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Effect of Statin in Treatment of Endometriosis: A Comparative, Observational Study

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ABSTRACT

Endometrial glands and stroma like lesions seen outside the uterus are referred to as endometriosis. The lesions may be peritoneal, ovarian cysts, superficial implants, or deep-seated illness. To find out the effectiveness of Statin addition in control of pain symptoms, menstrual irregularities, dyspareunia experienced in endometriosis. Materials and The present study was an institution-based Comparative, Observational Study. This Study was conducted for 18 months in the Department of Obstetrics and Gynaecology, Eden Hospital, Medical College and Hospital, Kolkata. In our study, 16 (26.7%) patients had Endometrioma, 26 (26.7%) patients had S/O Endometriosis and 28 (46.7%) patients had WNL (No Significant USG Findings). Our study showed that, a greater number of patients had Regular Menstrual Cycle [43 (71.7%)] and [17(28.3%)] had Cycle Irregularity, 34 patients were Obese (56.7%) and 26 (43.3%) were Overweight in BMI Group. It was found that mean BMI of patients was 27.2717±1.5126. 28 patients (46.7%) had Non-Significant USG finding (WNL), 16 (26.7%) had Endometrioma and other 16 (26.7%) had other signs of Endometriosis. Hence from our study it is concluded that addition of Statin to the usual treatment of Endometriosis has resulted in Significant Reduction of Pain (Dysmenorrhea, Dyspareunia and Chronic Pelvic Pain).

INTRODUCTION

Endometrial glands and stroma like lesions outside of the uterus are considered signs of endometriosis[1]. The lesions might be deep infiltrating illness, ovarian cysts or superficial implants, or peritoneal lesions[2]. There are a number of theories as to how endometriotic lesions form, even though there is no known cause for endometriosis. Retrograde menstruation, a characteristic of the menstrual cycle in females and non-human primates, is one potential explanation. Retrograde menstruation is the expulsion of the endometrial lining into the pelvic cavity through the patent fallopian tubes. In addition to possible hematogenous or lymphatic circulation, this retrograde flow may cause the seeding of endometrial tissue in ectopic locations. However, endometriosis is far less prevalent than retrograde menstruation, which is common (perhaps universal among women who menstruate). Therefore, whether lesions deposited in the pelvic cavity implant and remain may depend from other elements including hormonal, inflammatory, or immunologic environmentAlternatively, Müllerian remnants that were improperly differentiated or migrated during fetal development, or circulating blood cells that transdifferentiated into endometriosis, may be the cause of endometriosis lesions. Similar to how local environmental factors might affect these endometriotic lesion's maintenance. It is crucial to understand that endometriotic lesions are antigenically similar to eutopic endometrium but are not necessarily endometrial when taking these etiologic ideas into account.

Endometriosis is a crippling gynaecological disease with lot of morbidities and it robs the women of her fundamental right of child birth.

Endometriosis is defined as the presence of endometrium like tissue (glands and/or stoma) outside the uterus. It is an estrogen -dependent disease 4 that affects about 10% of reproductive age women.

70% of women with persistent pelvic discomfort and 10-15% of all women in reproductive age have endometriosis[3]. Unfortunately, for a lot of these women, endometriosis is frequently diagnosed later than required, causing extra pain and a lower quality of life. A 6.7-year delay is typical for individuals between the ages of 18 and 45. Given that the majority of endometriosis sufferers claim that their symptoms first appeared in their youth, early detection, diagnosis and treatment of the condition may lessen discomfort, stop the illness from progressing and preserve fertility. The high expense of diagnosis and therapy in teenage patients and the appearance of confusing symptoms including cyclic and acyclic pain are obstacles to early identification. Therefore, a non-invasive technique for endometriosis detection might enable early diagnosis and treatments, which could eventually enhance quality of life and protect fertility.

The most frequent sites of implantation are the pelvic viscera and peritoneum but although rare can be found in pericardium, pleura, lung, even in brain. Theories to explain the pathogenesis of endometriosis are abound. These include retrograde menstruation and direct implantation (Sampson's Theory) which is the most widely accepted theory. While the others are Celomic metaplasia, Lymphatic and Vascular Theory, Direct implantation by surgeon (latrogenic), Altered immune response, other genetic, environmental factors and epigenetic influences.

