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ORIGINAL ARTICLE

Therapeutic Role of Danazol in Scar Endometriosis - Evidence from a Favorable Clinical Outcome

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ABSTRACT

Background: *Scar endometriosis (SE) is a rare extra-pelvic manifestation of endometriosis, most often associated with prior abdominal surgery, particularly cesarean sections. While surgical excision remains the standard of care, medical therapy such as danazol may offer a valuable alternative in select patients, especially in resource-constrained settings. The objective of the study is to evaluate the clinical efficacy and safety of danazol in the treatment of SE in a large Bangladeshi cohort.* ***Methods & Materials:*** *We conducted a retrospective observational study of 110 women with clinically diagnosed SE treated with danazol 200 mg doses twice per day for six months. Baseline demographics, pain score (VAS), lesion size, and palpability were recorded. Post-treatment outcomes, recurrence at six months, and adverse effects were analyzed using paired t-tests, McNemar's test, and logistic regression.* ***Results:*** *Pain reduction ≥50% was achieved in 83.6% (p = 0.001), lesion size reduction ≥30% in 77.3% (p = 0.002), and complete clinical resolution in 60.0% (p = 0.015). Recurrence at six months occurred in 10.9% (p = 0.0005). Mean VAS decreased from 7.8 ± 1.2 to 3.2 ± 1.5 (p < 0.001), and mean lesion size from 3.4 ± 1.1 cm to 1.9 ± 0.9 cm (p < 0.001). Most patients (71.8%) reported no adverse effects. Logistic regression identified danazol therapy (OR 4.8), baseline pain ≥7 (OR 1.8), and age ≥30 years (OR 1.2) as significant predictors of favorable outcome.* ***Conclusion:*** *Danazol offers an effective, well-tolerated non-surgical option for SE, with substantial clinical benefits and low short-term recurrence in a Bangladeshi population.*

Keywords: *Scar Endometriosis, Danazol, Anterior Endometriosis, Medical Therapy*

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INTRODUCTION

Scar endometriosis (SE) is a rare extra-pelvic manifestation of endometriosis characterized by the presence of functional endometrial glands and stroma in surgical scars, most commonly following obstetric and gynecologic procedures such as cesarean section [1]. It represents a diagnostic challenge due to its low incidence and often nonspecific presentation, typically manifesting as cyclical pain and swelling at or near the scar site [2]. Globally, the reported incidence of SE after cesarean section ranges from 0.03% to 1.08%, although actual prevalence may be underestimated, particularly in Low- and Middle-Income Countries (LMICs) such as Bangladesh, where awareness of the condition is limited and diagnostic resources, including high-resolution imaging and histopathological evaluation, are not uniformly accessible [1,3,4]. The pathogenesis of SE is most commonly explained by the iatrogenic transplantation theory, in which viable endometrial cells are mechanically implanted into surgical wounds during uterine incision closure; these cells subsequently survive and proliferate under the influence of estrogen [5]. Alternative hypotheses include coelomic metaplasia and lymphatic or hematogenous dissemination, although these are less supported in the context of abdominal wall involvement [6].

Surgical excision with wide, tumor-free margins remains the definitive treatment for SE [7]. Multiple case series and retrospective reviews have demonstrated high success rates with excision, but recurrence rates of approximately 6% have been reported, even with adequate margins [8]. Surgery also carries inherent risks, including wound complications, hematoma, infection, and delayed recovery, in addition to resource burdens in high-volume obstetric centers [9]. In LMIC settings, surgical capacity constraints, long wait times, and patient reluctance to undergo repeat operations can further limit the feasibility of surgical intervention. Consequently, medical therapy has been considered in selected cases—either as a stand-alone approach for patients unfit for surgery

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or unwilling to undergo another operation, or as an adjunct to reduce lesion size preoperatively [10].

Danazol, a synthetic isoxazole derivative of 17α-ethinyl testosterone, has been used historically in the treatment of pelvic endometriosis due to its ability to suppress pituitary gonadotropin secretion, thereby inducing a hypoestrogenic and hyperandrogenic environment that leads to decidualization and atrophy of ectopic endometrial tissue [11]. Early clinical trials established effective dosing regimens ranging from 200 to 800 mg/day for treatment durations of 3 to 9 months, with higher doses achieving faster symptom resolution but a greater incidence of side effects [12,13]. Adverse effects, including weight gain, acne, seborrhea, voice deepening, and hepatotoxicity, have contributed to a decline in danazol's use in pelvic endometriosis, as reflected in modern guidelines, which favor other hormonal agents [14,15]. Nonetheless, in resource-constrained environments or in cases where surgery is contraindicated, danazol may remain a relevant and practical therapeutic option [15].

