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Correlation of Serum Procalcitonin and Severity of Post-Cesarean Wound Infection

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ABSTRACT

Background: After a Caesarean section (CS), surgical site infections (SSIs) result in maternal morbidity as well as financial and psychological costs to society.

Objectives: This study aimed to evaluate the correlation between serum procalcitonin and severity of post CS wound infection.

Patients and methods: This prospective cohort study was conducted at the Obstetrics and Gynecology Department and included 64 patients who were divided into 2 groups. Group A (n=32) where secondary suture was done and group B (n=32) where no secondary suture was done. The study started from March 2020 until May 2022.

Results: Procalcitonin (PCT) increased significantly in secondary suture group (234.10 ± 50.20) compared to the non-secondary suture group (161.94 ± 25.55). Pre-operative CRP was 0.698, post-operative CRP was 0.788, pre-operative TLC was 0.689, and post-operative TLC was 0.714, whereas PCT's area under the curve (AUC) for predicting the SSI was 0.977 (95%CI=0.946-1.000). The pre-operative CRP cutoff was ≥ 4.50, the post-operative CRP was ≥ 6.50, the pre-operative TLC was 7.45, and the post-operative TLC was > 10.25.

Conclusion: Serum PCT levels tested during the postoperative period were found to be more sensitive and specific than other traditional infection markers like CRP and TLC in the early detection of SSI following CS.

Keywords: Post-Cesarean severity, Serum procalcitonin, Wound infection.

INTRODUCTION

Bacterial infection is mostly a clinical concept that may need to be confirmed or ruled out with supportive bedside or laboratory investigations. The presence of inflammation or systemic dysfunction as well as direct or indirect evidence of a suitable bacterial infection are the two main elements that are always required to validate the diagnosis. Localized or systemic inflammatory response syndrome can develop from inflammation (SIRS) [1]. With the development of effective antibiotics, widespread immunization, and contemporary sanitation, infection control and prevention are currently improving. However, in many healthcare systems around the world, infection continues to be the cause of morbidity and mortality [2].

Infection at surgical site is one of the most frequent and serious surgical consequences. The presence of liquid pus or an abscess that grows on a lesion within 30 days is known as a SSI [3]. Clinical and analytical testing are used to diagnose SSI. An examination is conducted to look for any pus, abscess, or inflammatory reaction at the surgical site before making a diagnosis. Additionally, an open incision and any pus or abscess that oozes from the site are both examined. A pus or tissue sample should be collected for a culture test, and a routine blood count should be performed to check the leucocyte count and procalcitonin level [4].

Procalcitonin (PCT) which is peptide precursor of calcitonin. It has 116-amino-acid, which released from all tissue cells when microbes are infected. It can be seen in plasma two hours after endotoxins, growing within six to eight hours, and plateauing after twenty to seventy-two hours [5]. Leucocyte count and PCT are signs of systemic infection. One useful marker for identifying bacterial infection in adults is procalcitonin. Plasma PCT level, especially for invasive or likely-invasive microorganisms, is comparable to the specific response of bacterial infection [6].

High PCT concentrations are indicative of sepsis, severe sepsis or possibly septic shock condition. Additionally, it might represent a distinct setting and provide the traditional clinical data greater meaning. Several research suggest that procalcitonin is just as effective at diagnosing infections as another sign of infection, such as CRP, leukocytosis and fever if not better [7]. So, this study aimed to assess the correlation between blood procalcitonin levels and the severity of post-CS section wound infection.

PATIENTS AND METHODS

Sixty-four patients in the Obstetrics & Gynecology Department, Menoufia University Hospital, Shebin Elkom, Egypt, participated in this prospective cohort study. It began in March 2020 and ran through May 2022.

The study's participants were divided into 2 groups: Those who received secondary suture were in **Group A (n=32).** These patients who required the suture for treatment of their wound after developing post-cesarean section surgical site infection. While, in **group B (n=32)** included individuals who skipped the second suture. These patients were monitored without a secondary suture for their wound care after developing post-CS surgical site infection.

Sample size: Based on previously conducted studies that showed a median difference of 16 ng/ml between infected (with secondary suture) and infected (no suture) groups for procalcitonin [8], the sample size

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computed at CI 95% and power 80% was predicted to be 64 patients divided into 2 equal groups [9].

Inclusion criteria: Patients experienced surgical site infections following CS. To identify the incisional SSI, at least one of the following symptoms should be found: redness, purulent discharge from the wound and/or swelling of the incision and wound separation must be present.

