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A prospective observational study on feto-maternal risk factors for different degree of perineal tear among the mothers delivered vaginally with episiotomy wound

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Abstract

Introduction: This study seeks to elucidate the maternal and fetal factors that predispose women to varying degrees of perineal tear during vaginal delivery with episiotomy. By identifying these predictors, the research aims to inform strategies to reduce the risk of complications associated with perineal and vaginal lacerations, thereby minimizing the maternal morbidity and optimizing obstetric outcomes.

Aims and Objectives: This study aims to determine the factors linked to episiotomy wound extension after vaginal delivery, in order to better understand the underlying causes and develop effective prevention strategies.

Methodology: A prospective observational study was conducted at the Department of Obstetrics and Gynecology, Midnapore Medical College and Hospital, from August 1, 2023, to October 31, 2023. The study enrolled 180 women who underwent vaginal delivery with episiotomy, meeting the specified eligibility criteria. A comprehensive data collection tool was utilized to gather sociodemographic, maternal, fetal, and intrapartum risk factors. The collected data was analyzed using descriptive statistics and presented in a structured format.

Results: Among the maternal risk factors, both mild and severe degree of perineal tear were more significantly seen in the age groups of 20-30 years (p-value-0.004). Severe perineal trauma also most commonly seen in primipara women (85.18%, p-value-0.01). There was also significant association of extension of episiotomy wound with overweight (p value-0.004) and pregnancy interval less than 2 years (p value-0.00001). There was significant association of severe degree of perineal injury with increase fetal birth weight (92.59%, p value-0.01), fetal head circumference (81.48%, p-value-0.00001) and persistent occipito-posterior position of fetal head (74.07%, p value-0.00001). Prolonged duration of active 1st stage of labor (81.48%, p value-0.000027) and induced labor (77.77%, p value-0.00001) are significantly more prone to severe degree of perineal tear.

Conclusion: Mothers who experience vaginal delivery with episiotomy are at risk of perineal tears, particularly those in extreme age groups, primiparas, overweight mothers, those with short pregnancy intervals, increased fetal birth weight, persistent occipito-posterior fetal head position, prolonged active first-stage labor, and induced labor. To mitigate this risk, careful attention should be given to mothers with these factors. A well-planned and executed episiotomy, appropriate procedure and guarding of perineum can help in prevention of severe perineal trauma, although certain maternal, fetal, and intrapartum factors may still contribute to the extension of the episiotomy wound from mild to severe.

Keywords: Prolonged 2nd stage of labour, perineal tear, episiotomy, overweight mother, fetal birth weight

Introduction

Vaginal delivery is a complex natural process that can lead to various complications, including perineal and vaginal lacerations [1]. A perineal tear is defined as disruption in the integrity of the perineal area, involving a break in the skin, mucous membrane, muscles, connective tissues, anal sphincter, or rectal mucous membrane.

The prevalence of birth-related perineal tear varies widely across different countries. In Africa, studies have reported a prevalence of perineal tear ranging from 24.8%, with severe perineal tears occurring in 0.1% to 15% of cases [2]. In low and middle-income countries, the overall rates of birth-related perineal tear and severe perineal tear are significantly higher, at 46% and 1.4%, respectively, highlighting a substantial burden of this condition in these regions.

Global data reveals that nearly 9 out of 10 first-time mothers (primi) who give birth vaginally suffer some degree of perineal injury, which can lead to short-term and long-term health issues. Studies indicate a significant variation in perineal tear rates across regions and a rising incidence over the last decade [3-6]. Although increased awareness and advanced diagnostic techniques may play a role in this trend, the exact cause of the surge remains uncertain.

Perineal trauma is a significant contributor to postpartum hemorrhage, encompassing a range of injuries from mild to severe. The severity of perineal trauma is classified into four degrees by the Royal College of Obstetrics and Gynaecology [7]; first degree-superficial injury to perineal skin and/or vaginal mucosa, second degree-deeper injury to perineal muscles excluding the anal sphincter, third degree-Injury extending to the anal sphincter complex, fourth degree: Extensive injury involving the external and internal anal sphincters, and anorectal mucosa. This classification system distinguishes between mild (first and second-degree) and severe (third and fourth-degree) perineal tear/lacerations.