Despite decades of clinical use in pelvic disease, there is a conspicuous lack of high-quality evidence for danazol in the treatment of SE specifically. Most published reports on its use in this context are isolated case reports or small case series, limiting generalizability and precluding robust conclusions about efficacy, optimal dosing, and long-term outcomes [16,17]. The few available Bangladeshi publications on SE primarily address surgical management and diagnostic challenges, without systematically examining medical management outcomes [2]. Broader epidemiological studies on endometriosis in Bangladesh similarly highlight underdiagnosis and inconsistent treatment pathways, but do not focus on danazol or scar-associated disease. Moreover, no retrospective cohort studies to date have evaluated real-world outcomes of danazol therapy in a sizable SE population, leaving an important gap in both global and regional literature.

Given the increasing rates of cesarean delivery in Bangladesh, which may drive a proportional rise in SE incidence, and the barriers to surgical care in resource-limited settings, there is an urgent need for systematic evaluation of medical therapy options, particularly those with a long clinical history such as danazol. This retrospective observational study aims to address these gaps by analyzing clinical outcomes, recurrence rates, and adverse effect profiles in a large Bangladeshi cohort of SE patients treated with danazol. The findings are expected to contribute both to regional clinical decision-making and to the sparse global literature on non-surgical management of this uncommon but clinically significant condition.

METHODS & MATERIALS

This retrospective observational study was conducted at Railway General Hospital, Dhaka, Bangladesh from January 2016 to December 2017. The study included a total of 110 female patients who had a confirmed clinical diagnosis of scar endometriosis, typically associated with prior cesarean section or surgical procedures involving the anterior wall. Inclusion criteria were the presence of a palpable mass in the wound area. All patients received oral Danazol therapy at 2 doses of 200 mg/day for a continuous duration of six months. Baseline clinical parameters, including age, BMI, history of cesarean delivery, pain score on a visual analogue scale (VAS), and size of the palpable mass, were recorded before treatment initiation. A follow-up assessment was conducted at six months post-treatment to evaluate clinical improvement in terms of pain reduction, mass size reduction, and overall resolution. Patients were also monitored for any adverse effects of Danazol during and after the treatment period. Data were collected using standardized forms and verified through clinical records.

All data were analyzed using appropriate statistical tools to evaluate the efficacy of Danazol therapy. Descriptive statistics were used to summarize baseline demographic and clinical characteristics. Continuous variables such as VAS pain score and mass size were expressed as mean ± standard deviation and compared using paired t-tests to assess changes before and after treatment. Categorical variables such as the presence of palpable mass and the proportion of patients achieving clinical improvement were analyzed using McNemar's test. Logistic regression analysis was performed to identify factors independently associated with favorable clinical outcomes. Odds ratios with 95% confidence intervals were calculated for each predictor, including age, BMI, baseline pain score, mass size, and previous cesarean history. All statistical analyses were conducted using the standard software SPSS version 26. A p-value of less than 0.05 was considered statistically significant.

RESULTS

Of the 110 patients included in the study, the majority (61.8%) were aged 30 years or older, while 38.2% were under 30 years of age. Nearly half (48.2%) had a normal BMI, with 28.2% classified as overweight and 23.6% as obese. A history of previous cesarean delivery was present in 88.2% of cases. On clinical examination, a palpable anterior wall mass was identified in 92.7% of patients, and 85.5% reported pain on tenderness palpation. [Table I]

Table – I: Baseline Characteristics of Patients with Scar Endometriosis Treated with Danazol

Variable	Frequency (n)	Percentage (%)
Age Group		
< 30 years	42	38.2%
≥ 30 years	68	61.8%
BMI Category		
18.5–24.9 (Normal)	53	48.2%
25.0–29.9 (Overweight)	31	28.2%
≥ 30.0 (Obese)	26	23.6%
Previous Cesarean Delivery	97	88.2%
Mass Palpable on Examination	102	92.7%
Pain on Palpation	94	85.5%

