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Prevalence of cesarean scar defect and evaluation of risk factors among patients in a tertiary care teaching hospital in South India

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Abstract
Introduction: Cesarean scar defect, is one of the recognized complications after a cesarean section with a wide prevalence of 6.9% to 69%.
Objectives: The aim of this study was to estimate the prevalence and evaluate the risk factors in the development of cesarean scar defect in patients who delivered in a tertiary care teaching hospital.
Materials and Methods: This was a prospective cohort study among 389 women who underwent cesarean section from a single center. Transvaginal ultrasonography was done to evaluate the presence of cesarean scar defect. The primary outcome variable was prevalence of cesarean scar defect.
Results: The prevalence of cesarean scar defect was 25.19%. Repeat cesarean section, cesarean section done in advanced labour, post-partum haemorrhage and surgical site infections were all independently predictive of its development.
Conclusion: Development of scar defect is increased with repeat cesarean section, cesarean section in advanced labour, post-partum haemorrhage and surgical site infection.

Keywords: Cesarean scar defect, transvaginal ultrasonogram, cesarean section, isthmocele, niche

1. Introduction
Cesarean section (CS) is performed for various indications. The rate of cesarean section is on the rise worldwide. In India, there is a significant increase in cesarean section rates over the past 23 years. In India, the 2015-16 National Family Health Surey-4 (NFHS-4) data showed an average cesarean section rate of 17.2%, ranging from 5.8 to 58% across the country [1]. The trend of cesarean sections from 1992 to 2015 showed an average annual rate of increase of cesarean sections to be 8% in India [2].
A number of complications are recognized in association with patients who had undergone previous cesarean section. Cesarean scar defect, also termed isthmocele, diverticulum or niche is one such complication. Cesarean scar defect (CSD) is defined as a myometrial defect of at least 2 mm at the site of cesarean section scar [3]. The condition also called cesarean scar syndrome can have different clinical presentations like postmenstrual spotting, chronic pelvic pain, dysmenorrhea or secondary infertility. This condition can also lead to life threatening complications like cesarean scar pregnancy and placenta accreta spectrum. It can also be detected as an incidental finding.
The prevalence of CSD varies widely from 6.9% to 69% [4, 5]. The exact prevalence in India is not known owing to paucity of evidence. True prevalence is difficult to estimate since the condition can be asymptomatic. Within a sample, there is a wide variation owing to symptomatology, incongruence of the operative techniques, inadequate reporting and follow up.
Literature search shows few prospective studies on risk factors involved in the development of the cesarean scar [5, 6]. Some of the risk factors implicated in CSD are advanced age, obesity, pre-labour rupture of membranes, anemia, multiple cesarean sections, type of uterine closure, cesarean section done in the second stage of labour and chorioamnionitis [7, 8]. Evaluation of risk factors and the conditions associated with the development of scar defect is imperative in understanding this morbidity and avoiding it.
The diagnosis of cesarean scar defect can be done by trans-vaginal ultrasonography or saline sonohysterography. Direct visualization can be done by hysteroscopy. Recently, magnetic resonance imaging has been recognized as a second line tool in the diagnosis of CSD [9].

The detection rates are higher with sonohysterography (SHG) as compared to transvaginal ultrasound (TVS). The diagnosis of scar defect and the delineation of its borders were said to be better with saline sonohysterography [10]. However, the ease of the procedure without any pre-procedural analgesia makes TVS the initial imaging modality of choice.

In India, despite the increasing trend of CS, there are no prospective studies on the etiology and follow up of patients who underwent CS. In this study, we aim to estimate the prevalence and evaluate the risk factors in the development of cesarean scar defect (CSD) of patients who underwent delivery in our hospital.

2. Methods

This was a prospective observational study done in the department of Obstetrics and Gynecology, Aarupadai Veedu Medical College, a tertiary care teaching hospital in Pondicherry from January 2019 to December 2019 after approval by the institutional research committee and ethics committee. A prevalence rate of 65% was used to calculate the sample size. The sample size was estimated to be 350 subjects in this study [6]. All subjects who delivered by one or more cesarean section done at least 6 months back from the time of enrolment in the study, over the past 5 years in our hospital irrespective of clinical symptoms suggestive of cesarean scar defect were included for the study. Informed written consent was obtained from all the participants. Women who were pregnant, those seeking abortion services, women who delivered elsewhere and those with incomplete or no medical records were excluded from the study.