It is associated mainly with chronic pelvic pain[4], menstrual irregularities like dysmenorrhea, dyspareunia and infertility. 8 Angiogenesis, the development of new capillaries from pre-existing blood vessels, has been proposed as a key mechanism in the pathogenesis of endometriosis. Again, from an etiological perspective the formation of endometriotic implants requires ectopic fixation and proliferation of endometrial stroma and glands. The process of invasive insertion of endometriosis tissues involves the degradation of the extracellular matrix and altered expression of matrix metalloproteinases (MMPs) in the eutopic and ectopic endometrium.

The treatment of this condition involves multiple modalities like medical, surgical or combined but none of them is definitive. There is plethora of pharmacological agents like OC Pills, progestogens, GnRH agonists and also many new agents are in pipeline[5].

AIMS AND OBJECTIVES

Primary: To find out the effectiveness of statin addition in control of pain symptoms, menstrual irregularities, dyspareunia experienced in endometriosis.

Secondary: To analyse the side effects of statin if any in due process.

MATERIALS AND METHODS

Experiment design: It is an institutional based Comparative, Observational Study.

Study setting: Tertiary Care Hospital.

Place of study: Outpatient as well as Inpatient Department of Obstetrics and Gynaecology, Eden Hospital, Medical College and Hospital, Kolkata.

Period of study: The Study will start with the submission of research proposal. After receiving clearance from the ethical committee, data collection

was done for 12 months. Analysis was done for 2-3 months and report writing was done for another 1-2 months. So, a total of 18 months was needed for this study purpose.

Study population: Patients presenting at OPD as well as admitted Inpatients of Obstetrics and Gynaecology, MCH with diagnosed Endometriosis.

Inclusion criteria:

Female patients with a diagnosis of endometriosis either clinically, by ultrasound, by laparoscopy or surgically.

Exclusion criteria:

- Use of hormonal suppression for pain control (OCP, GnRH agonist) within 6-months
- Other causes of abdominal pain and menstrual irregularities Like-PID, Fibroid etc
- History of surgery for endometriosis within 6- months
- Current renal or hepatic active disease
- Current or history of myopathic disease
- Medication that may interact with statins (erythromycin, gemfibrosil, antifungals, antiretrovirals, other cholesterol lowering drugs)

RESULTS

In our study, 16 (26.7%) patients had Endometrioma, 26 (26.7%) patients had S/O Endometriosis and 28 (46.7%) patients had WNL (No Significant USG Findings).

In Case, the mean Dysmenorrhea Pain Scale before Treatment (Mean±SD) of patients was 6.567±3.126. In Case, the mean Dysmenorrhea Pain Scale after Treatment (Mean±SD) of patients was 3.6±2.044. Distribution of mean Dysmenorrhea (Based on Pain Scale) before and after treatment was statistically significant ($p<0.0001$). In Control, the mean Dysmenorrhea Pain Scale before Treatment (Mean±SD) of patients was s 5.833± In Control the mean Dysmenorrhea Pain Scale after Treatment (Mean±SD) of patients was 4.967±2.988. Distribution of mean Dysmenorrhea (Based on Pain Scale) before and after treatment was not statistically significant ($p = 0.297$).

In Case, the mean Dysmenorrhea Pain Scale after Treatment (Mean±SD) of patients was 3.6±2.044. In Control the mean Dysmenorrhea Pain Scale after Treatment (Mean±SD) of patients was 4.967±2.988. Distribution of mean Dysmenorrhea (based on pain scale) after Treatment between case and control was statistically significant ($p = 0.0432$).

In this study out of 60 Patients 48 Patients had Dysmenorrhea. Among these 48 patients 25 were in Case group who received Statin and 23 were in Control group who did not received Statin. In Case group out of 25 patients 22 had undergone significant Dysmenorrhea pain reduction while in control group out of 23 patients 8 had undergone significant d Dysmenorrhea pain reduction. Comparing case and control group Dysmenorrhea pain reduction attributed to Statin was statistically significant with p-value of 0.0002, Relative Risk of 2.53, 95% Confidence Interval of 1.419-4.510.

