



# Maternal morbidity following caesarean deliveries with barbed suture for uterine closure

Raanan Meyer<sup>1</sup> · Nataly Sharon<sup>2</sup> · Eyal Sivan<sup>1,3</sup> · Michal Fishel Bartal<sup>4</sup> · Anat Kalter<sup>1</sup> · Estela Derazne<sup>3</sup> · Aviva Asher<sup>1</sup> · Arnon Afek<sup>3,5</sup> · Avi Shina<sup>1,6</sup>

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## Abstract

**Purpose** Information regarding the use of barbed suture in gynecologic surgery is limited. Our aim was to compare maternal morbidity following caesarean deliveries performed with barbed compared with non-barbed suture for uterine closure.

**Methods** A historical cohort study from a single tertiary institution. The study group composed of all women that underwent term, uncomplicated singleton caesarean deliveries, where uterine closure was performed with ETHICON's Stratafix<sup>®</sup>, a polydioxanone barbed suture, compared with caesarean deliveries where uterine closure was performed with ETHICON's VICRYL<sup>®</sup>, a Polyglactin 910 non-barbed suture. The primary outcomes were the rate of maternal morbidity including the rate of red packed cells transfusion and a composite of infectious morbidity. Operation duration was also evaluated. An analysis restricted to elective caesarean deliveries was performed comparing the suture types.

**Results** Three thousand and sixty patients were included in the study; 1337 in the study group and 1723 in the control group. There was no significant difference in the rate of the primary outcomes (red packed cells transfusion: 2.5% in the barbed suture vs. 2.1% in the non-barbed suture groups;  $p=0.47$ ; composite maternal morbidity: 3.8% vs. 4.8%, respectively;  $p=0.18$ ). Barbed suture was associated with reduced risk of postoperative ileus compared with the non-barbed suture (0.3% vs. 1.0%, respectively;  $p=0.02$ ) and a longer operation time (31 vs. 29 min, respectively;  $p<0.001$ ). In the analysis restricted to elective caesarean deliveries only the duration of operation remained significantly different between the groups.

**Conclusions** The rate of short term maternal morbidities among patients undergoing uterine closure with barbed suture during caesarean delivery is similar to the non-barbed suture.

**Keywords** Barbed suture · Blood transfusion · Caesarean delivery · Duration of operation · Maternal morbidity · Infectious morbidity

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✉ Raanan Meyer  
raananmeir@gmail.com

<sup>1</sup> The Department of Obstetrics and Gynecology, Chaim Sheba Medical Center, Tel Hashomer, Ramat-Gan, Israel

<sup>2</sup> The Department of Obstetrics and Gynecology, Assaf Harofeh Medical Center, Be'er Ya'akov, Israel

<sup>3</sup> The Sackler School of Medicine, Tel Aviv University, Tel Aviv, Israel

## Introduction

Caesarean delivery (CD) is one of the most common operations performed on women, accounting for up to 31.9% of deliveries in Europe [1–3]. Techniques used for each portion of the surgery, from skin incision to uterine closure, vary widely. Uterine closure techniques and the types of sutures

<sup>4</sup> Division of Maternal Fetal Medicine, The Department of Obstetrics, Gynecology and Reproductive Sciences, McGovern Medical School at The University of Texas Health Science Center at Houston (UT Health), Houston, TX, USA

<sup>5</sup> The Chaim Sheba Medical Center, Tel Hashomer, Ramat-Gan, Israel

<sup>6</sup> The Dr. Pinchas Bornstein Talpiot Medical Leadership Program, Sheba Medical Center, Tel Hashomer, Ramat-Gan, Israel

used differ between studies, with inconsistent results regarding infectious morbidity, duration of surgery and wound complications [4, 5].

Barbed suture has barbs facing a direction opposite that of the driving needle, creating an anchoring quality while requiring no knots when used for tissue approximation [6]. In the field of gynecologic surgery, barbed sutures have been used in minimally invasive myomectomy, hysterectomy and sacrocolpopexy as well as excision of ovarian endometriomas, showing reduced suturing time and blood loss [7–11].

There is limited evidence comparing the use of barbed with non-barbed sutures in caesarean uterine closure. Two randomized clinical trials showed that the use of barbed suture for uterine incision closure at caesarean delivery was associated with shorter uterine closure time and similar early perioperative complications compared with conventional smooth suture [12, 13]. As caesarean delivery, an increasingly common procedure is associated with relatively high maternal complication rates such as intraabdominal infection and haemorrhage, establishing which surgical suture decreases these complications is advantageous.

## Objective

The aim of our study was to assess haemorrhagic and infectious complications in women that underwent term, uncomplicated caesarean deliveries of singletons, where uterine closure was performed with a barbed suture compared with a non-barbed suture. We hypothesized that the rate of haemorrhagic complications with barbed suture will be lower compared with non-barbed suture, and the rate of infectious complications will be higher.