Exclusion criteria: History of mastitis, pneumonia, or upper respiratory tract infections as well as premature or prolonged membrane rupture, urinary tract infections, or other infectious condition beside to infection at the site of operation.

Method: Complete medical history and physical examination, including information on the mother's age, weight, socioeconomic status, length of wound exposure, recovery time following surgery, and length of hospital stay. The hospital was visited by every person who had SSI. Following the collection of blood samples to assess serum procalcitonin (PCT), C-reactive protein (CRP) and total leukocytic count (TLC), antibiotic therapy by using second-generation cephalosporin as cefzil had been administered. Blood was aseptically drawn from a nearby vein. It was centrifuged to separate the sample. The following information was written on the labels of plastic frozen vials with leak-proof screw lids after the serum was transferred using sterile procedure (patient name and date). The moment the serum was placed into the plastic freezing vials, it was frozen. At -80^{o}C, the sample was maintained.

Procalcitonin human ELISA kit:

Sensitivity: Procalcitonin normally has a minimum detectable dosage of less than 12.4 pg/ml. The protein concentration at lowest level could be distinguished from zero was used to define the sensitivity of this test also known as the Lower Limit of Detection (LLD). The concentration was calculated by multiplying the mean optical density value of twenty zero standard replicates by two standard deviations.

Specificity: Procalcitonin can be detected with this test with great sensitivity and excellent specificity. Between procalcitonin and its counterparts, there was no observable cross-reactivity or interference.

Detection range: 31.2-2000 pg/mL. Standard curve values of 2000 pg/mL, 1000 pg/mL, 500 pg/mL, 250 pg/mL, 125 pg/mL, 62.5 pg/mL, and 31.2 pg/mL were used for the ELISAs.

Primary outcome measure:

In order to treat incisional SSI following a Caesarean section, the study compared between PCT levels in patients who needed secondary sutures and patients who did not.

Ethical approval: Before the study began, all patients signed written informed consent forms. The study protocol (ID: 12/2020OBSG14) was accepted by The Ethical Scientific Committee of Menoufia University, and it was also registered on the clinical Trails.gov Identifier: NCT 05164224. The study adhered to the Helsinki Declaration throughout its execution.

Statistical Analysis

The data were collected, tabulated, and statistically analyzed using the Statistical Package for SPSS version 23 on a personal computer that was compatible with IBM. Quantitative information was displayed as percentages (%) and numbers (N). Chi-Square, Student's t-test (t), Paired t-test (t), Wilcoxon test, Mann-Whitney's (U) test, and Receiver Operating Characteristic (ROC) curves are examples of analytical statistics. Cutoff points: Additionally, they represent a suitable value to identify a healthy individual from a particular condition. They represent both standard ranges and ranges for optimal health. Specificity, negative predictive value, positive predictive value, and sensitivity were calculated. $P \leq 0.05$ and $P \leq 0.01$ were used to determine whether the results were significant or very significant.

RESULTS

Sixty-four patients were enrolled in the trial and were divided into two equal groups. Patients in group A underwent secondary suture. Patients in group B did not receive secondary suture. Age, BMI, and employment status did not significantly differ between study groups ($p > 0.05$). However, parity, Caesarean section, education, and income significantly differed ($p<0.05$) (Table 1).

Table (1): Comparison between group A and group B regarding socio-demographic and obstetric data

		Group(A) Secondary suture group (n=32)		Group (B) Non-Secondary suture group (n=32)		Test of significance	*P-value*
		No	%	No	%		
Age (years):	Mean ± SD Range	29.09±4.93 21-36		28.78±4.79 20-39		**t**= 0.257	0.798
BMI (kg/m²):	Mean ± SD Range	30.42±2.53 25.39-35.38		30.06±3.65 20.76-36.63		**t**= 0.461	0.646
Parity:	< 2 ≥ 2	5 27	15.6 84.4	16 16	50.0 50.0	χ^2= 8.576	**0.003***
CS:	< 2 ≥ 2	9 23	28.1 71.9	21 11	65.6 34.4	χ^2= 9.035	**0.003***
Education:	Illiterate Primary school High school University	8 16 8 0	25.0 50.0 25.0 0.0	4 14 12 2	12.5 43.8 37.5 6.3	χ^2= 4.267	**0.0354***
Job:	Yes No	8 24	25.0 75.0	7 25	21.9 78.1	**χ^2=0.090**	**0.798**
Income:	Less than expense Equal More	8 23 1	25.0 71.9 3.1	3 24 5	9.4 75.0 15.6	χ^2= 4.961	**0.014***

t: student t test, χ^2: Chi square test, *significant (P <0.05), SD: standard deviation, BMI: body mass index, CS: cesarean section. Group A: Secondary suture group, Group B: Non- Secondary suture group.

