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Original Research Article

A study to compare the effects of platelet rich plasma and cryotherapy on cervical erosion

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ABSTRACT

Background: This research work aimed to study the effects of platelet rich plasma (PRP) application on cervical erosion and to compare its efficacy with cryotherapy as alternate mode of therapy.
Methods: 100 sexually active women more then 20 yrs of age with symptomatic cervical erosion were included in the study. 50 were treated with PRP and remaining 50 were treated with cryotherapy. PRP was prepared from patients own blood, no anaesthesia was used. Patients were followed at 2 weeks, 4 weeks and 12 weeks.
Results: At 2 weeks follow up significant relief was obtained in PRP group (82%) while patients who underwent cryotherapy had a lot of white discharge (only 4% were relieved). At 4 weeks and 12 weeks the difference in symptomatic relief was almost similar in both groups.
Conclusions: PRP is a safe, effective, easy to obtain, economical and a promising modality in the treatment of cervical erosion. Relief obtained after single application of PRP was extremely remarkable at 2 weeks.

Keywords: Cervical erosion, Platelet rich plasma, Preeclampsi

INTRODUCTION

A cervical erosion is a condition in which the squamous covering of the vaginal aspect of the cervix is replaced by columnar epithelium which is continuous with that lining endocervix.[1] It is not an area denuded of epithelium as the name applies. Small areas of ulceration sometimes seen microscopically are the results of secondary infection and local trauma, or are artefacts. An ectopy has a bright red appearance with a clearly defined edge, the color is being explained by underlying vascular tissue showing through thin epithelium. The columnar epithelium may be arranged in a regular pattern but is sometimes proliferated and heaved up to form villous projection- papillary ectopy. Beneath the epithelium the tissue often shows round cell infiltration and glandular proliferation. Some assume that these signs are indicative of a chronic infection, which precedes and causes the ectopy. Any inflammatory process, however, is more likely to be secondary, the columnar epithelium having less power of resistance to infection than the normal stratified covering. Cervical erosion/ectopy is a common condition seen in women of all age group.[2]

Some of the common causes of cervical erosion are trauma, excessive use of chemicals, infections (sexually transmitted diseases like chlamydia, gonorrhea, trichomonas vaginalis), viral infections like herpes simplex virus and human papilloma virus, malnutrition, poor immunity and hygiene, multiple partners and early age of sexual activity.[3]

Symptoms of cervical erosion are vaginal discharge**,** low backache**,** lower abdominal pain, post coital bleeding,

intermittent bleeding and spotting, dyspareunia and occasionally burning micturition.[4,5]

Role of Platelet rich plasma (PRP) in cervical erosion comes from fact that the body's first response to tissue injury is to deliver platelets to the injured area. These platelets promote healing through growth factors and other cytokines release. The theory underlying this treatment modality was derived from natural healing processes as Autologous PRP is derived from an individual's whole blood, which is centrifuged to remove red blood cells.[6,7] The remaining plasma has a 3-5-fold higher concentration of platelets than the whole blood.[8] These activated platelets release growth factors (platelet derived growth factor, transforming growth factor beta, fibroblast growth factor insulin like growth factor 1 and 2, vascular endothelial growth factor, epidermal growth factor). which have been found to promote natural healing responses and attract stem cells to the site of injury which help in regeneration of tissue. Applying autologous platelet-rich plasma to diseased tissue is a simple, natural, low-cost, and noninvasive way of ensuring a good local concentration of autologous growth factors, and the method holds promise.[9] Not surprisingly, in recent years, autologous platelet-rich plasma (PRP) has received more and more attention in the fields of orthopaedics, dentistry, dermatology, ophthalmology, and cosmetic surgery.[10-13]

Cryotherapy is another comparative treatment modality for cervical erosion.[14,15] The basic principle of cryotherapy is controlled destruction of tissue by freezing.[16] It is double freezing technique in which the tissue is frozen for period of 3 minute, thawed for 5 minutes and refrozen for 3 minutes. In order to achieve hypothermia, nitrous oxide is forced through a small hole at a pressure range 750-900 pounds per inch (psi).[17] This produces a very low temperature at the surface of the probe due to the Joule-Thompson effect. The temperature at the probe tip can range from -65 ℃ to- 85 ℃. Cell death occurs secondary to crystallization of intracellular water at -20 ℃ to -30℃. Nitrous oxide is by far the most popular in current use. Its efficacy is due to low temperature achievable (-197℃), Its effects are predictable and well documented. Nitrous oxide is favored as storage has no problem and cylinders are easily portable.

