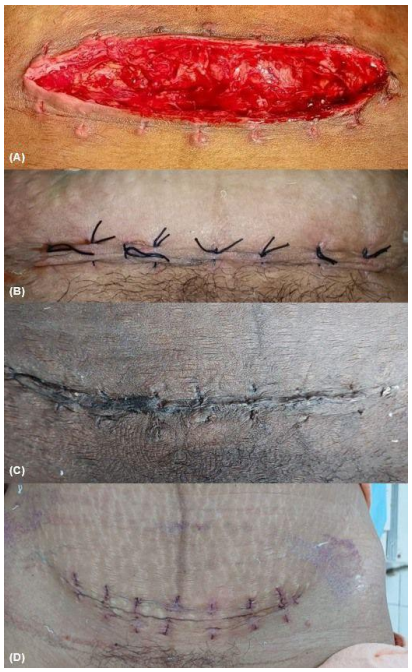

Figure 2: (A) Deep surgical site infection in control group, (B) Superficial surgical site infection in control group, (C) Healthy surgical wound after suture removal in control group, (D) Healthy surgical wound after suture removal in case group

DISCUSSION

PRP has been used for various chronic degenerative orthopaedic, dermatological and wound related conditions such as diabetic ulcer. Recently, its use has been explored in gynaecological conditions such as Infertility.

However prevention of SSI and improvement of wound quality with PRP in patients undergoing caesarean delivery remains a potentially unexplored territory. The above study aims to explore the same. The outcomes of the above study are solely attributed to the intervention i.e. PRP, as randomization has ensured that both the groups were similar in baseline demographic, pre and intraoperative parameters.

The study done by Tehranian et al,[4] showed a significant effect of PRP on reduction of REEDA score. The mean REEDA Score on Day 1, day 5 and at 8 weeks was compared between the case and control group. In our study however, the assessment of wound was done on day 3, day 8 for primary caesarean and day 10 for repeat caesarean and finally at day 42. These days were judiciously chosen in a way to ensure more patient compliance since following discharge these are the days when the patients made a visit to our hospital for suture removal and for attending the PNC OPD respectively. There was no significant difference in REEDA score on Day 3 (2.36 ± 0.58 for case and 2.77 ± 0.81 for controls, p=0.071). However, on day 8 or day 10 the REEDA score in case group of our study was 1.77 ± 0.61 compared to 3.27 ± 2.1 in control group with a p value of 0.009. Similar to our study the study by Tehranian et al also found a significant difference between REEDA score on day 5 of case and control group which was 1.34±0.59 for case group and 1.85±0.61 for control group with a p value of 0.001.

Finally in our study, on day 42 the REEDA score was 0.55 ± 0.51 in case group and 1.41 ± 1.01 in control group with a p value of 0.001 which was statistically significant. As opposed to this in the study by Tehranian et al the REEDA score at 8 weeks was compared between case and control which was found to be 0.77±0.51 and 0.98±0.52 respectively. However the study by Tehranian et al did not study the incidence of SSI with use of PRP which was found to be 4.55% in patients who received PRP compared to 31.82% in the control group in our study.

This single-centre study had limitations of having a small sample size, lack of double-blinding, and potential inter and intra observer biases. PRP being a novel agent has found its way in regenerative medicine. Indications for caesarean in this study were of emergency nature. Hence this study also studies the impact of PRP in an emergency setup where infection causing agents are rampant.

CONCLUSION

Prophylactic application of PRP during caesarean wound closure was found to reduce the incidence of SSI leading to decreased post-operative morbidity of the patient. There was a lower incidence of SSI in the case group. Also, there was significantly better REEDA score in patients who received PRP. Thus, not only incidence of SSI but also the quality of wound in terms of healing indicators such as better approximation, less redness, ecchymosis and oedema were also seen with the use of PRP.

PRP application should be done in all patients undergoing caesarean delivery especially in high risk emergency caesarean in order to reduce the incidence of SSI and improve the quality of caesarean wound and thus leading to a seamless post operative experience.

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