Approximately 80% of women experience perineal tears during childbirth, with first-time mothers (primiparous women) being more likely to be affected than those who have given birth before (multiparous women) [8]. Several studies have identified independent risk factors for perineal tear and obstetric anal sphincter injury, including maternal obesity, prolonged second stage of labour, fetal birth weight exceeding 4 kg and fetal occipito-posterior position. These factors contribute to an increased likelihood of perineal trauma and anal sphincter injury, making them important considerations for obstetric care [9-11].

To accurately diagnose perineal lacerations, a thorough examination is necessary, focusing on the extent of tissue involvement. Immediately after childbirth, a prompt assessment should be conducted to determine the severity of the laceration before primary suturing. This evaluation typically involves a visual examination of the vaginal and perineal areas with the patient in the lithotomy position and a gentle palpation to assess potential anal sphincter involvement. To ensure patient comfort, adequate anesthesia, typically a pudendal block, should be administered before the examination. Additionally, a comprehensive perineal examination should be performed postpartum to confirm the diagnosis and guide appropriate management.

Assessing perineal lacerations can be challenging due to postpartum edema, bleeding, and complex anatomy. However, it's crucial to accurately distinguish between isolated perineal lacerations and anal sphincter injuries in the acute phase to prevent long-term complications. Failing to identify sphincter injuries can lead to debilitating consequences, including chronic perineal pain, fecal incontinence or recto-vaginal fistula. These complications can significantly impact a woman's quality of life, causing discomfort, disability, and inconvenience. Therefore, a thorough and accurate diagnosis is essential to ensure appropriate treatment and prevent long-term sequelae.

Research has revealed that undiagnosed anal sphincter injuries, referred to as occult sphincter tears, can occur due to unidentified anal sphincter tears, inadequate repair of diagnosed injuries, suture tears after repair etc. Studies report that occult sphincter tears occur in 20-41% of cases. Severe perineal tears, particularly those resulting in anal sphincter injuries, are more common in deliveries attended by unskilled birth attendants or those without proper medical care. While there is evidence suggesting a global increase in severe perineal tears, it is unclear

whether this is due to improved detection, reporting, or an actual rise in incidence. To minimize severe perineal trauma and its complications, it is essential to enhance knowledge and awareness of clinical signs of anal sphincter injury, conduct systematic and thorough examinations and accurately document findings in clinical practice. This will help ensure timely diagnosis and appropriate treatment, reducing the risk of long-term consequences.

Maternal mortality in low- and middle-income countries is primarily caused by acute complications such as hemorrhage and puerperal sepsis, while chronic complications like urinary incontinence, fecal incontinence due to anal sphincter injury, persistent pain, dyspareunia, pelvic organ prolapse, and fistulas can have a lasting impact on women's lives, affecting their overall health, physical and psychological well-being, social relationships, and sexual health, making it crucial to prioritize prevention, early detection, and effective management to mitigate these consequences [10,12].

Despite its significance, there remains a lack of awareness among women about perineal tears, leading to neglect and delayed treatment. Many women who deliver at home often overlook or downplay the severity of perineal and vaginal tears, only to present later with severe complications such as vulval hematoma, wound infections, recto-vaginal fistula, and fecal incontinence. This delayed presentation significantly increases the risk of morbidity and mortality for the mother, highlighting the need for education and timely medical attention to prevent such adverse outcomes.

Obstetric anal sphincter injury is related with substantial short/long term implications on mothers and sometime also results into maternal mortality and morbidity. Bowel symptoms appeared to be the most common marker of identification of obstetric anal sphincter injury that varies from 7.6% to 61% depending upon the severity of the condition [13]. The present study was designed for assessing the risk factors of the perineal trauma during vaginal delivery with episiotomy in pregnant women for better understanding of its effects which can be further controlled.

Aims and Objectives

This study aims to determine the factors linked to episiotomy wound extension after vaginal delivery, in order to better understand the underlying causes and develop effective prevention strategies.

Materials and Methods

A prospective observational study was conducted at the Department of Obstetrics and Gynaecology, Midnapore Medical College and Hospital, from August 2022 to October 2022, after receiving approval from the Institutional Ethics Committee. The study enrolled 180 women who underwent vaginal delivery with episiotomy, meeting specific eligibility criteria, and provided informed written consent. Data was collected using a comprehensive tool and pre-designed proformas to gather sociodemographic, maternal, fetal, and intrapartum risk factors. The collected data was analyzed using descriptive statistics and presented in a structured format

The following factors were evaluated

1. Sociodemographic risk factors
2. Antenatal risk factors
3. Obstetric risk factors
4. Fetal risk factors

Inclusion criteria

All women with singleton pregnancies with labour pain at 37 completed weeks of gestation or above, admitted for delivery were included in this study.