A detailed history regarding age, parity, socio-economic status according to modified BG Prasad classification, number of cesarean sections, menstrual history, interval between pregnancies, blood transfusion, were obtained from all the study participants. Participants who were enrolled in this study underwent a trans-vaginal ultrasonography, on the day of their hospital visit irrespective of the time of menstrual cycle using a 7 to 9 MHz trans-vaginal probe by a single operator (Mindray M7, India). Presence or absence of a cesarean scar defect, defined as an ultrasonographic demonstration of a hypoechoic defect of 2 mm or more at the site of the uterine scar, was noted. Participants' medical records were then accessed, maintaining strict confidentiality. Variables that were noted were presenting complaints, parity, time of admission during labour, period of gestation, presence of comorbidities namely anemia, gestational diabetes, pre-pregnancy obesity if any, according to the Asia Pacific guidelines for obesity, indication and method of induction, use of oxytocin for augmentation, emergency or elective cesarean section, indication of cesarean section, presence or absence of angle extension during the cesarean section, birth weight of the baby, presence or absence of post-partum hemorrhage, blood transfusions if any, surgical site infection and clinical or laboratory factors suggestive of acute chorioamnionitis. Cesarean section incision closure was done in two layers for all the patients as an institutional policy. Surgical site infections (SSI) included deep incisional SSI involving the deep fascial and muscle layers and infections draining through the incision and organ space infection.

Data entry was done in excel sheet. The primary outcome variable was prevalence of cesarean scar defect. Explanatory variables were age, parity, socioeconomic status, gestational age, body mass index (BMI), use of induction, oxytocin, emergency or elective section, indication of section, any accidental extension of uterine incision during the cesarean section, PPH, blood transfusion, post-operative wound infection, chorioamnionitis, and presence or absence of cesarean scar defect.

Data analysis was done with SPSS software (IBM Corp. Released 2013. IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp). Data was analysed as mean and standard deviation for quantitative variables, and as frequency and proportion for categorical variables. All quantitative variables were checked for normal distribution within each category of explanatory variable by using visual inspection of histograms and normality Q-Q plots. Shapiro-Wilk test was also conducted to assess normal distribution. According to Shapiro-Wilk test, p value of >0.05 was considered to be normal distribution for the variables.

The association between explanatory variables and categorical outcomes was assessed by cross tabulation and comparison of percentages. Categorical outcomes were compared between study groups using Chi square test.

For non-normally distributed quantitative parameters, medians and interquartile range (IQR) were compared between study groups using the Mann Whitney U test (2 groups).

Univariate binary logistic regression analysis was performed to test the association between explanatory variables and outcome variables. Unadjusted odds ratio along with 95% confidence interval (CI) is being presented in data analysis. Variables with statistical significance in univariate analysis were used to compute multivariate regression analysis. Adjusted odds ratio along with their 95% CI is also being presented in data analysis. P value < 0.05 was considered to be statistically significant.

3. Results

A total of 389 subjects were included in the final analysis of data. The time of recruitment since cesarean section was at an average of 35.5 months (7 months to 57 months). The mean age was 26.11 ±3.26 (18 to 35 years) years in the study population (95% C.I 25.78- 26.43). The majority of study participants belonged to class II socioeconomic status (50.13%). 306 (78.7%) participants had anaemia of whom 162 (41.65%), 113 (29.05%) and 31 (7.97%) participants had mild, moderate and severe anaemia, respectively during their antepartum period. Among the study subjects, 116 (29.82%) had gestational diabetes and 28 (7.20%) were obese.

A majority of cesarean sections were done in primigravida subjects (73.26%), and were emergency cesarean sections (83.03%). A total of 19 subjects (4.88%) had preterm cesarean sections. No hysterotomy was done among the study subjects. None of the patients had previous vaginal deliveries.

Induction of labour was done in 133 (34.19%) subjects and oxytocin augmentation was given in 110 (28.28%) patients prior to cesarean section. The most common indication for cesarean section among the study subjects was cephalo-pelvic disproportion (65.04%). 2.57% of subjects had emergency cesarean delivery during the second stage of labour owing to cephalo-pelvic disproportion. Other common indications for cesarean section were failed induction (13.11%) and breech presentation with preterm pre-labour rupture of membranes (1.54%).

17.99% of the cesarean sections performed were repeat sections. 1.8% of subjects were patients with history of two cesarean sections. 30% of repeat cesarean sections were done for threatened scar integrity. But none of the patients had any documented evidence of scar dehiscence or rupture per-operatively.

During the cesarean section, 11.31% had accidental extension of the uterine incision which was corrected surgically, 3.86% had postpartum haemorrhage that was managed medically. The mean birth weight of babies who were delivered in the hospital was 2.82±0.32 kg (95% C. I 2.79 - 2.86) ranging from 1.80 to 3.5 kg.