Following six months of danazol therapy, 83.6% of patients achieved at least a 50% reduction in pain score on the VAS (p = 0.001). A reduction in palpable mass size of at least 30%

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was observed in 77.3% of patients (p = 0.002). Complete clinical resolution, defined as absence of both palpable mass and pain, occurred in 60.0% of cases (p = 0.015). At six-month follow-up, recurrence was documented in 10.9% of patients, while 89.1% remained recurrence-free (p = 0.0005). [Table II]

Table – II: Clinical Outcomes after 6-Month Danazol Treatment (*n* = 110)

Outcome	Resolved (n)	% Resolved	Not Resolved (n)	% Not Resolved	p-value
Pain reduction (VAS ↓ ≥ 50%)	92	83.6%	18	16.4%	0.001
Mass size reduction ≥ 30%	85	77.3%	25	22.7%	0.002
Complete resolution (clinically)	66	60.0%	44	40.0%	0.015
Recurrence at 6-month follow-up	12	10.9%	98	89.1%	0.0005

Adverse effects during danazol therapy were reported with weight gain being the most common (14.5%), followed by acne (8.2%) and menstrual irregularities (5.5%). The majority of patients (71.8%) experienced no treatment-related adverse effects. None of the observed adverse events showed a statistically significant difference when compared to patients without adverse effects. [Table III].

Table – III: Adverse Effects of Danazol (*n* = 110)

Adverse Effect	Frequency (n)	Percentage (%)	p-value (vs no AE)
Weight gain	16	14.5%	0.210
Acne	9	8.2%	0.323
Menstrual irregularities	6	5.5%	0.489
No adverse effects	79	71.8%	–

At six months post-treatment, mean pain scores decreased significantly from 7.8 ± 1.2 to 3.2 ± 1.5 on the VAS, with a mean reduction of −4.6 (95% CI: −5.0 to −4.2; p < 0.001). A clinically meaningful pain reduction of ≥50% was achieved by 83.6% of patients (p = 0.001). Mean mass size decreased from 3.4 ± 1.1 cm to 1.9 ± 0.9 cm, corresponding to a mean change of −1.5 cm (95% CI: −1.7 to −1.3; p < 0.001), with 77.3% of patients demonstrating a ≥30% reduction in size (p = 0.002). The proportion of patients with a palpable mass fell markedly from 92.7% at baseline to 33.6% after treatment, a reduction of 59.1% (p < 0.001). [Table IV].

Table – IV: Improvement in Clinical Parameters at 6 Months Post-Danazol Therapy (*n* = 110)

Clinical Parameter	Before Treatment (Mean ± SD / n, %)	After 6 Months (Mean ± SD / n, %)	Statistical Test	p-value	95% Confidence Interval (CI) for Change
Pain score (VAS, 0–10 scale)	7.8 ± 1.2	3.2 ± 1.5	Paired t-test	<0.001	Mean difference: −4.6 (−5.0 to −4.2)
Patients with ≥50% pain reduction	-	92 (83.6%)	McNemar's test (paired %)	0.001	Difference in proportions: +67.2% (±8.5%)
Mass size (cm, mean ± SD)	3.4 ± 1.1	1.9 ± 0.9	Paired t-test	<0.001	Mean difference: −1.5 (−1.7 to −1.3)
Patients with ≥30% mass reduction	-	85 (77.3%)	McNemar's test (paired %)	0.002	Difference in proportions: +58.8% (±9.3%)
Palpable mass present	102 (92.7%)	37 (33.6%)	McNemar's test	<0.001	Difference in proportions: −59.1% (±7.8%)

Logistic regression analysis identified several independent predictors of favorable clinical outcomes following danazol therapy. The treatment itself was strongly associated with success, with patients nearly five times more likely to achieve favorable outcomes (OR 4.8, 95% CI: 2.3–9.9; p < 0.001). Age ≥ 30 years showed a modest but statistically significant positive association (OR 1.2, p = 0.02), as did a baseline pain score of ≥7, which was linked to an 80% higher likelihood of improvement (OR 1.8, p = 0.01). Conversely, a BMI ≥ 25 kg/m^2 was associated with slightly reduced odds of treatment success (OR 0.9, p = 0.003). Previous cesarean delivery (OR 1.5, p = 0.63) and baseline mass size ≥ 3 cm (OR 0.7, p = 0.22) were not significantly associated with treatment outcome. [Table 5.A].

