Clinical Efficacy of Placentrex Injection in Pelvic Inflammatory Disease

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Abstract

Pelvic inflammatory disease (PID) is one of the most frequent infections seen in reproductive age group and is associated with major clinical and pelvic health problem. It is Infection & inflammation of upper genital tract organs typically involving fallopian tubes, ovaries & surrounding structures. PID is polymicrobial in nature and is associated with different etiological agents. Clinical presentations may vary from mild to severe. No specific signs and symptoms are pathognomic of PID. Laboratory tests are also poor predictors of PID. There may be subclinical symptoms and patient later may present with infertility. CDC recommends treatment for even mild cases of PID. Therapeutic goal in management of PID is to prevent chronic residual disease. Failure of antibiotic therapy to prevent sequelae of salpingitis reflects the emphasis of additional therapy along with antibiotics. Placentrex is a drug containing Peptides (FNP-III, CRF), Nucleotides (PDRN) & Glutamate and is derived from an extract of fresh term, healthy, human placenta. It has significant anti inflammatory effect involving chemical mediators of immunological response. Effect of placentrex is well documented in wound healing1 and in treatment of burns and radiation effects 2. It has been recommended for prescription for PID but there is not much data in literature regarding the efficacy in PID. So we conducted a trial to find efficacy of placentrex in comparision with azithromycin for the treatment of PID.

Keywords: Placentrex Injection Pelvic Inflammatory Disease, Azithromycin menstrual irregularity, Dysmennorrhoea

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Introduction

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PID is polymicrobial in nature and is associated with different etiological agents. Clinical presentations may vary from mild to severe. No specific signs and symptoms are pathognomic of PID. Laboratory tests are also poor predictors of PID. There may be subclinical symptoms and patient later may present with infertility.

CDC recommends treatment for even mild cases of PID. Therapeutic goal in management of PID is to prevent chronic residual disease. Failure of antibiotic therapy to prevent sequelae of salpingitis reflects the emphasis of additional therapy along with antibiotics.

Placentrex is a drug containing Peptides (FNP-III, CRF), Nucleotides (PDRN) & Glutamate and is derived from an extract of fresh term, healthy, human placenta. It has significant anti inflammatory effect involving chemical mediators of immunological response. Effect of placentrex is well documented in wound healing[1] and in treatment of burns and radiation effects[2]. It has been recommended for prescription for PID but there is not much data in literature regarding the efficacy in PID. So we conducted a trial to find efficacy of placentrex in comparision with azithromycin for the treatment of PID.

Materials and Methods

Open randomised prospective clinical trial was conducted in department of OBG Cheluvamba hospital Mysore from December 2013 to December 2014 after obtaining ethical clearance. A total of 50 patients of PID within reproductive age group of 20-45 years were recruited. Diagnosis of PID was made on clinical history and examination.

- **Inclusion criteria:**
  a) female subjects of child bearing age.
  b) patients diagnosed to have PID in the last 6 to 12 months
  c) patients with primary or secondary infertility with diagnosis of PID
  d) patients with persistent PID despite antibiotic treatment within past 6 weeks
  e) willingness to receive intramuscular injections for 14 days.
- **Exclusion criteria:**
  a) post menopausal women or women outside reproductive age group.
  b) subjects who are pregnant or breast feeding
  c) subjects on active treatment or with evidence of active TB/STD
  d) subjects with endometriosis

e) history of more than 3 episodes of documented PID / bacterial STD.
f) any hepatic or renal impairment.

Patients were randomly assigned to two groups. Group1 (25 patients) was given inj. placentrex 2ml IM daily for 14 days, Group2 (25 patients) were given tab. azithromycin 1000mg stat and repeated the same dose after 1week.

Patients were followed up at 2,4 & 12weeks after starting the treatment, the first follow up at 2weeks after initiation of the therapy was to assess the immediate relief of symptoms while on therapy. 2nd follow up at 4weeks was to assess persistence of relief. 3rd follow up at 12weeks was to assess recurrence of symptoms.

History suggestive of PID are lower abdomen pain, discharge per vagina, menstrual irregularity, dysmennorrhoea and dispareunia. Clinical signs consisted of presence of discharge, uterine tenderness, restricted mobility of uterus and adnexal tenderness. The response of treatment were made based on history and examination.

Results

Total 50 cases of PID were recruited , 25 in group 1 and 25 in group 2, mean age of patients were 30.36yrs in group1 and 31.1 in group2, most of them were P2L2, 2 cases in group1 and 5 cases in group2 were lost out of follow up. There were no major or minor side effects in both the groups except mild gastric upset seen in 2 cases in group2. No patients had allergic reaction, fever or pain at injection site in group1.