8.74% of the study participants had blood transfusion in view of anaemia or postpartum haemorrhage. Chorioamnionitis was seen as a complication in 0.51% of the subjects. 8.23% of the 389 study subjects had post-operative surgical site infection.

Among the study population, 98 participants had cesarean scar defect which was detected by trans-vaginal ultrasonography. The prevalence of CSD in our study population was 25.19% (detected by TVS).

Association of baseline and clinical parameters with CSD is shown in table 1. Overall, the odds of developing a CSD were 2.842 times higher when a repeat cesarean section was done when compared to that in patients undergoing cesarean section for the first time (95% CI 1.119- 7.213, p = 0.028). 51% of the patients with a repeat cesarean section had demonstrable CSD.

Table 1: Association of baseline and clinical parameters with Cesarean Scar Defect (N=389)

Parameter	CSD present (n=98) Median (IQR)	CSD absent (n=291) Median (IQR)	Unadjusted odds ratio	95%CI	P value
Age	26 (24- 28.5)	26 (24- 28)	1.029	(0.959- 1.104)	0.422
Socioeconomic status					
Class II	4 (4.1%)	32 (11.0%)	2.986 2.803	1.008 to 8.848	0.048
Class III	53 (54.1%)	142 (48.8%)			
Class IV	41 (41.8%)	117 (40.2%)		0.934 to 8.410	0.066
Anaemia	19 (19.4%)	64 (22.0%)			
Mild	46 (46.9%)	116 (39.9%)	1.604	0.645 to 3.987	0.309
Moderate	23 (23.5%)	90 (20.9%)	1.336	0.722 to 2.472	0.357
Severe	10 (10.2%)	21 (7.2%)	0.861	0.433- 1.711	0.669
Primigravida	48 (49%)	237 (81.4%)	2.842	1.119 to 7.213	0.028
Repeat CS	50 (51%)	54 (18.6%)			
Gestational diabetes mellitus					
Absent	61 (62.2%)	212 (72.9%)	1.628	1.004 to 2.639	0.048
Present	37 (37.8%)	79 (27.1%)			
Term	89 (90.8%)	281 (96.6%)	0.352	0.139 to 0.893	0.023
Preterm	9 (9.2%)	10 (3.4%)			
Obese	11 (11.2%)	17 (5.8%)	2.1513	0.966 to 4.788	0.0606
Overweight	4 (4.1%)	18 (6.2%)	0.7388	0.2428 to 2.2485	0.5940
Normal **	77 (78.6%)	256 (88%)			
No Induction					
Induction	77 (78.6%)	179 (61.5%)	0.436	0.255 to 0.746	0.002
	21 (21.4%)	112 (38.5%)			
No Oxytocin Oxytocin	76 (77.6%)	203 (69.8%)	0.668	0.391 to 1.142	0.140
	22 (22.4%)	88 (30.2%)			
Elective CS	25 (25.5%)	41 (14.4%)	0.479	0.273 to 0.840	0.010
Emergency CS	73 (74.5%)	250 (85.9%)			
Indication for emergency CS					
Breech/ PPROM	4 (4.1%)	2 (0.7%)	8.200	1.312 to 51.258	0.024
CPD	29 (29.6%)	224 (77%)	0.531	0.240 to 1.172	0.117
Previous CS	47 (48%)	22 (7.6%)	8.759	3.718 to 20.634	<0.001
II stage CS	10 (10.2%)	41 (14.1%)	16.400	3.006 to 89.476	0.001
Failed Induction	8 (8.2%)	2 (0.7%)			
Birth weight (kg)	2.9 (2.5- 3)	3 (2.6- 3)	0.632	0.312 to 1.280	0.203
Chorioamnionitis Absent	2 (2.0%)	0 (0.0%)	*		*
Present	96 (98.0%)	291 (100%)			
Accidental extension of uterine incision:					
Absent	80 (81.6%)	265 (91.1%)	2.293	1.196 to 4.397	0.012
Present	18 (18.4%)	26 (8.9%)			
PPH:					
No	90 (91.8%)	284 (97.6%)	3.606	1.272 to 10.221	0.016
Present	8 (8.2%)	7 (2.4%)			
Blood transfusion:					
No	86 (87.8%)	269 (92.4%)	1.706	0.811 to 3.591	0.159
Yes	12 (12.2%)	22 (7.6%)			
SSI					
Absent	15 (15.3%)	17 (5.8%)	2.913	1.395 to 6.084	0.004
Present	83 (84.7%)	274 (94.2%)			