Also, TLC and CRP were considerably higher in the secondary suture group during the pre-operative investigation compared to the non-Secondary suture group. While, Hb level was considerably higher in the non-secondary suture group compared to the secondary suture group. Compared to the non-secondary suture group, surgery times were considerably longer in the secondary suture group**.** Additionally, TLC and CRP considerably increased following surgery compared to non-secondary suture group in the post-operative research. Compared to the secondary suture group, Hb considerably elevated in the non-secondary suture group. Moreover, the temperature (24 hours) post-operative and hospital stay were considerably elevated in the secondary suture group than in the non-secondary suture group while there was no significant difference in the two groups' exposed wound times**.** PCT was considerably higher in the secondary suture group (234.10±50.20) than in the non-secondary suture group (161.94±25.55), (P= 0.001) (Table 2).

Table (2): Comparison between group A and group B regarding pre-operative and post-operative investigations and operative assessment

	Group(A) Secondary suture group (n=32)	Group (B) Non-Secondary suture group (n=32)	Test of significance	P-value
	Mean ± SD Range	Mean ± SD Range		
Pre-operative investigations				
Hb (g/dl)	10.26±1.08	10.83±1.13	**t**= 2.080	**0.042***
TLC (× 10⁹/L)	10.10±2.40	7.81±1.92	**U**= 2.627	**0.009***
CRP (mg/L)	7.97±1.82	5.16±1.18	**U**= 2.746	**0.006***
Surgery duration (minutes)	39.37±4.71	31.84±6.43	**t**= 5.345	**<0.001****
Post-operative investigations				
Hb (g/dl)	9.45±1.11	9.99±0.98	**t**= 2.079	**0.042***
TLC (× 10⁹/L)	15.76±3.82	11.95±2.47	**U**= 2.959	**0.003***
CRP (mg/L)	47.81±11.61	15.16±3.11	**U**= 3.985	**<0.001****
Temperature (24-H) post-operative	37.68±0.45	37.03±0.50	**t**= 5.550	**<0.001****
Hospital stay/hours	35.12±8.52	29.91±6.39	**t**= 2.403	**0.02***
Exposure wound time/ day	7.09±0.93	6.72±0.63	**t**= 1.887	**0.064**
PCT (Pg/mL)	234.10±50.20	161.94±25.55	**t**= 7.247	**<0.001****

t: student t test, U: Mann-Whitney test, *significant (P <0.05), **Highly significant (P <0.001) , Hb: hemoglobin, TLC: total leukocytic count , CRP: C reactive protein

According to ROC curve analysis, measuring blood PCT was the most effective method for identifying the presence of post-Cesarean wound infection**.** At AUC of 0.977 and a cutoff value of ≥ 190.525, it exhibited a sensitivity of 93.8% and a specificity of 87.5% as compared to preoperative. Pre-operative CRP had a cutoff value of ≥ 4.50 at AUC of 0.698 with a sensitivity of 71.9% and specificity of 68.7% (**Figure 1a).** Post-operative CRP at AUC of 0.788 and a cutoff point value of ≥ 6.50 had a sensitivity of 84.4% and a specificity of 40.6% **Figure (1b)** and **Table 3)**. Furthermore, pre-operative TLC had a cutoff point of > 7.45, with sensitivity of 75% and specificity of 50% at AUC of 0.689, according to ROC curve analysis. Post-operative TLC had a cutoff point of > 10.25, with sensitivity of 84.4% and specificity of 31.2% at AUC of 0.714. **(Table 3** and **figure 1c).**

Table (3): ROC curve for procalcitonin (PCT), pre- and post-operative CRP, pre- and post-operative TLC in Post-Cesarean SSI management by secondary sutures

Variables	Cut-off point	AUC	Accuracy	Sensitivity	Specificity	95% CI
Procalcitonin (PCT) (Pg/mL)	≥190.525	0.977	97.7%	93.8%	87.5%	0.946-1.000
Pre-operative CRP (mg/L)	≥ 4.500	0.698	69.8%	71.9%	68.7%	0.565-0.832
Post-operative CRP (mg/L)	≥ 6.50	0.788	78.8%	84.4%	40.6%	0.674-0.902
Pre-operative TLC ($\times 10^9$/L)	≥ 7.45	0.689	68.9%	75%	50%	0.558-0.820
Post-operative TLC ($\times 10^9$/L)	≥ 10.25	0.714	71.4%	84.4%	31.2%	0.581-0.848