In Case, the mean Dyspareunia Pain Scale before Treatment (Mean±SD) of patients was 5.0000±3.343. In Case, the mean Dyspareunia Pain Scale after Treatment (Mean±SD) of patients was 2.633±1.884. Distribution of mean Dyspareunia (Based on Pain Scale) before and after treatment was statistically significant ($p = 0.0013$).

In Case, the mean Dyspareunia after Treatment (Mean±SD) of patients was 2.633±1.884. In Control, the mean Dyspareunia after Treatment (Mean±SD) of patients was 4.833±2.692. Distribution of mean Dyspareunia (Based on Pain Scale) after Treatment between case and control was statistically significant ($p = 0.0005$).

In this study out of 60 Patients 46 Patients had Dyspareunia. Among these 46 patients 22 were in Case group who received Statin and 24 were in Control group who did not received Statin. In Case group out of 22 Patients 19 had undergone significant dyspareunia pain reduction while in Control group out of 24 patients 8 had undergone significant dyspareunia pain reduction. Comparing Case and control group Dyspareunia pain reduction attributed to Statin was statistically significant with p-value of 0.0003, Relative Risk of 2.591, 95% confidence interval of 1.435-4.673.

In this study out of 60 Patients 46 Patients had Dyspareunia. Among these 46 patients 22 were in case group who received Statin and 24 were in control group who did not received Statin. In Case group out of 22 Patients 19 had undergone significant dyspareunia pain reduction while in Control group out of 24 patients 8 had undergone significant dyspareunia pain reduction. Comparing case and control group Dyspareunia pain reduction attributed to Statin was statistically significant with p-value of 0.0003, Relative Risk of 2.591, 95% Confidence Interval of 1.435-4.673.

In Case, the mean Chronic Pelvic Pain after Treatment (Mean±SD) of patients was 3.033±1.921. In Control the mean Chronic Pelvic Pain after Treatment (Mean±SD) of patients was 5.1±2.354. Distribution of mean Chronic Pelvic Pain (Based on Pain Scale) After Treatment between case and control was statistically significant ($p = 0.0004$).

Table 1: Distribution of USG (TVS)

USG(TVS)	Frequency	Percentage
Endometrioma	16	26.7
S/O endometriosis	16	26.7
WNL	28	46.7
Total	60	100.0

Table 2: Distribution of mean dysmenorrhea before and after treatment: case

	No	Mean	SD	Minimum	Maximum	Median	p-value
Case							
Dysmenorrhea before treatment	30	6.567	3.126	0.0000	9.0000	8.0000	<0.0001
Dysmenorrhea after treatment	30	3.6	2.044	0.0000	8.0000	4.0000	
Control							
Dysmenorrhea before treatment	30	5.833	3.374	0.0000	9.0000	8.0000	0.297
Dysmenorrhea after treatment	30	4.967	2.988	0.0000	8.0000	6.0000	

Table 3: Distribution of mean dysmenorrhea pain scale (after treatment): Group

	No	Mean	SD	Minimum	Maximum	Median	p-value
Dysmenorrhea pain scale after treatment							
Case	30	3.6	2.044	0.0000	8.0000	4.0000	0.0432
Control	30	4.967	2.988	0.0000	8.0000	6.0000	

Table 4: Comparison of significant reduction of dysmenorrhea (case and control group)

Comparison of significant reduction of dysmenorrhea after treatment		
No of patients with significant reduction	Significant reduction of dysmenorrhea	
	Yes	No
Control (23)	8	15
case(25)	22	3

Table 5: Distribution of mean dyspareunia before and after treatment: case

	No	Mean	SD	Minimum	Maximum	Median	p-value
Case							
Dyspareunia before treatment	30	5.0000	3.343	0.0000	9.0000	6.0000	0.0013
Dyspareunia after treatment	30	2.633	1.884	0.0000	5.0000	3.0000	
Control							
Dyspareunia before treatment	30	5.633	3.023	0.0000	8.0000	7.0000	0.2835
Dyspareunia after treatment	30	4.833	2.692	0.0000	8.0000	5.5	

