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Incidence of wound complications in cesarean deliveries following closure with absorbable subcuticular staples versus conventional skin closure techniques

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ABSTRACT

Objective: To determine if there is a significant difference in composite wound complications among traditional closure techniques versus absorbable subcuticular staple closure.
Study design: This study is a retrospective cohort study of cesarean sections performed from January through September of 2014. Composite wound complications included surgical site infection, separation, and fluid collection. Medical records were reviewed and data including the patient demographics, comorbidities, closure type and wound complications were recorded. Patients with incomplete data were excluded. Data were analyzed with ANOVA or Fisher exact test, according to data type.
Results: Of the 186 patients identified, 176 patients were included in the data analysis ($n = 83$ suture, $n = 49$ traditional staple, $n = 44$ the absorbable subcuticular staple). The groups were similar in all demographic categories; labor prior to delivery, estimated blood loss, and medical and pregnancy related comorbidities. The overall incidence of wound complications at our institution during this study was 5.7%. The incidence of complications among the suture and subcuticular staple closure was not significantly different (3.6% versus 0%, $p = 0.3$), however there were significantly less complications in the suture and subcuticular staple closure groups when compared to traditional staple closure (14.3%) ($p = 0.03$ and $p = 0.01$, respectively).
Conclusion: Herein, we report a decreased incidence of composite wound complications with subcuticular staple closure versus traditional staple closure in patients undergoing cesarean section. Absorbable subcuticular staple closure represents a convenient, safe and cost-effective closure technique.

Introduction

Cesarean section is the most common surgery performed worldwide. As such, the incidence of this procedure is increasing, as is the number of patients having subsequent cesarean sections. Wound morbidity, including infection, separation, and fluid collection, is an expensive complication and poses a significant burden to the patient, affecting up to 16% of high risk patients undergoing cesarean [1]. Therefore, it is of importance to determine the most effective, and safest closure method with which to decrease patient morbidity. There exists in the literature a longstanding debate regarding the superiority of primary suture versus staple closure in terms of wound morbidity, closure time and aesthetics. Convincing arguments can be made for the use of both closure types in a variety of surgical settings and in patients with a wide array of medical comorbidities. However, a third option is currently available that may combine the benefits of both suture and staples, in the form of absorbable subcuticular staple closure.

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The available absorbable staple product is a self-contained sterile stapling unit that on manual compression of the device dispenses staples composed of polyactic/polyglycolic copolymer with a half-life of approximately 10 weeks, maintaining 40% of their tensile strength at 14 days [2]. This product everts the skin edges, delivering a subcuticular staple without puncturing the epidermis. The reported benefits of this type of closure include decreased tissue inflammation [3] and attenuated risk of skin contamination [4]. In studies comparing absorbable staples with suture closure there was a decreased incidence of wound infection and shorter intraoperative time [4], and in those comparing with traditional staples, decreased incidence of wound separation [4–6]. Currently there is no study comparing all three closure types in cesarean section. The purpose of the current study was to determine the incidence of composite wound morbidity among closure types at the time of cesarean delivery and to determine if absorbable subcuticular staple closure is a safe alternative to traditional closure types.

Materials and methods

This study was approved by the Institutional Review Board at Saint Luke's Hospital, Kansas City, Missouri as a retrospective cohort study of cesarean sections performed at the home institution. Data from consecutive cesarean sections among three services were recorded, including two private services and the service covered by the residency service, over a 9 month period from January to September of 2014. Although the distinction is made among private and resident service, this applies to the clinic in which patients receive their antenatal care; all cesarean sections are performed with resident as the primary surgeon with attending physicians that also cover their own services and the resident service at night and on the weekends. The primary resident physician is primarily a first or second year resident, with senior level resident or attending first assistant. Closure type was based on preference of the surgeon. Sample size was determined using a power analysis with a set power of 80% and an alpha of 5%. This calculation indicated that approximately 40 patients in each group would be necessary to detect a 50% difference in composite wound complications among closure types based on data from a preliminary study and the incidence of wound complications at our institution. Data from the preliminary study was similar to what is presented in this report, with a significant difference in composite wound complications in the staple group compared to the other closure types, however demographic information had not been collected, and thus was incomplete for publication. Data was collected over a 9 month time period to account for an N of 40 in the smallest group. Composite wound complications included surgical site infection, wound separation, and fluid collections including seromas and hematomas. As this was a retrospective study, uniform objective measurements were not available. Reliance on documentation in each patient's chart was necessary for diagnosis of these pathology. Therefore wound infection was defined as either a positive wound culture or physician perception of infection based on appearance of the wound as erythematous with purulent discharge with accompanying antibiotic treatment; appearance of isolated cellulitis was not recorded as a wound complication. Further, separation was defined based on documentation as such at the time of postoperative assessment including need for incisional packing with healing by secondary intention. Fluid collection was defined by subjective appearance of the wound at the postoperative assessment with indurated region with drainage of either serous or sanguinous fluid. In a previous study at our institution including 970 consecutive cesarean sections, the incidence of composite wound complications was 5.2% (unpublished data). Medical records were reviewed and data including the patient demographics, comorbidities, pregnancy complications, closure type and wound complications at post-operative assessment were recorded. The postoperative day of staple removal was also noted. Patients with incomplete data or those who were seen at an outside facility for postoperative follow-up were excluded ($N = 9$). Further, patients with negative pressure wound systems were excluded ($N = 4$). Data analyses were performed using the statistical software package, SAS 9.4. Continuous demographic data were analyzed for homogeneity among groups using Student's t-test or ANOVA where appropriate; categorical data regarding composite wound complications (including infection, separation, seroma, and hematoma) were analyzed with Fisher Exact test. p value <0.05 is considered statistically significant.