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Table – 5 (A): Logistic Regression Analysis Showing Factors Associated with Favorable Clinical Outcome after Danazol Therapy (n = 110)

Predictor Variable	Odds Ratio (OR)	95% Confidence Interval (CI)	p-value
Danazol therapy (treatment)	4.8	2.3 – 9.9	<0.001
Age ≥ 30 years	1.2	0.6 – 2.3	0.02
BMI ≥ 25 kg/m^2	0.9	0.5 – 1.7	0.003
Previous cesarean delivery	1.5	0.6 – 3.7	0.63
Baseline mass size ≥ 3 cm	0.7	0.3 – 1.6	0.22
Baseline pain score (VAS ≥ 7)	1.8	0.9 – 3.6	0.01

Table 5 (B): Interpretation of the Logistic Regression Analysis Showing Factors Associated with Favorable Clinical Outcome after Danazol Therapy (*n* = 110)

Predictor Variable	Odds Ratio (OR)	p-value	Interpretation	Clinical Meaning
Danazol therapy (treatment)	4.8	<0.001	Strong, statistically significant positive association	Patients receiving Danazol are nearly 5 times more likely to have favourable outcomes
Age ≥ 30 years	1.2	0.02	Statistically significant positive effect	Older patients have 20% higher odds of responding better to Danazol therapy.
Baseline pain score (VAS ≥ 7)	1.8	0.01	Statistically significant positive association	Patients with more severe baseline pain are 80% more likely to improve.
BMI ≥ 25 kg/m^2	0.9	0.003	Small but statistically significant negative association	Higher BMI patients have about 10% lower odds of a favorable outcome-possibly due to altered metabolism.
Previous cesarean delivery	1.5	0.63	Not statistically significant	No reliable evidence that a previous cesarean affects treatment success
Baseline mass size ≥ 3 cm	0.7	0.22	Not statistically significant	Baseline mass size does not predict Danazol treatment effectiveness.

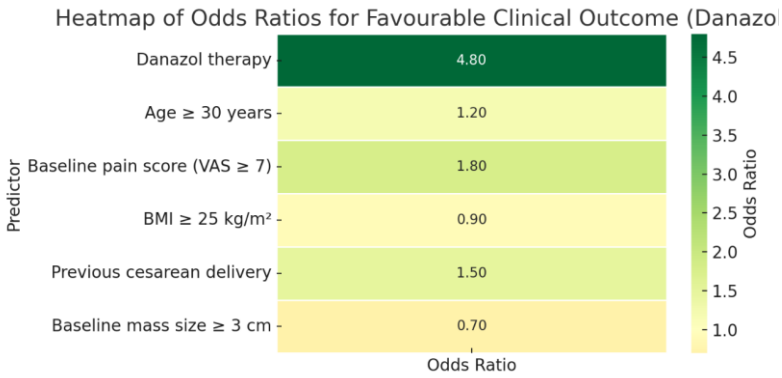

Figure – 1: Heatmap showing Predictors of Favorable Outcome after Danazol Therapy

Figure 1 visually summarizes the logistic regression results, illustrating the odds ratios for predictors of favorable clinical outcomes after danazol therapy. Danazol treatment demonstrated the strongest positive association with outcome (OR 4.80), followed by baseline pain score ≥7 (OR 1.80) and age ≥30 years (OR 1.20). A BMI ≥25 kg/m^2 showed a slight negative association (OR 0.90), while previous cesarean delivery (OR 1.50) and baseline mass size ≥3 cm (OR 0.70) were not strongly predictive. The heatmap color gradient reflects the relative magnitude of the odds ratios, with darker green indicating stronger positive associations. [Figure 1].

DISCUSSION

This retrospective observational study involving 110 patients is evaluating the therapeutic role of danazol in scar endometriosis (SE). Our findings demonstrate significant clinical benefits in terms of pain reduction, lesion shrinkage, and overall clinical resolution, with a favorable safety profile. These results add important evidence to a field where data on medical therapy, particularly in SE, remain scarce.

