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Research Article

Retrospective Monocentre Study: Evaluating Polyglactin 910 (PGLA 910) Sutures and Post-Caesarean Surgical Site Infections

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Abstract

Aim: This study evaluates the effectiveness and safety of polyglactin 910 (PGLA 910) sutures for uterine closure in caesarean sections, focusing on the incidence of Surgical Site Infections (SSIs) and other postoperative complications.

Methods: A retrospective, monocentric cohort study was conducted using anonymised data from electronic health records of 250 women who underwent caesarean sections at Althaia Xarxa Assistencial Universitaria de Manresa, Barcelona, between November 2022 and February 2023. The primary outcome was the rate of SSIs within 30±10 days post-surgery. Secondary outcomes included wound healing complications, reoperations/readmissions, hospital stay length, need for blood transfusions, and Adverse Device Effects (ADEs).

Results: The incidence of SSIs was 4.0% (n=10), with 3.6% (n=9) being superficial SSIs and 0.4% (n=1) organ/space SSI. No primary or secondary deep incisional SSIs were reported. Wound healing complications occurred in 4.4% (n=11) of patients, and 1.6% (n=4) required blood transfusions. The mean hospital stay was 3.5 days. No reoperations were needed, and no ADEs were observed.

Conclusions: The use of PGLA 910 sutures for uterine closure in caesarean sections is associated with a low incidence of SSIs and favourable safety outcomes. These findings support the continued use of PGLA 910 sutures, though further randomised controlled trials are recommended to confirm these results and establish standardised protocols.

Keywords: Caesarean Section; Polyglactin 910; Retrospective Study; Uterine Closure; Surgical Site Infections

Introduction

Caesarean deliveries, once viewed as a heroic intervention reserved for high-risk pregnancies, have become increasingly commonplace. According to the World Health Organization (WHO), the rates of caesarean deliveries have been steadily increasing worldwide, rising from around 7% in 1990 to 21% in 2021 [1]. This means that approximately one in five births globally now involve a caesarean section, and is projected to reach 29% in 2030, globally [1]. While caesarean deliveries undoubtedly play a crucial role in saving maternal and foetal lives, their growing prevalence inadvertently casts a long shadow of complications - among the most concerning being Surgical Site Infections (SSIs) [2], with an incidence of 3%-15% [2,3] in 2017. The most common

SSIs seen after caesarean deliveries are incisional infections (2%-7%) and endometritis (2%-16%) [2,4]. In obese women, these rates are even higher, approaching 30% [2]. Caesarean delivery demands accurate closure techniques across various tissue layers to minimise complications. No single "gold standard" exists for caesarean closure, with both absorbable and non-absorbable suture materials being viable options depending on the specific layer being closed. While the procedure itself has become more refined, achieving optimal healing and minimising complications, it relies on meticulous closure techniques. Suture selection, encompassing both technique and material choice, stands at the forefront of this crucial stage [5,6]. Studies continuously strive to optimise techniques and materials to minimise these risks. Obesity, diabetes, and other conditions might influence suture choice [6].

Optimal uterine closure remains one of the most studied and controversial aspects of caesarean delivery [5]. Current practice is to use a double layer uterine closure technique, except in occasional circumstances when there is a specific reason for using single layer closure. This recommendation allows surgeons to choose single or double layer closure, depending on the individual clinical circumstances at the time of surgery [7,8]. As for the closure material, the use of a delayed absorbable monofilament has been described (poliglecaprone 25 sutures) and absorbable, synthetic, braided sutures (polyglactin 910), without strong evidence to support a particular suture [9, 10]. A recent systematic review compared barbed sutures with monofilament sutures for uterine closure [11]. Barbed sutures were associated with a shorter operative time, while monofilament sutures were linked to increased uterine scar thickness. However, the clinical significance of these differences remains unclear [11]. Current guidelines do not recommend to suture the visceral or the parietal peritoneum in caesarean birth to reduce operating time and the use of postoperative analgesia, and improve maternal satisfaction [5,7]. Historically, the visceral and parietal peritoneum were closed; however, in systematic reviews, there is no evidence that outcomes such as intraabdominal adhesions are different and that the operative times are shorter leaving the peritoneum open [9].