Results

Over the course of 9 months, 186 patients were identified for inclusion in the study. Complete clinical data was available for 176 and were included in the data analysis, $N = 83$ for the suture closure group, $n = 49$ for the traditional staple closure group and $N = 44$ for the absorbable subcuticular staple closure group. On average, staples were removed on postoperative day number seven (± 1.3 d). The groups were similar in age (27 ± 6, 28 ± 6, 31 ± 5), BMI (31 ± 6, 34 ± 9, 30 ± 7), gestational age at the time of delivery, parity, and number of previous cesarean deliveries. A greater proportion of patients with absorbable subcuticular staples were non-Hispanic white, with greater disparity between this group and the suture group, however this result was not statistically significant. In the data analysis hypertensive diseases (chronic hypertension, gestational hypertension, and preeclampsia) and diabetic diseases (preexisting and gestational) were analyzed both separately and grouped together due to the small incidence. The distribution of medical and pregnancy related comorbidities known to significantly affect wound healing, including hypertension and tobacco use, were similar. Diabetes, calculated as a combination of preexisting and gestational, was more prevalent in the traditional staple group, however this was not statistically significant. Because an urgently performed surgery and prolonged labor course are both independent risk factors for wound morbidity, labor prior to cesarean delivery was recorded. Although there was a larger percentage of patients who did not have labor prior to cesarean delivery in the absorbable staple group compared to the other groups, there was not a significant difference. Estimated blood loss was similar. The incidence of intrapartum infection was very low and not statistically different among groups (Table 1).

The overall incidence of composite wound complications in this study was 5.7%. The incidence of complications among the suture and subcuticular staple closure was not significantly different ($p = 0.3$), 3.6% in the suture group with no complications observed in the current study in the subcuticular staple closure group. There were significantly less complications in the suture and subcuticular staple closure groups when compared to traditional staple closure ($p = 0.03$ and $p = 0.01$, respectively). The composite incidence of wound complications in the staple group was 14.3% with the majority of reported complications listed as wound separations (Table 2).

Comment

The current study demonstrates that absorbable subcuticular staple closure is a safe alternative to traditional closure methods. To our knowledge, this is the first report comparing this closure method versus traditional closure with both subcuticular suture and staples in cesarean section, a clean-contaminated procedure. Consistent with previous studies, there was a higher incidence of

Table 1
Characteristics of study population.

Variable	Suture ($n = 83$)	Staple ($n = 49$)	Absorbable staple ($n = 44$)	p value
Age (y)	27 ± 6.4	28 ± 6.3	31 ± 5.3	0.697
BMI	31 ± 6.3	35 ± 9.9	30 ± 6.9	
BMI > 30	56.8	59.2	55.4	0.602
Ethnicity				0.083
White, non-Hispanic	36.9	57.1	68.1	
Black	38.1	22.4	11.3	
Hispanic	21.4	16.3	9.1	
Other	3.6	4.0	11.3	
Gravidity	2.1 ± 1.6	2.6 ± 1.9	2.6 ± 1.5	0.609
Parity	1.5 ± 1.2	1.6 ± 1.6	1.5 ± 1.5	0.911
Prior CD	1.7 ± 0.93	1.6 ± 0.73	1.6 ± 0.82	0.382
Gestational age	38.4 ± 2.9	38.5 ± 2.0	38.1 ± 2.7	0.625
Hypertensive disease	10.7	14.3	15.9	0.884
Diabetes	4.8	8.2	9.1	0.722
Tobacco use	13.1	14.3	15.9	0.169
Labor	45.2	55.1	31.8	0.269
Blood loss	713.0 ± 308.5	826.5 ± 348.7	802.3 ± 258.1	0.137
Chorioamnionitis	3.6	6.1	4.5	0.895

Data are presented as mean ± standard deviation, frequency (presented as %) and (n) unless otherwise specified. BMI, body mass index; CD, cesarean delivery.

composite wound complication observed in the traditional staple group, with wound separation representing the most frequently encountered complication [3,7–10]. Our noted complication rate is similar to what is previously published in the literature; 13% incidence associated with staple closure versus 5–6% with suture closure based on three separate published metaanalyses [8,9,11]. Subcuticular staple closure was similar to suture closure with significantly less complications compared to traditional staples.