Exclusion criteria

1. Those who have not given consent.
2. Breech presentation.
3. Severely ill mothers.

Results

This prospective observational study was conducted at the Department of Obstetrics and Gynaecology, Midnapore Medical College and Hospital, from August 1, 2023, to October 31, 2023, enrolling 180 women who underwent vaginal delivery with episiotomy and met the specified eligibility criteria. In our study 153 cases were diagnosed as mild perineal tear (first and second degree perineal tear) and 27 cases were diagnosed as severe perineal tear (third and fourth degree perineal tear).

Table 1: Distribution of cases according to their age

Age	Mild perineal tear (1 st & 2 nd degree), [N=153]	Severe perineal tear (3 rd & 4 th degree), [N=27]
< 20 years	28 (18.30 %)	9 (33.33 %)
20-30 years	110 (71.89 %)	11 (40.74 %)
> 30 years	15 (9.80 %)	7 (25.92 %)

P-value-0.004

Mild and severe degree of perineal trauma were more significantly seen in the age groups of 20-30 years (71.89% and 40.74% respectively), having p value of 0.004.

Table 2: Distribution of cases according to their parity

Parity	Mild perineal tear (1 st & 2 nd degree) [N=153]	Severe perineal tear (3 rd & 4 th degree) [N=27]
Primipara	95 (62.09%)	23 (85.18%)
Multipara	58 (37.90%)	4 (14.81%)

P-value-0.01

Mild and severe both type of perineal tear mainly found in primipara mothers (62.09% and 85.18% respectively). There was significant association of extension of episiotomy wound with primipara women.

Table 3: Distribution of cases according to their educational status (N=180)

Variables	Number of cases	Percentage (%)
Illiterate	40	22
Primary	50	28
Secondary	83	46
Graduate	7	4

Among our study subjects, about one-fifth of the mothers (22%) was illiterate and the graduate was least (4%). 28% of mothers were educated up to primary level and 46% mothers were educated up to secondary level.

Table 4: Distribution of cases according to their residence

Residence	Mild perineal tear (1 st & 2 nd degree) [N=153]	Severe perineal tear (3 rd & 4 th degree) [N=27]
Rural	136 (88.35 %)	21 (77.78 %)
Urban	17 (11.65 %)	6 (22.22 %)

P-value-0.11

Most of the mild and severe degree perineal tear cases were from rural area (88.35% and 77.78% respectively).

Table 5: Distribution of cases according to their socio-economic status (N=180)

Socio-economic status	Number of cases	Percentage (%)
Upper middle	10	6
Middle	72	40
Lower middle	58	32
Lower	40	22

Most of the perineal trauma mothers belong to middle and lower middle class (40% and 32% respectively), and the upper middle class was least frequent (6%). Lower socio-economic status was found in 22% cases.

Table 6: Distribution of cases according to their BMI

BMI	Mild perineal tear (1 st & 2 nd degree) [N=153]	Severe perineal tear (3 rd & 4 th degree) [N=27]
Normal	110 (71.89%)	12 (44.44%)
Overweight	43 (28.10%)	15 (55.55%)

P-value-0.004

In our study, we found that mild degree perineal tear mostly was found in cases with normal BMI (71.89%), whereas severe degree of perineal tear was found more in overweight cases (55.55%) than normal weight cases (44.44%). It indicates the association of severe perineal tear with overweight mothers.

Table 7: Distribution of cases according to their gestational age

Gestational age	Mild perineal tear (1 st & 2 nd degree) [N=153]	Severe perineal tear (3 rd & 4 th degree) [N=27]
Term	137 (89.54%)	18 (66.66%)
Post-term	16 (10.45%)	9 (33.33%)

P-value-0.001

Both mild and severe degree of perineal tear were found in term cases (89.54% and 66.66% respectively).