In the present study, therefore we are comparing PRP which is an innovative and upcoming treatment modality with cryotherapy (conventional way of treating) for cervical erosion.

METHODS

Study design and place

This was prospective and interventional randomized comparative study. This study was conducted in the Department of Obstetrics and Gynecology, Tirath Ram Shah Hospital, New Delhi from July 2022 to July 2023.

Study population

All sexually active women, above the age of 20 years, with history and examination suggestive of cervical erosion were taken into study.

Block randomization

Block randomization with sealed envelope system

In this, ten randomly generated treatment allocations within sealed opaque envelopes assigning A and B in 5 envelopes each, where A represents Group A receiving PRP and B represents Group B receiving cryotherapy. Once a patient's consent to enter a trial an envelope was opened and the patient was then be offered the allocated group. In this technique, patients were randomized in a series of blocks of ten.

Inclusion criteria

All sexually active women, above the age of 20 years with symptoms suggestive of cervical erosion like PV discharge, pain lower abdomen, backache, post coital bleeding, dyspareunia and patients who were having cervical erosion detected by clinical examination, attending clinic of obstetrics and gynaecology department at Tirath Ram Shah Hospital were included.

Exclusion criteria

Pregnant women, women who were using oral contraceptive pills or on HRT, women with abnormal pap smear malignant changes), women with abnormality of platelets, and women with prolapse uteri were excluded.

Methodology

A prospective and Interventional Randomized Comparative Study, with due ethical consideration, after taking written and informed consent from each patient and after explaining the procedure in detail, its beneficial outcome and side effects, was carried out in the hospital. After proper history, pelvic examination, routine and specific investigations, 100 sexually active women age above 20 years age group with cervical erosion, were studied during period of 12 months. Around 20 ml of whole blood was collected by venipuncture in four preloaded anticoagulant tubes and the sample was checked for platelets counts. The sample was processed by density dependent separation in laboratory at 1800 rpm for 12 minutes. The plasma including buffy coat was put into another tubes. The remaining sample was put for centrifugation at 3200 rmp for 6 minutes. Supernatant was removed. The lower part was rich in platelets and 0.2 ml of this sample was checked for platelet count. Platelets were homogenized in the tube of plasma. This is how PRP was made for application. Approximately 20 ml of venous blood yield 2 ml of PRP, with 18 G needle, around 1.5 ml of platelet rich plasma was injected into intra and peri

cervical tissue precisely in targeted area at 2 to 4 sites and around 0.5 ml applied directly over the lesion.

Another 50 patients were treated with cryotherapy. The cryogenic device consists of gas tank containing non-explosive, non-toxic gas. Nitrous oxide gas was used in this study. The gas was delivered using flexible tubing through a gun type attachment to a cryoprobe. The procedure was performed during post menstrual period. Depending upon the size, appropriate cryoprobe was selected. A cryoprobe was placed in contact with the cervix and system was activated. An ice ball was allowed to develop up to 5mm lateral spread beyond the lesion. The freeze time of cryo-cauterization was 3 min and the thaw time was 5 minutes. The system was deactivated and the probe was allowed to separate from the frozen cervical tissue. The patient was explained that they may experience a heavy watery discharge for first month after cryotherapy resulting from the sloughing of dead tissue and exudate from the treatment site. They were explained about possibility of mild cramp like pain and will be told to report if fever, heavy bleeding or severe pain.

The patients were asked to refrain from sexual intercourse and tampon use for 4 weeks after procedure to avoid infection, bleeding and allow re-epithelization of lesion.