*No statistical test was applied due to zero subjects in the cells

** No statistical significance was found in underweight women in relation to CSD

Induction of labour was done in 34.19 % of the study subjects. However, induction of labour did not influence the development of CSD (OR= 0.436, 95% CI 0.255- 0.746). The most common indication for cesarean section among these patients was failed induction. As per the institutional policy, failed induction was considered when the latent phase of labour extended beyond 24

hours, repeat induction and oxytocin administration.
Oxytocin was administered in 28.8% of the study subjects. There was no significant difference in terms of development of CSD in the groups with and without oxytocin usage. However, the odds of developing CSD were 16.4 times higher in patients with emergency cesarean section done in the second stage of labour (95% CI – 3.006 to 89.476, p= 0.001) when compared to those patients where it was done for failed induction. Yet, there seemed to be no significant risk for development of CSD in emergency CS in comparison with CS which was done electively (OR= 0.479, 95% CI – 0.273 to 0.840, p= 0.010).
Among those patients who underwent emergency CS, repeat CS was associated with a higher risk of developing CSD when compared to patients in which CS was done for failed induction (unadjusted OR=16.400, 95% CI 3.006- 89.476, p= <0.001). Other indication which showed an association with scar defect was emergency CS that was done in patients with preterm premature rupture of membranes with breech presentation (unadjusted OR= 8.200, 95% CI – 1.312 to 51.258, p= 0.024) in comparison with CS which was done for failed induction.
In univariate analysis, the risk of developing CSD was 1.628 times higher in patients who had gestational diabetes mellitus (95% CI – 1.004 to 2.639, p = 0.048).
15.3% of study subjects had SSI. Patients with SSI had 2.913 times higher odds of developing CSD (95% CI 1.395- 6.084, p= 0.004). Two of the recruited subjects had acute chorioamnionitis. Both of them demonstrated CSD at 8 and 9 months respectively. Another factor which showed a higher risk of CSD was accidental extension of uterine incision during cesarean section (OR= 2.293, 95% CI 1.196- 4.397, p= 0.012). Post-partum haemorrhage was documented in 3.86% of the study subjects which seemed to increase the odds of developing CSD by 3.606 times (95% CI 1.272- 10.221, p= 0.016).
Other parameters namely socioeconomic class, maternal obesity, maternal anaemia, birth-weight of the baby and blood transfusion showed no significant association with CSD.

Table 2: Multi-variate logistic regression analysis of factors associated with Cesarean Scar Defect (N=389)

Parameter	Adjusted odds ratio	95% C.I for adjusted odds ratio		P value
		Lower	Upper	
Repeat CS	37.941	4.432	324.809	0.001
Gestational diabetes mellitus	1.369	0.732	2.561	0.326
Emergency CS	0.719	0.340	1.517	0.386
Second Stage CS	15.856	2.278	110.390	0.005
Accidental extension of scar	2.172	0.843	5.599	0.108
Post-partum haemorrhage	4.635	1.304	16.469	0.018
Surgical site infection	4.114	1.569	10.787	0.004

Multivariate analysis (table 2) was done with variables which showed statistical significance in univariate analysis. Emergency cesarean section was also included in this analysis. Repeat CS, CS done in the second stage of labour, post-partum haemorrhage, SSI were all independently predictive of the development of CSD. Factors which failed to show any significant association in multivariate analysis were gestational diabetes, gestational age at CS, obesity and use of drugs for induction of labour.