Table 6: Distribution of mean dyspareunia after treatment: group

	No	Mean	SD	Minimum	Maximum	Median	p-value
Dyspareunia after treatment							
Case	30	2.633	1.884	0.0000	5.0000	3.0000	0.0005
Control	30	4.833	2.692	0.0000	8.0000	5.5	

Table 7: Comparison of significant reduction of dyspareunia (case and control group)

Comparison of significant reduction of dyspareunia after treatment		
No of patients with significant reduction	Significant Reduction of Dyspareunia	
	Yes	No
Case (22)	19	3
Control (24)	8	16

Table 8: Distribution of mean chronic pelvic pain before and after treatment: case

	No	Mean	SD	Minimum	Maximum	Median	p-value
Case							
Chronic pelvic pain before treatment	30	5.433	3.159	0.0000	8.0000	7.0000	0.0008
Chronic pelvic pain aqfter treatment	30	3.033	1.921	0.0000	5.0000	4.0000	
Control							
Chronic pelvic pain before treatment	30	6.067	2.625	0.0000	9.0000	7.0000	0.1386
Chronic pelvic pain after treatment	30	5.1	2.354	0.0000	8.0000	6.0000	

Table 9: Distribution of mean Chronic pelvic pain after treatment): group

	No	Mean	SD	Minimum	Maximum	Median	p-value
Chronic pelvic pain after treatment							
Case	30	3.033	1.921	0.0000	5.0000	4.0000	0.0004
Control	30	5.1	2.354	0.0000	8.0000	6.0000	

Table 10: Comparison of significant reduction of chronic pelvic pain (case and control group)

Comparison of significant reduction of chronic pelvic pain after treatment		
No of patients with significant reduction	Significant reduction of chronic pelvic pain	
	Yes	No
Case (23)	19	4
Control (26)	10	16

In this study out of 60 Patients 49 Patients had Chronic Pelvic Pain. Among these 49 patients 23 were in Case group who received Statin and 26 were in Control group who did not received Statin. In Case group out of 23 Patients 19 had undergone significant Chronic Pelvic Pain reduction while in Control group out of 26 patients 10 had undergone significant Chronic Pelvic Pain reduction. Comparing Case and Control group Chronic Pelvic Pain reduction attributed to Statin was statistically significant with p-value of 0.0032, Relative Risk of 2.148, 95% Confidence Interval of 1.275-3.617.

DISCUSSION

The present study was an institutional based Comparative, Observational Study. This study was conducted 18 months at Outpatient as well as Inpatient Department of Obstetrics and Gynecology, Eden Hospital, Medical College and Hospital, Kolkata. 60 patients were included in this study. All were patients having endometriosis. 30 patients were treated with oral contraceptive pills. 30 patients were treated with oral contraceptive pills and statins. All these patients were followed up after 6 months of treatment.

In our study, out of 60 patients 8 (13.3%) patients were $\leq$20 years of age, 42 (70.0%) patients were 21-30 years of age and 10 (16.7%) patients were$\geq$31 years of age. The mean Age (mean±SD) of patients was 25.5667±4.4086.

We found that, most of the patients had Parity P (0+0) 26 (43.3%)], 11 (18.3%) patients had parity P (0+1), 11 (18.3%) patients had parity P (0+2), 3 (5.0%) patients had parity P (1+0) and 9 (15.0%) patients had parity P(2+0) and we also found that number of patients who were Smoker and had H/O Alcohol Intake-about 3 (5.0%) in both category.

Yilmaz *et al*.[6] found that to contrast the effectiveness of simvastatin and GnRH agonist (Decapeptyl 3.75 mg) on pain caused by endometriosis after endometriosis surgery. After laparoscopic diagnosis and conservative laparoscopic surgery, sixty women with pelvic endometriosis received either simvastatin (n = 30) for 16 weeks or decapeptyl (n = 30) once every four weeks for four doses. Six months following laparoscopic surgery, both groups' VAS scores for dyspareunia, dysmenorrhea, and pelvic pain greatly decreased (p=0.001) but there was no statistically significant difference between the two group's outcomes (p>0.05). In the management of endometriosis-related pain, both therapeutic approaches shown equivalent efficacy.