Table 1: Symptomatology and Signs

	Group 1				Group 2			
Symptomatology	Initial (25)	2weeks (25)	4weeks (23)	12weeks (23)	Initial (25)	2weeks (23)	4weeks (20)	12weeks (20)
Lower abd pain	23 (92%)	12 (48%)	10 (43.5%)	10 (43.5%)	22 (88%)	16 (69.6%)	14 (70%)	14 (70%)
Back ache	16 (64%)	6 (24%)	5 (21.7%)	4 (17.4%)	17 (68%)	7 (30.4%)	8 (40%)	8 (40%)
Menstrual irregularities	8 (32%)	4 (16%)	3 (13%)	3 (13%)	9 (36%)	5 (21.7%)	6 (30%)	7 (35%)
Dysmennorrhoea	16 (64%)	7 (28%)	6 (26.1%)	6 (26.1%)	11 (44%)	8 (34.8%)	7 (35%)	6 (30%)
Dyspareunia	9 (36%)	4 (16%)	3 (13%)	3 (13%)	6 (24%)	4 (17.4%)	3 (15%)	3 (15%)
Signs								
Discharge per vagina	15 (60%)	9 (36%)	8 (34.8%)	5 (21.7%)	14 (56%)	5 (21.7%)	8 (40%)	8 (40%)
Uterine tenderness	16 (64%)	10 (40%)	9 (39.1%)	7 (30.4%)	16 (64%)	6 (26.1%)	11 (55%)	9 (45%)
Rerstricted uterine mobility	8 (32%)	3 (12%)	2 (8.7%)	2 (8.7%)	9 (36%)	6 (52.2%)	5 (25%)	5 (25%)
Fornix tenderness	19 (76%)	5 (21.7%)	10 (50%)	12 (60%)	20 (80%)	15 (60%)	10 (43.5%)	9 (39.1%)
Cervical erosion	4 (16%)	1 (4%)	2 (8.7%)	2 (8.7%)	3 (12%)	2 (8.7%)	2 (10%)	2 (10%)

Overall Efficacy

Parameter	Group 1	Group 2
Complete remmission on Rx at 2weeks	12 (48%)	8 (32%)
Complete remmission on Rx at 12weeks	17 (68%)	5 (20%)
Lack of response at 2weeks	5 (20%)	9 (36%)
Recurrence at 12weeks	4 (16%)	9 (36%)
Patient's satisfaction of more than 75% on therapy	9 (36%)	4 (16%)

Discussion

Pelvic inflammatory disease is the frequent infection seen in reproductive aged women. Despite availability of antibiotics treatment of PID is still not satisfactory. In our study we have evaluated efficacy of placentrex injection with azithromycin in curing PID.

On analyzing the results for each symptom and signs we found that, the lower abdominal pain markedly reduced in group 1; 48.5% vs 18% in group 2 which was significant statistically (p value 0.01).

Relief in backache was better with group 1; 46.6% vs 28% in group2 and was found to be statistically significant (p value 0.01). As far as menstrual irregularity is concerned it was observed that there was marginally better but not statistically significant (p value 0.263). Small study has shown that improvement

in menstrual irregularities[3]. Dysmenorrhoea improved to some extent in both the groups but not statistically significant (p value 0.11). Relief of dyspareunia did not show significant improvement in both the groups (p value 0.128). Small study showed that relief of dyspareunia was better with placentrex treatment[4]. Response to vaginal discharge was present in both the groups with marginal benefit in group 1 (p value 0.50) but not statistically significant.

Uterine tenderness improved more in group 1 - 33.6% vs 19% in group2 but not statistically significant. Uterine mobility improved in both groups 16.4% in group1 and 11 % improved in group2 but was not statistically significant. Fornix tenderness showed improvement in both the groups but was statistically better in group 1 (p value 0.02). There was no improvement in cervical erosion in both the groups. Efficacy of placentrex in cervical erosion has been reported but in local application of placentrex gel[5].

Thus overall, group 1 had better and sustained effect of therapy in relieving lower abdominal pain, backache, fornix tenderness which was statistically significant. In other symptoms there was marginal improvement when compared with group 2.

Complete remission with treatment at 2 weeks occured in 12 cases (48%) in group 1 versus 8(32%) cases in group 2. Complete remission at 12 weeks follow up was seen in 17 cases (68%) in group 1 versus 5 (20%) cases in group 2. Lack of response to treatment at 2 weeks was seen in 5 (20%) in group 1 versus 9 cases (36%) in group 2. Recurrence at 12 weeks was seen in 4 (16%) cases in group 1 compared to 9 (36%) in group 2. Overall patients satisfaction was seen that it was better in group1 36% vs 16 % in group 2.

Conclusion

PID is one of the most frequent infection encountered in gynaecology. Conventional antibiotic therapy does not provide maximum relief of symptoms and its sequelae. Conventional anti-inflammatory and proteolytic enzymes leave the therapeutic gap. Placentrex injection is expected to fill up the gaps adequately. It leads to marked relief in symptoms than compared with antibiotic therapy alone. As placentrex decreases adnexal inflammation to significant level it can be a good option specially to reduce symptoms and sequelae of pelvic inflammatory disease.

Conflict of Interest: None
Source of Support: Nil

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