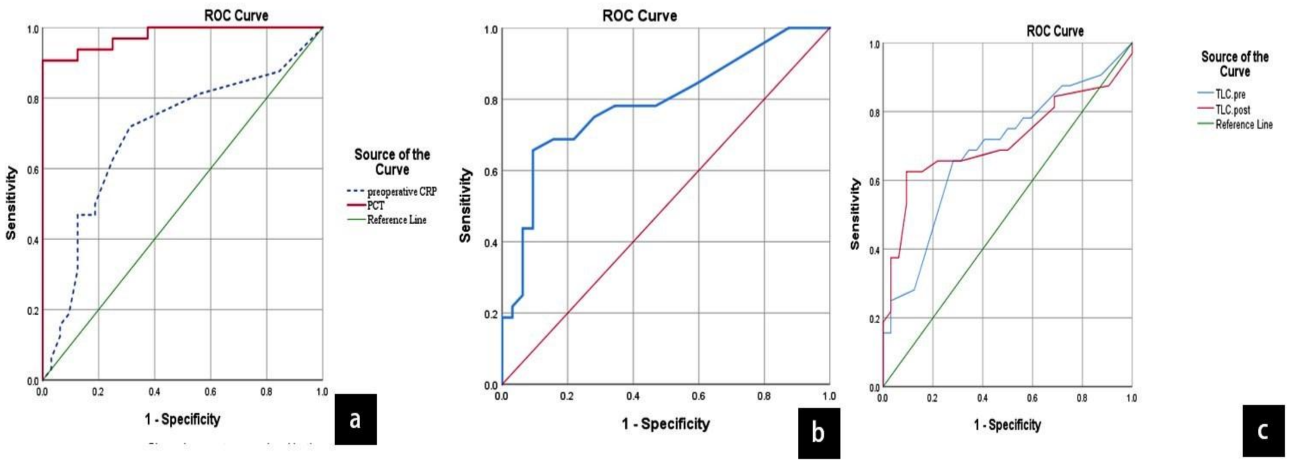

Figure (1): (a) Accuracy of PCT and pre-operative CRP in secondary suture group. **(b)** Accuracy of post-operative CRP in secondary suture group. **(c):** Accuracy of pre- and post-operative TLC in secondary suture group.

Also, with a p value of 0.035, a multi-logistic regression analysis showed that PCT was the most important predictor for post-Cesarean SSI management with secondary sutures **(Table 4).**

Table (4): Multiple logistic regression analysis for predictors of post-cesarean SSI management by secondary sutures

	B	P-value	OR (95% CI)
Parity: ≥ 2	0.221	0.940	1.248 (0.004-402.314)
CS ≥ 2	- 2.402	0.552	0.091 (0.001-245.965)
Pre-operative Hb	0.528	0.664	1.695 (0.157-18.349)
Pre-operative TLC	0.845	0.179	2.328 (0.679-7.980)
Pre-operative CRP	0.447	0.184	1.563 (0.809-3.020)
PCT	0.252	**0.035**	1.287 (1.018-1.628)

OR: odds ratio, CI: confidence interval.

DISCUSSION

Surgical site infection (SSI) is one of the most frequent problems linked to Caesarean sections. Significant maternal morbidity, a longer hospital stays, readmission, and expense are all brought on by SSIs following Caesarean sections [10]**.** The patient's total leukocytic cell (TLC) count and CRP levels are most regularly measured during the postoperative time to assess infections and their sequelae. In the past ten years, doctors have begun to employ other potential markers to identify infections. Procalcitonin is a typical biomarker used to identify many infectious diseases including sepsis [9]**.**

The polypeptide precursor of calcitonin which has 116-amino-acid is known as PCT [11]. A surgical complication and the early identification of sepsis and bacterial infections are both aided by elevated PCT levels [12]. So, this study's purpose was to assess the connection between blood procalcitonin levels and the severity of post-Cesarean section wound infection. In agreement with our result **Zejnullahu** ***et al.*** [13] revealed that SSI was 7.4 times more likely to occur in patients who had previously undergone Caesarean sections than in those who had not. Additionally, they discovered that shorter surgeries - less than 1 h- had a protective impact against SSI. Similarly, the study conducted by **Rano and Patel** [14] in which a C-section with an operation lasting more than one hour improves the probability of developing SSI and a protracted operation is a separate risk factor for SSI development.