Kaur *et al*.[7] found that Endometrial glands and stroma are present in extrauterine locations in endometriosis, an inflammatory oestrogen-dependent illness. The excruciating pain that endometriosis causes as well as infertility in patients who are in the reproductive age group are being addressed by current advances in endometriosis care. Surgical or medicinal methods can be used to do this, however most often a mix of the two is necessary. In most situations, long-term therapy is necessary. Unfortunately, after medication is stopped, pain symptoms often return between 6 and 12 months later.

Our study showed that, a greater number of patients had Regular Menstrual Cycle [43 (71.7%)] and [17 (28.3%)] had Cycle Irregularity, 34 patients were Obese (56.7%) and 26 (43.3%) were Overweight in BMI Group. It was found that mean BMI of patients was 27.2717±1.5126. 28 patients (46.7%) had Non-Significant USG finding (WNL), 16 (26.7%) had Endometrioma and other 16 (26.7%) had other signs of Endometriosis.

Wang *et al*.[8] found that a potential new medication for the treatment of endometriosis is simvastatin. Simvastatin treatment and control groups did not substantially vary in MCP-1 gene expression on endometriotic cysts (P = 0.99). Compared to the control group, CD68 expression was greater in the treatment group, although this was not statistically significant (P = 0.055). Simvastatin-treated samples had greater serum MCP-1 levels than untreated samples (297.89 70.77 and 255.51 63.79 pg mL^{-1}, respectively) (P = 0.01). Taking 20 mg d^{-1} of simvastatin for two weeks had no effect on the expression of the macrophage-specific genes or the chemokine MCP-1 gene.

Chen *et al*.[9] found that endometriosis is a prevalent gynecologic condition that commonly causes subfertility, severe dysmenorrhea and persistent pelvic discomfort. First-line hormonal therapy can affect ovulation and may result in recurring pelvic discomfort, hence research into novel non-hormonal therapeutic modalities is becoming more and more important. The objective of this review was to assess the pre-clinical and clinical efficacy and safety of non-hormonal endometriosis therapy. Up to October 2019, databases such as PubMed, Embase, Cochrane Library, Sinomed, Clinical Trials.gov and Google Scholar were searched using the phrases "endometriosis" and "non-hormonal therapy".

Barra *et al*.[10] found that endometriosis is a chronic benign estrogen-dependent disease characterized by the presence of endometriotic glands and stroma outside the uterine cavity. Although combined hormonal contraceptives and progestins, currently available first-line treatments for endometriosis, are efficacious and well tolerated for treating disease-related pain, some women experience partial or no improvement of pain or its recurrence is frequent

after discontinuation of the therapies. For these reasons, new drugs are under investigation for the treatment of endometriosis. This review aims to give to the reader a complete and updated overview of hormonal and biological therapies for the treatment of endometriosis, underlining the latest developments in this field of research.

In our study, the mean Dysmenorrhea of Case after treatment was 3.6±2.044 whereas Dysmenorrhea before treatment was 6.567±3.126 which was statistically significant (p<0.0001). The mean Dysmenorrhea of Control after treatment was 4.967±2.988 whereas Dysmenorrhea before treatment was 5.833±3.374 but this was not statistically significant (p = 0.297). We also found that the mean of Dysmenorrhea. after Treatment in Case was 3.6±2.044 and Control was 4.967±2.988 and it was statistically significant (p=0.0432). Hence, from our study it is concluded that addition of statins to the existing mode of treatment (OCP-in this study) has resulted in significant reduction of Dysmenorrhea.

In our study, the mean Dyspareunia of Case after treatment was less 2.633±1.884 whereas Dyspareunia Before Treatment was 5±3.343 which was statistically significant (p = 0.0013). The mean Dyspareunia after treatment in Control was 4.833± when compared to dyspareunia before treatment 5.633±3.023 but this was not statistically significant (p = 0.2835). We also found that, the mean of Dyspareunia after Treatment in Case was 2.633±1.884 and Control was 4.833±2.692 and it was statistically significant(p = 0.0005). Hence, from our study it is concluded that addition of statins to the existing mode of treatment (OCP-in this study) has resulted in significant reduction of Dyspareunia.