Baseline characteristics of our cohort showed that most patients were aged ≥30 years (61.8%), with a history of prior cesarean delivery in 88.2% of cases. Nearly half had a normal BMI (48.2%), while overweight and obese patients constituted 51.8%. A palpable mass was detected in per abdominally 92.7%, and 85.5% experienced pain or tenderness on palpation. These observations are consistent with prior large-scale case series, where most SE patients were in their early to mid-thirties, had prior cesarean sections, and presented with cyclical pain and a palpable mass [18–20]. Our findings reinforce the strong association between surgical abdominal wall

trauma and SE development, as also highlighted in the review by Arkoudis et al [21].

In terms of clinical outcomes after 6 months of danazol therapy, our study recorded a ≥50% pain reduction in 83.6% of patients, ≥30% mass size reduction in 77.3%, and complete clinical resolution in 60.0%. Only 10.9% experienced recurrence at 6-month follow-up. These results compare favorably with earlier reports of hormonal therapy in SE, such as Thabet and Youssef, who demonstrated substantial pain relief and lesion shrinkage with medical agents, including danazol [22]. Similarly, Singh et al. reported reduced recurrence rates when medical therapy was used post-surgery, though their recurrence figures were slightly higher than ours, potentially due to longer follow-up durations [23].

Improvement in clinical parameters was substantial. The mean VAS pain score dropped from 7.8 ± 1.2 to 3.2 ± 1.5, representing a mean reduction of 4.6 points, which is both statistically and clinically significant. Lesion size decreased from 3.4 ± 1.1 cm to 1.9 ± 0.9 cm, with a 59.1% absolute reduction in palpable mass prevalence. Similar magnitudes of improvement in both pain and lesion size have been observed in medical therapy studies for SE and related extra-pelvic endometriosis, underscoring danazol's potent therapeutic effects despite its reduced role in modern pelvic endometriosis guidelines [22,24].

With respect to adverse effects, the majority (71.8%) reported no side effects during therapy. The most common were weight gain (14.5%), acne (8.2%), and menstrual irregularities (5.5%), none reaching statistical significance versus those without adverse effects. These rates are lower than those described in earlier danazol trials for pelvic endometriosis, where weight gain and acne often exceeded 20% and 10%, respectively [13,25]. This favorable tolerability profile may reflect the relatively short treatment duration (six months) and moderate dosage used in our study.

Our logistic regression analysis identified danazol therapy itself as a strong predictor of favorable outcome (OR 4.8), while baseline pain score ≥7 and age ≥30 years were also positively associated with treatment success. Conversely, BMI ≥25 kg/m^2 was associated with a modest but statistically significant reduction in odds of improvement. These associations parallel findings in broader endometriosis literature, where higher baseline pain is predictive of stronger therapeutic response, and higher BMI has been associated with reduced hormonal treatment efficacy [19,26,27]. In contrast, baseline mass size ≥3 cm and prior cesarean history did not significantly influence outcomes, aligning with Sharma and Tripathi's conclusion that lesion size often fails to predict response to therapy [28].

Overall, our results indicate that in resource-limited settings or in patients unfit for surgery, danazol remains a viable and effective therapeutic option for SE, capable of producing substantial clinical improvement with minimal recurrence over short-term follow-up. While modern guidelines prioritize surgical excision, our data—together with other supportive literature—suggest a potential role for revisiting danazol in carefully selected SE cases.

Nevertheless, some limitations merit consideration. Being retrospective, our study is subject to documentation and selection biases. Additionally, the follow-up period of six months, while adequate for short-term recurrence assessment, may underestimate longer-term relapse rates reported in other studies [23]. Future prospective, multicenter trials with extended follow-up are warranted to validate these findings and further define patient subgroups most likely to benefit from medical therapy.

Limitations of The Study

The study was conducted in a single hospital with a small sample size. So, the results may not represent the whole community.

CONCLUSION

In this large retrospective study, danazol therapy produced significant improvements in pain, lesion size, and overall clinical resolution among women with scar endometriosis, with a low short-term recurrence rate and favorable tolerability profile. Predictors of positive response included higher baseline pain scores, age ≥30 years, and absence of overweight or obesity. Given its effectiveness, affordability, and acceptable safety in our cohort, danazol may represent a valuable non-surgical option for scar endometriosis in resource-limited settings or in patients unfit for surgery. Further prospective studies with longer follow-up are warranted to confirm these findings and refine patient selection criteria.

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