Table 7: Distribution of cases according to their pregnancy interval

Pregnancy interval	Mild perineal tear (1 st & 2 nd degree) [N=153]	Severe perineal tear (3 rd & 4 th degree) [N=27]
<2 years	32 (20.91%)	19 (70.37%)
>2 years	121 (79.08%)	8 (29.62%)

P-value-0.00001

In our study, we found that severe degree perineal tear was predominantly found in mothers who have less than 2 years pregnancy interval (70.37%) with P value 0.00001, indicating strong association between severe perineal tear and pregnancy interval.

Table 8: Distribution of cases according to their onset of labour

Onset of labour	Mild perineal tear (1 st & 2 nd degree) [N=153]	Severe perineal tear (3 rd & 4 th degree) [N=27]
Spontaneous	136 (88.88%)	6 (22.22%)
Induced	17 (11.12%)	21 (77.78%)

P-value-0.00001

88.88% cases of mild perineal tear had spontaneous onset of labour whereas 77.78% cases of severe perineal tear had induced labour.

Table 9: Distribution of cases according to their duration of active 1st stage of labour

Duration of active 1 st stage of labour	Mild perineal tear (1 st & 2 nd degree) [N=153]	Severe perineal tear (3 rd & 4 th degree) [N=27]
< 8 hours	95 (62.09%)	5 (18.51%)
>8 hours	58 (37.90%)	22 (81.48%)

P-value-0.000027

In our study, 62.09% cases with mild perineal tear had less than 8 hours duration of 1st stage of labour and 37.9% cases with mild perineal tear had more than 8 hours duration of active 1st stage of labour. 81.48% cases with severe perineal tear had more than 8 hours of active 1st stage of labour. It indicate that Severe degree of perineal tear is associated with prolonged active 1st stage of labour.

Table 10: Distribution of cases according to their duration of second stage of labour

Duration of 2 nd stage of labour	Mild perineal tear (1 st & 2 nd degree) [N=153]	Severe perineal tear (3 rd & 4 th degree) [N=27]
<30 mins	74 (47.57%)	6 (22.22%)
30-60 mins	43 (28.16%)	9 (33.33%)
>60 mins	36 (24.27%)	12 (44.45%)

P-value-0.023

Majority of severe perineal tear cases (44.45%) had prolonged 2nd stage of labour (>60 mins) whereas mild perineal tear was associated with the majority cases (47.57%) who had less than 30 mins of 2nd stage of labour.

Table 11: Distribution of cases according to their absence/present of precipitate labour

Precipitate Labour	Mild perineal tear (1 st & 2 nd degree) [N=153]	Severe perineal tear (3 rd & 4 th degree) [N=27]
Absent	150 (98.04%)	15 (55.55%)
Present	3 (1.96%)	12 (44.45%)

P-value-0.00001

Most of the cases of mild and severe degree perineal tear (98.04% and 55.55% respectively) were found associated with absence of precipitate labour.

Table 12: Distribution of cases according to the fetal birth weight

Fetal birth weight	Mild perineal tear (1 st & 2 nd degree) [N=153]	Severe perineal tear (3 rd & 4 th degree) [N=27]
<2.5kg	38 (24.84%)	2 (7.41%)
>2.5kg	115 (75.16%)	25 (92.59%)

P-value-0.01

Our study revealed that mothers who gave birth to infants weighing over 2.5 kg were more likely to experience both mild and severe perineal tears.

Table 13: Distribution of cases according to the fetal head circumference

Head circumference	Mild perineal tear (1 st & 2 nd degree) [N=153]	Severe perineal tear (3 rd & 4 th degree) [N=27]
<35 cm	117 (76.47%)	5 (18.52%)
>35 cm	36 (23.53%)	22 (81.48%)

P-value-0.00001

In our study, severe degree perineal tear found in mothers whose fetus had more than 35 cm of head circumference. Out of 180 cases, 5 fetus had persistent occipito-posterior position cases and

their face to pubis delivery occurred. Severe degree perineal tear was found in all these cases. 11 cases had operative vaginal delivery with episiotomy. Third and fourth degree vaginal tear (severe type) found in all these cases.

Discussion

This prospective observational study was conducted at the Department of Obstetrics and Gynaecology, Midnapore Medical College and Hospital, from August 1, 2023, to October 31, 2023, enrolling 180 women who underwent vaginal delivery with episiotomy and met the specified eligibility criteria. In our study 153 cases were diagnosed as mild perineal tear (first and second degree perineal tear) and 27 cases were diagnosed as severe perineal tear (third and fourth degree perineal tear).