Sample size

The study of Jain et al observed that 76.6% of patients were cured completely with PRP. Taking these values as reference and assuming difference of 28% in cure rate between PRP and cryotherapy, the minimum required sample size with 80% power of study and 5% level of significance is 43 patients in each study group. Taking lost to follow up of 10%, total sample size taken is 48 (48 patients per group). Formula used is:

$n>=((pc*(1-pc) + pe*(1-pe)) * (Z_\alpha + Z_\beta)^2)/(pc-pe)^2$

with pc= cure rate in PRP, pe= cure rate in cryotherapy.

Where; Z_α is value of Z at two-sided alpha error of 5% and Z_β is value of Z at power of 80%.

Calculations

$n\geq((.766*(1-.766) +.486*(1-.486)) * (1.96+.84)^2)/(.766-.486)^2$

$\geq 42.91=43$(approx.)

Taking lost to follow up as 10%, n>=43/.9>=47.78=48(approx.).

Statistical analysis

Categorical variables were presented in number and percentage (%) and continuous variables was presented as mean ± SD and median. Normality of data was tested by Kolmogorov-Smirnov test. If the normality was rejected then non parametric test was used.

Statistical tests were applied as follows: 1) Quantitative variables was compared using Unpaired t-test/Mann-Whitney Test (when the data sets were not normally distributed) between the two groups, 2) Qualitative variables was compared using Chi-Square test/Fisher's exact test, 3) p value of <0.05 was considered statistically significant.

The data was entered in MS EXCEL spreadsheet and analysis was done using Statistical Package for Social Sciences (SPSS) version 21.0.

RESULTS

The highest proportion of patients were in the 31-40 year age group in both the platelet rich plasma and cryotherapy treatment arms (25%), while the lowest proportions were seen in the 41-50 year age group, 16% in platelet rich plasma and 20% in cryotherapy treatment arm. distribution of age groups among the two treatment groups shows no significant difference at baseline (Table 1).

Table 1: Comparison of age group at baseline between the two groups (n=100).

Age groups (years)	Platelet rich plasma (N, %)	Cryotherapy (N, %)	Chi square test	P value
≤30	17 (34)	15 (30)	0.347	0.841
31-40	25 (50)	25 (50)		
41-50	8 (16)	10 (20)		
Total	50 (100)	50 (100)		

The highest proportion of patients had parity of '1-2' in both the platelet rich plasma (62%) and cryotherapy treatment arms (86%), while the lowest proportions were seen in the '5 and above' parity, none in platelet rich plasma and 2% in cryotherapy treatment arm. The distribution of parity among the two treatment groups showed significant difference at baseline (Table 2).

White discharge at baseline was present in 72% patients in both the platelet rich plasma and cryotherapy group (Table 3). Lower abdominal pain was seen in 38% of patients in the platelet rich plasma arm and in 34% of patients in the cryotherapy group, with no statistically significant difference in the proportions (Table 4).

Table 2: Comparison of parity at baseline between the two groups (n=100).

Parity	Platelet rich plasma (N, %)	Cryotherapy (N, %)	Chi square test	P value
1-2	31 (62)	43 (86)	10.207	0.037*
3-4	19 (38)	6 (12)		
5 and above	0	1 (2)		
Total	50 (100)	50 (100)		

*Statistically significant

Table 3: Comparison of white discharge between the two groups at baseline (n=100).

White discharge	Platelet rich plasma (N, %)	Cryotherapy (N, %)	Chi square test	P value
Absent	14 (28)	14 (28)	0.000	1.000
Present	36 (72)	36 (72)		
Total	50 (100)	50 (100)		

Table 4: Comparison of lower abdominal pain between the two groups at baseline (n=100).

Lower abdominal pain	Platelet rich plasma (N, %)	Cryotherapy (N, %)	Chi square test	P value
Absent	31 (62)	33 (66)	0.170	0.677
Present	19 (38)	17 (34)		
Total	50 (100)	50 (100)		

Itching was seen in 8% of patients in the platelet rich plasma group and12% of the patients in the cryotherapy group, with no statistically significant difference in the proportions (Table 5).