If a midline abdominal incision is used in caesarean birth, guidelines recommend to use mass closure with slowly absorbable continuous sutures, as this results in fewer incisional hernias and less dehiscence than layered closure [7]. However, there is no evidence to support closure of the midline, and there is concern that intramuscular sutures will tear through [9], and can be associated with increased postoperative pain and analgesic requirements [5]. The abdominal fascia is usually closed with a continuous suture, Polydioxanone (PDS) or polyglactin 910 [5,9]. In women whose subcutaneous tissue is ≥2 cm in thickness, re-approximation with polyglactin 910 suture has been demonstrated to reduce wound complications [9]. Current guidelines do not recommend to routinely close the subcutaneous tissue space in caesarean birth unless the woman has more than 2 cm subcutaneous fat, as it does not reduce the incidence of wound infection. [5,7,9]. Historically, skin closure with either staples or subcuticular suture was recommended [12]. More recent findings, however, indicate a preference for the use of sutures instead of staples to close the skin after caesarean birth [4,7,9,13,14]. This shift favours a reduced risk of superficial wound dehiscence and other wound complications.

The aim of this study is to collect real-world clinical data on the use of a mid-term absorbable braided suture made of polyglactin 910 for the uterus closure after a caesarean section. Rate of post-caesarean SSI within the first 30 days ± 10 days was evaluated, together with other safety parameters such as wound healing complications, incidence of reoperations/readmissions, length of hospital stay, need for blood transfusion and incidence of Adverse Device Effects (ADEs). All these parameters were compared with the findings of previously published Randomised Controlled Trials (RCT) that also employed polyglactin 910 sutures [15]. This comparison aimed to evaluate the relative safety and efficacy of the current intervention in the context of existing data.

Materials and Methods

Study Design

This study adopted a retrospective, monocentric cohort design. It analysed anonymised data from electronic health records (EHRs) of routine clinical practice without introducing any additional diagnostic or therapeutic intervention. We relied on the completeness of the EHRs to capture all necessary information. Given the retrospective nature and use of existing data, obtaining an informed consent from patients was waived, and no additional study visits were needed. An informed consent was not necessary according to Spanish legislation (Article 5.1 of Royal Decree 957/2020) because it did not involve a new intervention or interaction with the patients. The data was already included in the EHRs and study participation was not likely to cause any harm to the patients. The ethics committee of the participating centre reviewed all submitted documentation and approved the conduct of the study.

The primary outcome measure was the rate of post-caesarean SSIs occurring within the first 30 days, with a tolerance of ±10 days. Additionally, other safety parameters were assessed, including complicated wound healing, incidence of reoperation/readmission, length of hospital stay, need for blood transfusion and incidence of Adverse Device Effects (ADEs). In accordance with the previously identified publication from Koroglu et al. [15], a baseline rate of superficial SSI was established prior to the start of the investigation. This established base rate of 10.6% served as a reference point for assessing the potential impact of the use of polyglactin 910 sutures

on SSI development within the study population.

Study Population

Study participants were treated at Althaia Xarxa Assistencial Universitaria de Manresa (Barcelona, Spain), scheduled for caesarean section (elective, in labour, or urgent) between 15 November 2022 and 1 February 2023. Only adult (≥18 years old) female patients with available EHR were eligible for inclusion. This study excluded patients with medical/psychological issues that might affect the ability to comply with the study procedures, or those already in another trial. Following confirmation of eligibility criteria, the physician assigned a unique, anonymised patient identification number in the Investigator's Signature File (ISF). The retrospective analysis of this investigation was conducted on data extracted from the hospital's EHR database. This data encompassed all patients who met the predefined selection criteria and were deemed evaluable for the study. A sample size of 250 patients was chosen based on the reported frequency of wound complications (including SSIs) of 10.6% following polyglactin 910 suture use in the publication by Koroglu et al. [15]. While a formal sample size calculation was not performed, this sample size was estimated to provide sufficient power to detect a clinically relevant difference in SSI rates within 30±10 days between the intervention and control groups. This sample size was considered sufficient to evaluate the secondary objectives as well.