Both mild and severe perineal tear were found mostly in 20-30 years age group (71.89% and 40.74% respectively, P value-0.004) the difference was clinically significant. Mild and severe both type of perineal tear mainly found in primipara mothers (62.09% and 85.18% respectively, p-value-0.01). There was significant association of extension of episiotomy wound with primipara women. Among our study subjects, about one-fifth of the mothers (22%) was illiterate and the graduate was least (4%). 28% of mothers were educated up to primary level and 46% mothers were educated up to secondary level. Most of the mild and severe degree perineal tear cases were from rural area (88.35% and 77.78% respectively). Most of the perineal trauma mothers belong to middle and lower middle class (40% and 32% respectively), and the upper middle class was least frequent (6%). Lower socio-economic status was found in 22% cases. In our study, we found that mild degree perineal tear was mostly found in cases with normal BMI (71.89%), whereas severe degree of perineal tear was found more in overweight cases (55.55%) than normal weight cases (44.44%). It indicates the association of severe perineal tear with overweight mothers (p value-0.004). Both mild and severe degree of perineal tear were found in term cases (89.54% and 66.66% respectively). In our study, we found that severe degree perineal tear was predominantly found in mothers who have less than 2 years pregnancy interval (70.37%) with P value 0.00001, indicating strong association between severe perineal tear and pregnancy interval. 88.88% cases of mild perineal tear had spontaneous onset of labour, whereas 77.78% cases of severe perineal tear had induced labour. In our study, 62.09% cases with mild perineal tear had less than 8 hours duration of 1st stage of labour and 37.9% cases with mild perineal tear had more than 8 hours duration of active 1st stage of labour. 81.48% cases with severe perineal tear had more than 8 hours of active 1st stage of labour. It indicate that severe degree of perineal tear is associated with prolonged active 1st stage of labour. Majority of severe perineal tear cases (44.45%) had prolonged 2nd stage of labour (>60 mins) whereas mild perineal tear was associated with the majority cases (47.57%) who had less than 30 mins of 2nd stage of labour. Most of the cases of mild and severe degree perineal tear (98.04% and 55.55% respectively) were found associated with absence of precipitate labour. Our study revealed that mothers who gave birth to infants weighing over 2.5 kg were more likely to experience both mild and severe perineal tears. Severe degree perineal tear found in mothers whose fetus had more than 35 cm of head circumference. Out of 180 cases, 5 fetus had persistent occipito-posterior position and their face to pubis delivery occurred. Severe degree perineal tear was found in all these cases. 11 cases had operative vaginal delivery with episiotomy. Third and fourth degree vaginal tear (severe type) found in all these cases.