Post coital bleeding was seen in 10% of patients in the platelet rich plasma group and in 8% of the patients in the cryotherapy group. There was no statistically significant difference in the proportions between the two groups (Table 6).

Table 5: Comparison of itching between the two groups at baseline (n=100).

Itching	Platelet rich plasma (N, %)	Cryotherapy (N, %)	Chi square test	P value
Absent	46 (92)	44 (88)	0.440	0.505
Present	4 (8)	6 (12)		
Total	50 (100)	50 (100)		

Table 6: Comparison of backache between the two groups at baseline (n=100).

Backache	Platelet rich plasma (N, %)	Cryotherapy (N, %)	Chi square test	P value
Absent	42 (84)	41 (82)	0.070	0.790
Present	8 (16)	9 (18)		
Total	50 (100)	50 (100)		

Table 7: Comparison of post coital bleeding between the two groups at baseline (n=100).

Post coital bleeding	Platelet rich plasma (N, %)	Cryotherapy (N, %)	Chi square test	P value
Absent	45 (90)	46 (92)	0.120	0.727
Present	5 (10)	4 (8)		
Total	50 (100)	50 (100)		

Backache was seen in 16% of patients in the platelet rich plasma group and in 18% of the patients in the cryotherapy group. There was no statistically significant difference in the proportions of patients with backache between the two groups (Table 7).

Inflammatory smear was in 66% of patients in the platelet rich plasma group and in 74% of the patients in the cryotherapy group. There was no statistically significant difference in the proportions of patients with inflammatory smears between the two groups (Table 8).

Symptomatic relief at 2 weeks was seen in 82% of patients in the platelet rich plasma group and in only 4% of the patients in the cryotherapy group. There was a statistically significant difference in the proportions of patients with Symptomatic relief at 2 weeks between the two groups (Table 9).

Table 8: Comparison of PAP smear findings between the two groups at baseline (n=100).

PAP smear	Platelet rich plasma (N, %)	Cryotherapy (N, %)	Chi square test	P value
Chronic cervicitis	17 (34)	13 (26)		
Inflammatory smear	33 (66)	37 (74)	0.762	0.383
Total	50 (100)	50 (100)		

Table 9: Comparison of symptomatic relief at 2 weeks between the two groups after procedure (n=100).

Symptomatic relief at 2 weeks	Platelet rich plasma (N, %)	Cryotherapy (N, %)	Chi square test	P value
Absent	9 (18)	48 (96)		
Present	41 (82)	2 (4)	62.056	0.000*
Total	50 (100)	50 (100)		

*Statistically significant

Table 10: Comparison of symptomatic relief at 4 weeks between the two groups after procedure (n=100).

Symptomatic relief at 4 weeks	Platelet rich plasma (N, %)	Cryotherapy (N, %)	Chi square test	P value
Absent	5 (10)	3 (6)		
Present	45 (90)	47 (94)	0.150	0.695
Total	50 (100)	50 (100)		

Table 11: Comparison of per speculum examination at 4 weeks between the two groups after procedure (n=100).

Cervical erosion present at 4 weeks	Platelet rich plasma (N, %)	Cryotherapy (N, %)	Chi square test	P value
Absent	45 (90)	47 (94)		
Present	5 (10)	3(6)	0.540	0.461
Total	50 (100)	50 (100)		

Table 12: Comparison of per speculum examination at 12 weeks between the two groups after procedure (n=100).

Cervical erosion present at 12 weeks	Platelet rich plasma (N, %)	Cryotherapy (N, %)	Chi square test	P value
Absent	49 (98)	47 (94)		
Present	1 (2)	3 (6)	0.444	0.505
Total	50 (100)	50 (100)		

Table 13: Comparison in PAP smears 12 weeks after the procedures between the two treatment groups (n=100).