While the retrospective design of the present study represents a limitation, the results do merit further investigation with a prospective study design. In the current retrospective design the presence of a wound complication was assessed only by what was documented in the patient's chart; patients were often diagnosed and treated clinically, rather than based on objective measurements such as a wound culture, or specific measurements of skin separation. There were several patients that did not present for follow-up in the suture closure group as they had received their prenatal care at an outside facility. Further, although statistical significance was achieved, secondary to the low incidence of wound complications and the small number of patients in each group, a larger sample size would lend further merit to the present findings as well as reduced potential confounding and bias. As such, there were no complications among the patients in the absorbable subcuticular staple group, resulting in the stark contrast presented herein. Further, although there was not statistical significance, the authors recognize that there may be a clinically significant difference in ethnicity among the populations studies, which could potentially contribute to the findings presented.

The currently available subcuticular stapling device is a novel closure device that has multiple advantages over traditional closure methods. Like traditional staples this device everts the skin edges for ideal approximation [12], however, although it punctures the dermis, the staples are delivered subcuticularly and thus do not puncture the epidermis leading to decreased inflammatory response and reduced risk of skin contaminants reaching the deeper portions of the wound [13,14] which is a major consideration in the obstetric field in which procedures may be performed emergently without thorough abdominal preparation or in patients with evidence of current intrauterine infection. A number of studies have indicated that there are a higher number of wound infections in traditional staple versus suture closure [2,9,15], possibly secondary to the aforementioned exposure of skin contaminants. In fact, in both "clean" and in grossly "contaminated" procedures, there have been reports of significantly decreased wound infections using subcuticular staples [4]. Further, like traditional staples, subcuticular staples are individual clips that can be removed in isolation if areas of the wound need to be probed or left to drain, rather than disrupting the entire closure. The overall incidence of composite wound complications in the current study was 5.7%, with wound infection as a very small portion of these complications, and is not amenable to a subgroup analysis. Future studies comparing subcuticular staples compared to traditional closure methods focusing specifically on a reduction in wound infections in clean-contaminated procedures would be an important contribution to the field. This is especially significant when considering the nature of exposure of gynecologic and obstetric wounds to potential vaginal contaminants and in patients with compromised immunity in both pregnancy and gynecologic malignancy.

Another potential advantage that traditional staples have over suture is rapidity of closure, which results in both cost and time savings [11]. This is of particular importance in the obstetric field as there are unique time constraints that exist when operating on patients under regional anesthesia and amidst busy services, with other potentially urgent and emergent situations demanding attention. Subcuticular staples can reduce operating time by up to ten minutes when compared to subcuticular suture [4,14]. Although this is a similar time reduction as published in studies comparing traditional staples to suture, the subcuticular staples can be applied with a single operator rather than two as with traditional staples. Assessment of the length of closure time would

Table 2
Comparison of composite wound complications among closure types.

Closure type	Complication rate	p value (versus staples)	p value (versus suture)
Suture	3.6	0.019*	
Staple	14.3		
Absorbable staple	0	0.006*	0.551

Data are presented as frequency (presented as %).
* p values for comparison to traditional staple or suture closure. $p < 0.05$ is considering statistically significant.

require a much larger sample size and was thus beyond the scope of the present study but could be addressed in a future prospective design as a secondary endpoint.

Cosmesis is yet another important consideration when choosing a closure method. Although a number of studies have indicated that cosmetic outcome is similar between suture and staple closure [9–11,16,17], there is concern for use of traditional staples is the appearance of "train track" punctures if staples remain in longer than 4–7 days. In the general population this can be avoided by timely removal, however in patients with significant comorbidities, such as morbid obesity, a longer duration of staple retention is often necessitated to ensure wound closure [18,19]. The use of absorbable subcuticular staples eliminates the concern for early removal or longer retention needed pending the patient population and has been demonstrated to have similar cosmetic outcome to traditional closure techniques [5]. Unfortunately, analysis was not possible in this retrospective study, but again, could be analyzed in a prospective design.

Wound complications are a significant cause of surgical-related patient morbidity. Given that cesarean section is only second to hysterectomy as the most common procedure performed worldwide, choice of closure technique in both obstetric and open gynecologic procedures has the potential to make a large impact on reduction of perioperative complications in this patient population. In this study we report that absorbable subcuticular staple closure offers a safe alternative to traditional closure at time of cesarean section.

Conflicts of interest

The authors have no conflicts of interest to disclose.

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