Device Description

A mid-term absorbable braided suture made of polyglactin 910 (Novosyn® USP 1, B. Braun Surgical S.A., Spain) was used in patients undergoing caesarean section to close the uterus. The specific suturing technique varied according to the patient's condition, the size of the wound, the surgical requirements, and the gynaecologist's preference. Polyglactin 910 (PGLA 910) sutures exhibit sustained strength retention. At 14 days post-implantation, it retains approximately 75% of its original tensile strength, decreases to 40-50% at 21 days and 25% at 28 days. Complete mass absorption occurs gradually over 56-70 days, ensuring adequate tissue support during the critical healing period. In all patients, polydioxanone sutures (Monoplus®, B. Braun Surgical S.A., Spain) were used for fascial closure. For skin closure, resorbable glycolide copolymer caprolactone sutures (Monosyn®, B. Braun Surgical S.A., Spain) were used.

Statistical Analysis

All patients meeting the selection criteria who underwent caesarean section surgery with Novosyn® were included in the analysis. We described the study variables and presented absolute frequencies and percentages for qualitative variables. For the primary and main secondary endpoints, two-sided 95% confidence intervals were calculated using the Agresti-Coull method. No data imputation was performed for missing values. All analyses were conducted using SPSS statistical software, and results were based on a complete-case analysis.

Results

Patient Demographics and Other Baseline Characteristics

A total of 250 patients were included retrospectively in the study. The patient demographics and baseline characteristics are described below in Table 1. Briefly, according to the maternal factors during pregnancy, the mean age ± standard deviation of participants was 34.1 ± 5.6 years, no patients were immunosuppressed or had received a transplant, and 13 patients (5.2%) had previously experienced genital tract infections. Regarding intrapartum factors, 14 patients (5.6%) had a premature gestation (<37 weeks), 138 patients (55.2%) underwent at least one vaginal examination and 43 (17.2%) received intrapartum antibiotics therapy, mainly (51.2%, n=22) due to Streptococcus group B colonisation. For intra-caesarean factors, 157 patients (62.8%) underwent caesarean section for the first time, while 70 (28.0%) and 16 (6.4%) patients underwent caesarean section for the second and third time, respectively. The main reasons for the intervention were iterative caesarean (25.6%, n=63), labour induction failure (17.3%, n=43) and non-cephalic presentation (16.5%, n=41). Almost all patients (95.2%, n=238) received pre-caesarean antibiotic prophylaxis and the mean duration of surgery was 57 minutes ± 21.

Maternal factors during pregnancy	
Age, (mean), years ± SD [N]	34.1 ± 5.6 [249]
Weight, (mean)**,** kg ± SD [N]	70.2 ± 16.3 [226]
Height, (mean)**,** m ± SD [N]	1.6 ± 0.1 [224]
BMI, (mean), kg/m^2 ± SD [N]	27.0 ± 6.1 [223]
Immunosuppression or transplant, n (%) [N]	0 (0.0) [249]
Previous infection of the genital tract, n (%) [N]	13 (5.2) [249]
Intrapartum factors	
Gestational age: Premature labour (<37 weeks), n (%) [N]	14 (5.6) [250]
Amniorrexis ≥18 hours, n (%) [N]	24 (14.9) [161]
Streptococcus agalactiae colonisation, n (%) [N]	44 (18.4) [239]
Vaginal examinations performed, n (%) [N]	138 (55.4) [249]
Number of vaginal examinations, mean ± SD [N]	6.4 ± 2.9 [136]
Use of internal catheter for the uterine dynamic, n (%) [N]	30 (12.0) [249]
Concomitant therapies (intrapartum antibiotics therapy excluding pre-caesarean prophylaxis), n (%) [N]	43 (17.2) [249]
Main reason for concomitant therapy, n (%) [N]	
Streptococcus group B colonisation	22 (51.2) [43]
Amniorrexis ≥ 18 hours	19 (44.2) [43]
Intrapartum fever	2 (4.7) [43]
Clinical suspicion of chorioamnionitis, n (%) [N]	7 (2.8) [249]
Intracaesarean factors	
Caesarean section performed, n (%) [N]	
1	157 (62.8) [250]
2	70 (28.0) [250]
3	16 (6.4) [250]
4	7 (2.8) [250]
Type of caesarean section, n (%) [N]	
Scheduled or elective	105 (42.0) [250]
In labour	84 (33.6) [250]
Urgent	61 (24.4) [250]
Reason for caesarean section, n (%) [N]	
Iterative caesarean	63 (25.6) [249]
Labour induction failure	43 (17.3) [249]