PAP smear after 12 weeks	Platelet rich plasma (N, %)	Cryotherapy (N, %)	Chi square test	P value
Inflammatory	1 (2)	3 (6)		
No inflammatory cells	49 (98)	47 (94)	1.042	0.610
Total	50 (100)	50 (100)		

Symptomatic relief at 4 weeks was seen in 90% of patients in the platelet rich plasma group and in 94% of the patients in the cryotherapy group. There was no statistically significant difference in the proportions of patients with Symptomatic relief at 4 weeks between the two groups (Table 10).

Cervical erosion present at 4 weeks after treatment was seen in 10% of patients in the platelet rich plasma arm and in 6% of the patients in the cryotherapy arm. There was no statistically significant difference in the proportions of patients with cervical erosion present at 4 weeks after treatment between the two groups (Table 11).

Cervical erosion at 12 weeks after treatment was seen in 2% of patients in the platelet rich plasma arm and in 6% of the patients in the cryotherapy arm. There was no statistically significant difference in the proportions of patients with cervical erosion present at 4 weeks after treatment between the two groups (Table 12).

PAP smear after 12 weeks of treatment showed inflammatory cells in 2% of patients in the platelet rich plasma group and in 6% of the patients in the cryotherapy group. There was no statistically significant difference in the proportions of patients with inflammatory cells on PAP smear after 12 weeks of treatment between the two groups (Table 13).

DISCUSSION

Cervicitis is the most prevalent gynaecological condition among adult women, leading to a heavy financial burden on the patient. It remains one of the leading causes of morbidity and poor quality of life for women. Despite the availability of several modalities for treatment, the management of cervicitis remains a challenge. Local use of autologous PRP has been shown to have the ability to cure wounds, repair tissue and prevent infection in persistent cervicitis.[20-22] The present study attempts to provide further evidence to the utility of PRP in the management of the disease and compare it with cryotherapy, which is another commonly used method of treatment.

In the current study, at baseline, there was no significant difference regarding age (p=0.841) between PRP group and cryotherapy group. The average age of patients with cervicitis was 31-40 yrs in both groups. Jain et al, evaluated the post-treatment symptom alleviation and repair of the damaged cervix in 120 patients receiving conventional(antibiotic) or PRP therapy to treat chronic cervicitis as well as erosions.[8] In both groups, the average age of patients with chronic cervicitis was 32-34 years, similar to the present study.

The highest proportion of patients had parity of '1-2' in both the platelet rich plasma (62%) and cryotherapy treatment (86%)group, while the lowest proportions were seen in the '5 and above' parity, none in platelet rich plasma and 2% in cryotherapy treatment group. The distribution of parity among the two treatment groups showed significant difference at baseline, same as reported by Shivanna et al, where most (42.04%) of the patents were para 2.[23]

Hua and colleagues, conducted a randomized clinical trial evaluating the efficacy of autologous PRP administration to that of laser therapy for benign cervical erosion and found no significant variation among the groups in terms of the demographic parameters such as age and parity, symptoms like vaginal discharge, discomfort, and bleeding.[9] In the present study too, at presentation, no statistically significant differences was seen in between the groups in the proportion of patients with white discharge (p=1.000), lower abdominal pain (p=0.677), itching (p=0.505), post-coital bleeding (p=0.727) or backache (0.790). Also, the proportion of patients with chronic cervicitis/inflammation on PAP smear in the two treatment arms (p=0.383) were similar at baseline.

In the present research, overall symptomatic relief at 2 weeks was significantly higher in the in the platelet rich plasma arm (82%) than the cryotherapy group (4%) which was statistically significant. 41 out of the 50 patients in PRP group were relieved of their symptoms like white discharge, lower abdominal pain, backache, post coital bleeding and were very comfortable, while in the cryotherapy group only 2 patients were relived, and 48 out of 50 had a lot of white discharge (which is known after cryotherapy). In a retrospective study conducted by Jain et al, among 69 women that had undergone cryotherapy for cervical erosion, the most common problem experienced after cryotherapy by patients was hydrorrhea (watery discharge) in 81.15% which lasted for 2-4 weeks.[19] In the same study (Jain et al), 7.24% of patients complained of spotting, 4.34% complained of postcoital bleeding, and 2.89% complained of dyspareunia.[19] Similar findings were reported by Shivanna et al, and Shrish Seth, in both their studies, excessive watery discharge after cryotherapy was found in 50% and 66.80% patients respectively.[23]