4. Discussion

Despite the rising trend of cesarean sections in India, there are no prospective studies on factors involved in the development of cesarean scar defect. Among the 389 study subjects, 98 had demonstrable CSD with a prevalence rate of 25.19%. A prospective study on risk factors in the development of CSD by Riitta M. Antila-Långsjö *et al.*, showed a prevalence of 45.6% [5]. LF Van der Voet *et al.*, evaluated CSD at 6 to 12 weeks following CS and reported a prevalence of 64.5% in their study in relation to postmenstrual spotting and urinary incontinence [11]. The wide variation of prevalence noted in different studies could be due to selective sampling of patients with symptoms, varying operative techniques, method of evaluation and difficulties in follow-up [5, 7, and 11].
In our study, we recruited all patients with a history of previous cesarean section irrespective of symptomatology. All the recruited subjects had their cesarean sections performed in our hospital for different indications. The association of surgical technique involved with the development of cesarean scar defect shows conflicting evidence. A meta-analysis by A. Di Spizio *et al.*, which included 9 RCTs showed that compared to single layer closure, participants with double layer closure had thicker CS scars [12]. Hamar *et al.*, evaluated uterine scar thickness by ultrasonography in patients randomly assigned to one and two layer closure. It was found that the type of closure had no influence on scar thickness. This study also suggested that remodelling of the scar extends beyond the traditional post-partum period [13]. In an observational study by O Dicle *et al.*, the maturation time of myometrial scar tissue is approximately 3 months, with recovery of the original uterine anatomy taking as long as 6 months [14]. The recruitment of subjects was after 6 months since the time of CS, in our study. Our institutional policy included two layered closure for all patients with continuous locking sutures involving the first layer (including the decidua) followed by imbricating sutures. Probable reasons for lower prevalence of CSD in our study might have been due to two layered closure for all patients undergoing CS or because of lower detection rate by TVS.
Saline sonohysterography is considered the gold standard in diagnosing CSD. The prevalence of CSD was higher in subjects who were diagnosed by sonohysterography than in those who were detected by TVS [6]. However, TVS is a well-accepted modality of investigation in confirming a CSD. A retrospective study by Cecilia Fabres *et al.*, among 92 premenopausal women with previous CS showed 100% correlation of TVS with hysteroscopy [15]. Another prospective trial by O Vikhareva Osser showed that cesarean section scar can be detected by ultrasound with good reliability [16]. We evaluated all the study subjects based on the consensus statement for sonographic evaluation of CSD [3].
Among the factors that were evaluated in this study, participants with more than one previous CS, CS done in the second stage of labour, subjects with postpartum haemorrhage either intra-operatively or postoperatively and surgical site infections were independently predictive of detection of CSD by transvaginal ultrasonogram.
Multiple CS is a well-known risk factor for CSD. These patients are known to have larger scar defects when compared with

patients with history of one CS [17]. Our study also confirmed this association.

CS done in the second stage of labour shows a significant correlation with CSD. Similar outcome of incomplete healing of uterine incision when the CS was done in advanced labour, was also shown in an observational cross sectional study done by O Vikhareva *et al.*, in Sweden [6]. This is supported by the fact that the stretched out lower uterine segment renders it difficult to approximate during suturing. CS in advanced labour also increases propensity towards post-partum haemorrhage, wound infections, accidental extension of uterine incision and poor wound healing. A retrospective study by Padma Gurung, emphasized about the increased morbidities associated with CS done in the second stage of labour [18]. Accidental extension of uterine incision was another factor associated with CS that was done in advanced labour. However, it was not established to be an independent risk factor for the development of CSD in our study.

Emergency CS by itself was not a predictor of CSD. As per our results, the other interplaying factors were causative, namely CS in advanced labour, increased risk of post-partum haemorrhage and infections associated with emergency CS.

The prevalence of gestational diabetes in our study population was 29.82% as against the national average of 16.55% [19]. Though a significant number of subjects with history of GDM had associated CSD (37.8%), multivariate analysis did not show any independent association. This is in contrast to the findings by Antilla *et al.*, in their study in which gestational diabetes was an independent risk factor for CSD [5]. Further studies are needed to ascertain the same.

As per our study, surgical site infection (SSI) was associated with an increased rate of detection of CSD. About 2-7% of patients with CS are known to develop SSI as a complication. 2-16% of these patients also had an increased risk of developing endometritis. The rate of infection increases if the CS is done on an emergency basis, done in advanced labour and also in patients with pre-labour rupture of membranes. Several contributing factors for surgical site infection can be prolonged duration of labour, and maternal comorbidities such as obesity and gestational diabetes [20].

Chorioamnionitis is often associated with serious maternal morbidities [21]. CSD is recognized as a long term complication among patients with chorioamnionitis. Among our study subjects, 2 had clinical and laboratory evidence of acute chorioamnionitis. One of them presented as a preterm pre-labour rupture of membranes with intrauterine death of foetus. Emergency CS was done in view of failed induction of labour. Following treatment with antibiotics and discharge, she presented again with features suggestive of endometritis after 4 weeks which was managed medically. Another patient presented as pre-labour rupture of membranes with evidence of acute chorioamnionitis and fetal distress for which emergency CS was done. Both the above mentioned patients had evidence of CSD.

The limitation of our study was that subjects were evaluated irrespective of their menstrual cycle after ruling out pregnancy. Saline sonohysterography or hysteroscopy could not be done on an outpatient basis in our set-up. Furthermore, size of the CSD or the symptoms associated with CSD were not taken into consideration in our study.

5. Conclusion

Cesarean scar defect is prevalent in our population. Our prospective study showed that the risk of development of scar defect is increased with repeat cesarean section, cesarean section in advanced labour, and in the presence of associated post-partum haemorrhage and surgical site infections.

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