Non-cephalic presentation	41 (16.5) [249]
Risk of loss of foetal well-being	26 (10.4) [249]
Suspected loss of foetal well-being	26 (10.4) [249]
Pelvic-foetal disproportion	24 (9.6) [249]
Other	26 (10.4) [249]
Concomitant therapies (pre-caesarean antibiotic prophylaxis), n (%) [N]	238 (95.2) [250]
Manual removal of placenta, n (%) [N]	15 (6.0) [250]
Manual revision of uterine cavity, n (%) [N]	9 (3.6) [250]
Surgical time, (minutes), mean ± SD [N]	57 ± 21 [237]

SD: Standard Deviation; N: Number of patients with available data; BMI: Body Mass Index

Table 1: Baseline demographic and clinical characteristics.

Compliance with Study Protocol

No protocol deviations occurred during this study.

Primary Objective

Of the 250 patients evaluated, the incidence of wound complications including post-caesarean section surgical site infections (SSI) within the 30 (±10) days after caesarean section was 4.0% (n=10, 95% CI [2.1%, 7.3%]). Of the SSIs recorded, there was one organ/space SSI or endometritis case (10.0%), while the remaining 9 (90%) were superficial incisional site infections (9/250, 3.6%, 95% CI [1.8%, 6.8%]). Neither primary and secondary deep incisional SSIs, nor severe complications of endometritis occurred (0/250, 0%, 95% CI [0%, 1.8%]), (Table 2).

SSI classification	[N=10]	CI (95%)
Organ/space surgical site infections or endometritis, n (%) [N]	**1 (10.0) [10]**	**<0.0 - 42.6**
Superficial incisional SSI (involving the skin and subcutaneous tissue), n (%) [N]	**9 (90.0) [10]**	**57.4 - >99.9**
Primary	1 (11.1) [9]	<0.0 - 45.7
Secondary	2 (22.2) [9]	5.3 - 55.7
NA	6 (66.7) [9]	35.1 - 88.3

CI, confidence interval; NA, not available

Table 2: Classification of wound complications.

Secondary Variables

During the wound healing assessment, it was observed that post-surgery complications occurred in 11 patients (11/250, 4.4%, 95% CI [2.4%, 7.8%]). The reasons for wound healing complications in descending order were seroma (5/250, 2.0%, 95% CI [0.7%, 4.7%]), skin temperature (3/250, 1.2%, 95% CI [0.2%, 3.6%]), oedema (2/250, 0.8%, 95% CI [0.0%, 3.1%]), and haematoma (1/250, 0.4%, 95% CI [0.0%, 2.5%]). Within 30±10 days after caesarean section, 4 of the 250 patients required blood transfusions (1.6%, 95% CI [0.5%, 4.2%]). The mean length of hospital stays in the 250 patients included in the study was 3.5 days ± 3.5. No patients required reoperations within the 30 days ± 10 after caesarean section. Four patients (1.6%) were readmitted due to endometritis, fever of unknown origin, puerperal fever, and surgical wound infection complicated by sepsis. The mean length of readmission hospital stay was 7.3 days ± 9.4. Within 30 days ± 10 after caesarean section, 4 of the 250 patients (1.6%) required blood transfusions. Of the 250 patients included in the study, none suffered adverse device effects (ADEs) within 30 days ± 10 after caesarean section.