The current study showed that compared to non-secondary suture group (161.94 ± 25.55), PCT was considerably higher in the secondary suture group (234.10 ± 50.20), (p=0.001). In a previous study by **Aslan** ***et al.*** [9] found individuals who needed a secondary suture for the treatment of SSI following a Caesarean section had higher baseline PCT levels. The patients with incisional SSI have cutoff limit for the prediction of secondary suture, which was 0.142 ng/ml. CRP and length of hospital stay all positively linked with blood PCT levels. Despite, the fact that sepsis and several bacterial infections have been researched with procalcitonin, it is unknown how well PCT levels can diagnose SSIs following Caesarean delivery. It may take a long time and numerous visits to treat a secondary intention wound infection and it may take several months for the wound to fully recover. 2-7% of patients experience post-CS wound infections, which typically appear 4–7 days after the procedure**.** They discovered increased serum levels of procalcitonin in patients who needed a secondary suture for the therapy of SSI following CS [15].

The results of the current study indicated that post-operative levels of TLC and CRP were considerably greater than pre-operative levels for the secondary suture group (P=0.001), while Hb levels increased pre-operatively much more than post-operatively (P = 0.001). Additionally, post-operative TLC and CRP levels were considerably higher in the non-secondary suture group compared to pre-operative levels (P=0.001). The liver releases CRP in regard to infection and/or inflammation and is a well-researched infection indicator. CRP and PCT were compared in several studies and randomized control trials for the diagnosis of bacterial infections and sepsis. Some authors discovered that PCT is more specific and sensitive than CRP for the diagnosis or prognosis of sepsis [16]**.** In addition, **Park** ***et al.*** [17] stated that PCT is less accurate than CRP at identifying infections. The majority of research on PCT was done on seriously ill patients in intensive care units (ICU) or on those who had systemic bacterial infections like pneumonia. PCT level following surgery and in individuals who experienced SSIs is subjects of scant research. Taking into account the fact that CRP rises as a result of surgical trauma after surgery [18]. More research is required to assess the accuracy of CRP and PCT in the detection of infections and problems following surgery.

In another study by **Dias** ***et al.*** [19] it was reported that patients with acute abdominal pain who required surgery and patients with abdominal pain who were treated conservatively were compared with respect to PCT, CRP, and WBC counts. For patients with acute abdominal discomfort, they identified a cutoff of > 5 ng/ml with a 73% sensitivity and 80% specificity for PCT to indicate the need for an emergency surgery. However, they found no link between CRP levels and the need for surgery, despite mounting evidence that PCT serves as a key marker for the detection of infections and postoperative problems. In our result, serum procalcitonin PCT was found to be the best approach for detecting its amount as an indicator of post-Cesarean wound infection according to ROC curve research. At an AUC of 0.977 and a cutoff value of ≥ 190.525, it exhibited a sensitivity of 93.8% and a specificity of 87.5%. The current study is consistent with **GÜL** [20] who reported that the AUC was calculated to be 0.912 when the cutoff criterion for PCT was 0.099 ng/mL, according to the postoperative 6th hour PCT results. The sensitivity, specificity, and accuracy were 93.3%, 92.3%, and 92.4% respectively at this stability. Additionally, he observed that the sensitivity was 93.3% and the specificity was 91.5% when the PCT cutoff threshold was 0.1495 ng/ml at the postoperative 12th hour. Also, **Aslan** ***et al.*** [9] found that the PCT cutoff points and AUC for predicting the necessity for a secondary suture. AUC was 0.85, 95% CI: 0.772–0.922; cutoff point: 0.142 ng/ml; sensitivity: 75%; specificity: 97.8%. Furthermore, in a study by **Aljabi** ***et al.*** [21] Procalcitonin's sensitivity and specificity were 100% and 95.2%, respectively when used as a predictor of surgical site infection after spinal surgery according to their evaluation.

Strength of the study: Up to our knowledge, no further studies have been conducted on the relationship between procalcitonin and the severity of post-CS wound infection in Egypt. It reduced the price and time of hospital stays as well as maternal morbidity.

Limitation of the current study: Since the size of the sample was limited, it is difficult to generalize the findings. Results cannot be generalized since maternal characteristics such prenatal care, labor difficulties, gestational diabetes, pre-gestational diabetes, and patients with urinary tract infections after CS were not included in the current study. Some of these difficulties would be further addressed by bigger cohort research.

CONCLUSION

In comparison with other traditional infection markers like CRP, TLC and serum PCT levels measured in the postoperative period were found to be a more sensitive and specific indicator in the early identification of SSI following caesarean delivery.

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