In our study, comparison of individual symptoms at 4 weeks between the treatment groups shows amelioration of symptoms in a higher proportion of patients in the PRP therapy group compared to the cryotherapy group although the differences were not statistically significant [watery discharge (p=0.269), lower abdominal pain (p=0.126), Itching (p=0.475), Post coital bleeding (p=0.475) and backache (0.712)]. In the RCT conducted by Aitah et al in Egypt, comparing autologus platelet-rich plasma versus silver nitrate in the treatment of cervical erosion, there was no significant variation in the incidence of bleeding (p= 0.218) no significant difference in the presence of discharge (p=0.383) no significant difference regarding complications (p=0.079).[42]

By the end of 4 weeks, successful treatment, as shown by symptomatic relief was observed in a higher proportion of patients (94%) in the cryotherapy group as compared to the PRP group (90%) in our research. The result was however not statistically significant.

In the study by Hua et al, comparing PRP and Nd-YAG laser, at the end of the 12-week follow-up, overall, the treatment was effective for 46 (93.9%) and 45 (95.7%) patients, respectively, and the difference between the rates was not significant (P>0.05).[9] The study by Jain et al, reported that on clinical examination, healing of the cervix was found in 89.85% of the patient after 12 weeks of cryotherapy.[19] However, in the present study per speculum examination at 12 weeks shows healing of cervix in PRP group was 90% and in cryotherapy group was 94%, which is slightly higher in PRP group. PAP smear after 12 weeks of treatment showed inflammatory cells in 2% of patients in the PRP therapy group and in 6% of the patients in the Cryotherapy group, with no statistically significant difference between the two.

Although the rates of recovery were comparable between the two groups, the mechanism of actions were strikingly

different. The controlled freezing of tissue is known as cryotherapy. Its effects are clearly known and foreseeable. Re-epithelialization, which takes place in the majority of patients by 6 weeks and in all patients by 3 months, is how the cervix heals. Contrary to cryotherapy or laser, in PRP use, there is no tissue loss. Centrifugation is used to separate the platelets from whole blood; the resulting concentrate has a larger concentration of platelets and other cellular plasma components than whole blood, and growth factors (transforming growth factors beta, platelet derived growth factor, vascular endothelium growth factor, epidermal growth factor, fibroblast growth factors 2, fibroblast growth factors 90, hepatocyte growth factor). These encourage epithelialization.

Autologous PRP therapy is an emerging treatment strategy for chronic cervicitis, with promising result for inflamed and damaged cervical tissue with healing of erosions and better cervical health.[8] Since it is autologous, being generated from the patient's own blood, it is easy to obtain, and free from the development of immunogenic complications. The comfort and relief which the patients got soon after PRP application was very remarkable.

The population study was very small needs to be studied in large populations, limitations of study.

CONCLUSION

PRP is generated from the patient's own blood, making it a biologically safe, effective, easy to obtain, and economically viable option for the treatment of cervical erosions and its symptoms. It is rich in platelets and its growth factor like Platelet-rich plasma (PRP) include platelet derived growth factor aa (PDGFaa), PDGFbb, PDGFab, transforming growth factor beta-1 (TGF-b1), TGF-b2, vascular endothelial growth factor (VEGF), and epithelial growth factor (EGF). In addition, it does away with the troublesome side effect of watery discharge (which is known after conventional cryotherapy modality). Relief obtained after a single application of PRP was extremely remarkable at 2 weeks follow up in view of white discharge, backache, itching, lower abdominal pain and post coital bleeding. It was very rewarding for the patient also. It offers a promising modality for treatment of cervical erosion as a simple, non-immunogenic (autologous tissue) economical modality for providing early relief of symptoms without any major side effects.

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