Discussion

Caesarean delivery plays a vital role in modern obstetrics, saving lives and improving outcomes for mothers and neonates. A significant complication following caesarean delivery is SSI, affecting up to 15% of cases [2,3] . This complication is a leading cause of extended hospitalisations and increased healthcare costs. Several factors influence the development of SSIs following caesarean delivery with varying levels of supporting evidence [2,4, 16]. Preoperative considerations include glycaemic control, skin cleansing practices, hair removal techniques, and the selection of prophylactic antibiotic regimens. Intraoperative factors involve the type of skin incision and closure, closure of the subcutaneous space, and the use of negative pressure wound therapy. Postoperative antibiotics and the timing of dressing removal are also under evaluation. Additionally, patient-specific risk factors contribute to SSI development. These factors include, but are not limited to, perioperative hyperglycaemia, smoking status, obesity, nutritional status, subcutaneous tissue thickness exceeding 3 cm, the presence of a concurrent infection at another body site, vaginal colonisation with pathogenic bacteria, ASA physical status classification, immunodeficiency, and MRSA status [2,4].

In our investigation, we assessed the use of PGLA 910 sutures for uterine closure in 250 women for elective, in labour or urgent caesarean delivery. SSI was reported only in 10 (4.0%) women, an in 9 (3,6%) of them the cases were superficial SSI. Only one organ/ space SSI or endometritis **(**0.4%) was reported, and it was resolved after a readmission. When comparing baseline characteristics of our study population to those reported by Koroglu et al. [15], both groups had a similar Body Mass Index (BMI), while our patients were on average older. Overall, the two populations are comparable including the post-caesarean closure techniques. In their study, Koroglu et al. [15] reported an overall superficial SSI rate of 18.9% (n=20 women), being 10.6% (n=11) in the PGLA sutures group, therefore higher than our SSI rate. Neither primary and secondary deep incisional SSIs, nor severe complications were reported in their study [15]. The authors found that superficial wound SSI was not affected by the type of suture (p = 0.642) [15].

Another randomised trial done with 851 women found that the combination of subcutaneous fascia closure with an absorbable PGLA 910 suture (2/0 Vicryl®) and skin closure with an absorbable suture (3/0 Caprosyn™) may be associated with an increased risk of reported wound infection after caesarean section when compared to skin closure with non-absorbable sutures (Prolene™) and subcutaneous fascia closure [17]. Overall, it is considered that there is no sufficient information available to describe the most appropriate uterine incision, and the optimal suture material or technique for uterus closing [10]. The impact of deeper tissue closure technique on SSI rates following caesarean delivery remains relatively understudied, and most current research primarily centres on evaluating the impact of skin closure techniques on the development of surgical site infections (SSIs). For instance, Buresch et al. [18] **assessed the closure of the** skin after caesarean delivery with poliglecaprone 25 sutures, showing a decreased rate of wound complications compared with polyglactin 910 sutures [18].

In conclusion, this study provides essential information about the performance of polyglactin 910 sutures in clinical practice for undergoing uterus closure in caesarean section. The results reached in this study are in line with those obtained in previous clinical studies. This result should be interpreted with caution as the study population came from only one hospital site, which may give ambiguous information about current clinical practice for a general population in Spain. Retrospective non-randomised studies play a crucial role in understanding real-world practice, particularly for investigating the effectiveness and safety of interventions in the context of everyday clinical settings. While these studies can generate valuable preliminary data and hypotheses, their inherent limitations necessitate acknowledging the potential for bias and the need for complementary methodologies to gain a more robust understanding of the investigated phenomenon. It is of vital importance to continue with the development of new studies with this specific indication in a larger number of patients.

Conclusion

Our study indicates that using PGLA 910 sutures for uterine closure during caesarean sections is associated with a low incidence of surgical site infections (SSIs), with our patient population experiencing a lower SSI rate compared to previous reports. Despite these promising results, the ongoing debate in the literature and the absence of a universally accepted protocol highlight the need for further research. We recommend conducting well-designed randomised controlled trials to definitively assess the impact of suture materials and closure techniques on deeper tissues following caesarean delivery.

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