In our study, mild and severe perineal tear were most common in 20-30 years age group (71.89% and 40.74% respectively, P value-0.004). This study was similar to the study by Mathias *et al.* [14] done in Uganda, showing the age group of 20-30 years was 7.2 times more likely to get perineal trauma during vaginal delivery. Mild and severe both type of perineal tear mainly found in primipara mothers (62.09% and 85.18% respectively, p value-0.01). There was significant association of extension of episiotomy wound with primipara women. A similar study conducted by Ghamdi *et al.* [1] in Saudi Arabia reported comparable findings, with 78.7% of participants (primi) experiencing severe perineal trauma ($p < 0.001$). This suggests a consistent trend in the prevalence of severe perineal trauma among the studied populations. Among our study subjects, about one-fifth of the mothers (22%) was illiterate and the graduate was least (4%). 28% of mothers were educated up to primary level and 46% mothers were educated up to secondary level. A study by Ali *et al.* [15] reported a similar educational distribution, with 47.9% of participants having primary education, 38.8% having secondary education, and 9.6% having tertiary education. The comparable distribution pattern in our study likely reflects the high literacy rate in this region. Most of the mild and severe degree perineal tear cases were from rural area (88.35% and 77.78% respectively). It is not significant (P value 0.11). Similar result also found in a study by Mathias *et al.* [14]. Most of the perineal trauma mothers belong to middle and lower middle class (40% and 32% respectively), and the upper middle class was least frequent (6%). Lower socio-economic status was found in 22% cases. Opposite result was found in a study by Ali *et al.* [15]. In our study, we found that mild degree perineal tear mostly was found in cases with normal BMI (71.89%), whereas severe degree of perineal tear was found more in overweight cases (55.55%) than normal weight cases (44.44%). It indicates the association of severe perineal tear with overweight mothers (p value-0.004). A study was done by Ghamdi *et al.* [1] also noticed that the relation of the perineal tear with the body mass index was significant ($P = 0.004$). Both mild and severe degree of perineal tear were found in term cases (89.54% and 66.66% respectively, p value-0.001) akin to the study results by Vale-d-Castro-Monteiro M *et al.* [16]. In our study, we found that severe degree perineal tear was predominantly found in mothers who have less than 2 years pregnancy interval (70.37%) with p value 0.00001, indicating strong association between severe perineal tear and pregnancy interval. 88.88% cases of mild perineal tear had spontaneous labour, whereas 77.78% cases of severe perineal tear had induced labour with p-value-0.00001 indicating statistical significance. In our study, 62.09% cases with mild perineal tear had less than 8 hours duration of active 1st stage of labour and 37.9% cases with mild perineal tear had more than 8 hours duration of active 1st stage of labour. 81.48% cases with severe perineal tear had more than 8 hours of active 1st stage of labour (p value-0.000027). It indicate that severe degree of perineal tear is associated with prolonged active 1st stage of labour. Majority of severe perineal tear cases (44.45%) had prolonged 2nd stage of labour (>60 mins) whereas mild perineal tear was associated with the majority cases (47.57%) who had less than 30 mins of 2nd stage of labour (p value-0.023). Our study findings correlating with many studies [17,18,19]. Most of the cases of mild and severe degree perineal tear (98.04% and 55.55% respectively) were found associated with absence of precipitate labour. Our study revealed that mothers who gave birth to infants weighing over 2.5 kg were more likely to experience both mild and severe perineal tears (75.16% and

92.59% respectively, p value-0.01). In our study, severe degree perineal tear found in mothers whose fetus had more than 35 cm of head circumference (p value-0.00001). Our study results akin to the study by Gebuza *et al.* [20] and Jansson *et al.* [21]. Out of 180 cases, 5 fetus had persistent occipito-posterior position and their face to pubis delivery occurred. Severe degree perineal tear was found in all these cases. 11 cases had instrumental vaginal delivery with episiotomy. Third and fourth degree vaginal tear (severe type) found in all these cases. This suggests a strong correlation between the occipito-posterior position of the fetal head and instrumental vaginal delivery, increasing the risk of mild to severe perineal tears.

From our study we concluded that there are significant association of extension of episiotomy wound with primipara women, post term pregnancy, overweight and pregnancy interval of < 2yr, prolonged active 1st stage of labour and 2nd stage of labour, increased foetal birth weight, foetal head circumference, persistent occipito-posterior position of foetal head and instrumental vaginal delivery.

Strengths of this study

- The study's real-life setting at our teaching institute enhances its relevance and applicability.
- Accurate and detailed documentation of patient information was ensured through the study's design.
- Comprehensive data collection was achieved through a thorough datasheet, capturing risk factors, clinical presentation, and maternal outcomes.

Limitations of this study

- The small sample size limits the generalizability of the findings, highlighting the need for a larger, more extensive study.
- The single-center design restricts the applicability of the results to a broader population, necessitating a community-based study for extrapolation.
- The short study period of 12 months may not accurately reflect overall trends and outcomes, potentially impacting the validity of the findings.

Conclusion

Mothers who experience vaginal delivery with episiotomy are at risk of perineal tears, particularly those in extreme age groups, primi, overweight mothers, those with short pregnancy intervals, increased fetal birth weight, persistent occipito-posterior fetal head position, prolonged active first-stage and 2nd stage labour, induced labor and instrumental vaginal delivery. To mitigate these risk, careful attention should be given to mothers with these factors. A well-planned and executed episiotomy can help prevent severe perineal trauma, although certain maternal, fetal, and intrapartum factors may still contribute to the extension of the episiotomy wound from mild to severe.

Conflict of Interest

Nil.

Ethics Statement

This study received prior approval from the "Institutional Ethics Committee", ensuring strict adherence to ethical standards. Patient privacy and confidentiality were meticulously maintained throughout the research process. Participants received care and attention in accordance with established hospital protocols, guaranteeing their safety and well-being.

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