Davenport *et al*.[11] found that when it comes to the sensitization of nerve fibers and pathological pain pathways, ATP-dependent P2X3 receptors are absolutely essential. The researchers subsequently show that eliapixant continues to have these effects after stopping therapy in an animal model of endometriosis-related dyspareunia. According to their research, P2X3 antagonism may help endometriosis-affected women feel less pain, particularly non-menstrual pelvic discomfort, while also changing the pathophysiology of the illness. Eliapixant is now being tested in clinical settings to treat diseases linked to hypersensitive nerves.

In our study, the mean Chronic Pelvic Pain in Case after treatment was 3.033±1.921 whereas Chronic Pelvic Pain Before Treatment was 5.433± which was statistically significant (p = 0.0008). The mean Chronic Pelvic Pain after treatment in Control was 5.1±2.354 whereas Chronic Pelvic Pain Before Treatment was 6.067±2.625 but this was not statistically significant (p = 0.1386). We also found that, the mean of Chronic Pelvic Pain after Treatment in Case was 3.033±1.921. Compared to Control was 5.1±2.354 and it was statistically significant (p = 0.0004). Hence, from our study it is concluded that addition of statins to the existing mode of treatment (OCP-in this study) has resulted in significant reduction of Chronic Pelvic Pain.

In this study out of 60 Patients 48 Patients had Dysmenorrhea. Among these 48 patients 25 were in Case group who received Statin and 23 were in Control group who did not receive Statin. In Case group out of 25 Patients 22 had a significant reduction in Dysmenorrhea while in Control group out of 23 patients 8 had a significant reduction in Dysmenorrhea. Comparing the two groups the reduction in Dysmenorrhea (attributed to Statin) was statistically significant with p-value of 0.0002, Relative Risk of 2.53, 95% Confidence Interval of 1.419-4.510. Hence in our study it is found that Statins have caused a significant reduction in Dysmenorrhea.

In this study out of 60 Patients 46 Patients had Dyspareunia. Among these 46 patients 22 were in Case group who received Statin and 24 were in Control group who did not receive Statin. In Case group out of 22 Patients 19 had a significant reduction in dyspareunia while in Control group out of 24 patients 8 had a significant reduction in dyspareunia. Comparing the two groups the reduction in Dyspareunia (attributed to Statin) was statistically significant with P value of 0.0003, Relative Risk of 2.591, 95% Confidence Interval of 1.435 to 4.673. Hence in our study it is found that Statins have caused a significant reduction in Dyspareunia.

In this study out of 60 Patients 49 Patients had Chronic Pelvic Pain. Among these 49 patients 23 were in Case group who received Statin and 26 were in Control group who did not receive Statin. In Case group out of 23 Patients 19 had a significant reduction in Chronic Pelvic Pain while in Control group out of 26 patients 10 had a significant reduction in Chronic Pelvic Pain. Comparing the two groups, the reduction in Chronic Pelvic Pain (attributed to Statin) was statistically significant with p-value of 0.0032, Relative Risk of 2.148, 95% Confidence Interval of 1.275-3.617. Hence in our study it is found that Statins have caused a significant reduction in Chronic Pelvic Pain.

CONCLUSION

- We found that, most of the patients had P0+0. We also found that, a smaller number of patients were Smoker and had H/O-Alcohol intake
- Our study showed that, a greater number of patients had Regular Menstrual Cycle, a greater number of patients were Obese in BMI Group
- In case group, Mean Dysmenorrhea, Mean Dyspareunia and Mean Chronic Pelvic Pain before and after Treatment was statistically

significant-significant reduction in pain noted after treatment with statins

- Most of the patients had no significant USG findings
- Between the two groups (case and control) the Mean Dysmenorrhea, Mean Dyspareunia and Mean Chronic Pelvic Pain after treatment was statistically significant.
- In control group, Mean Dysmenorrhea, Mean Dyspareunia and Mean Chronic Pelvic Pain before and after treatment was not statistically significant
- Hence from our study it is concluded that addition of Statin to the usual treatment of Endometriosis has resulted in Significant Reduction of Pain (Dysmenorrhea, Dyspareunia and Chronic Pelvic Pain)

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