## Materials and methods

We performed a retrospective cohort study in a single tertiary center. The study group consisted of all patients that underwent CDs using a barbed suture for uterine closure (Stratafix®) between January 2016 to May 2017. The control group included patients that underwent a CD using a non-barbed suture (VICRYL®) between January 2015 to December 2015.

Prior to January 2016, CDs performed in our medical center were uniformly performed using the non-barbed type of suture. The barbed suture was introduced to our medical center in January 2016, and since then it became the default type of suture. Nevertheless, some surgeons have opted for the non-barbed suture after its introduction. To correctly identify the type of suture used in every case, we reviewed the CD mandatory surgical report to determine the suture type used for uterine closure.

Included in the study were patients with singleton pregnancy that had a CD at 37 + 0 weeks of gestation and later. Patients with multigestation pregnancies, preterm delivery, placenta accreta, clinical chorioamnionitis or fever up to 72 h prior to or during deliveries as well as non-low transverse uterine incision were excluded from the study. If a patient underwent more than one CD during the study period, only the last CD was included.

In the barbed suture group, a polydioxanone bidirectional barbed suture, size 2, with barbs facing opposite directions from the midpoint, mounted on taper point half circle 48 mm needle on each end for uterine closure was used. The suture is manufactured by ETHICON® under the commercial name Stratafix®.

In the non-barbed group, ETHICON's VICRYL®, a Polyglactin 910 braided suture, size 2, with one half circle 65 mm needle was used for uterine closure.

Skin preparation is uniformly done in our center with chlorhexidine for the abdomen and iodine for the vulva and vagina areas. All women receive standard prophylaxis (Cefazolin, 2 g IV) in the operating room before the initial surgical incision. Patients who are allergic to cephalosporins or penicillin receive clindamycin, 600 mg IV.

In the barbed suture group, the uterus was closed in a double layer technique. After passing one of the needles at one angle of the myometrial incision and adjusting the length of the barbed suture, the first layer was sutured with one of the two needles using a continuous, knotless technique. Upon reaching the opposing angle of the uterine incision, the first layer was completed by locking the suture in a backward fashion. The free edge of the suture was cut. The second layer was sutured as the first layer.

As for the non-barbed suture group, at our center, the two-layer continuous technique is most often used for uterine closure, with locking sutures for the first layer and non-locking technique for the second layer.

When additional sutures are required for adequate hemostasis of the uterine incision, a Polyglactin 910 braided suture, size 1, with one half circle 48 mm needle is usually used as interrupted sutures.

Details regarding patient demographics, pregnancy characteristics, labor charts, CDs details, postoperative follow up, neonatal characteristics and other data are thoroughly itemized by the operating room nurses and surgeons in a computerized database, allowing elaborate data abstraction of variables including suture type. Follow up for all outcomes concluded 6 weeks postoperatively.

The primary outcomes included red packed cells transfusion rates as well as composite maternal outcome of infectious morbidities (CMM) composed of any of the following: postpartum fever, wound infection, endometritis, abdominopelvic abscess, post-operative ileus, and septic pelvic thrombophlebitis. Fever was defined as

temperature  $\geq 38.0$  °C after post-operative day 1. Wound infection was defined as purulent drainage from skin incision, erythema or cellulitis after post-operative day 1. Endometritis was defined as the presence of at least two of the following: fever, uterine tenderness or purulent drainage from the uterus. Abdominopelvic abscess was defined as evidence of a fluid collection in the abdomen or pelvis found during relaparotomy or in imaging. Post-operative ileus was defined as abdominal distention with or without abdominal pain, inability to pass flatus, reduced bowel sounds or evidence in imaging  $\geq 24$  h postoperatively. Septic pelvic thrombophlebitis was diagnosed based on computed tomography using the standard criteria.

Other secondary outcomes included: duration of operation, calculated from time of birth to completion of skin closure; diagnosis of urinary tract infection, defined as culture proven bacteriuria; pneumonia; fever due to other etiologies; use of antibiotics due to suspected infection; abdominal reoperation; length of hospital stay after CD; emergency room visit after discharge; readmission to hospital.

As emergent CDs are a known risk factor for maternal infectious morbidity [14], we performed an analysis restricted to elective CDs. Elective CDs were defined as scheduled operations not in active labor. Emergent CDs were defined as unscheduled operations performed during labor, for obstetrical emergencies or after membrane rupture.

## Statistical analyses

### Sample size calculation

To compare red packed cells transfusion rate between barbed and non-barbed suture group assuming rates of 1% and 2.5%, respectively, at a significance level of 5% and a power level of 80%, a sample size (with continuity-correction) of 1329 in each group was required. To compare the CMM proportion between barbed and non-barbed suture group assuming rates of 8% and 5%, respectively, at the same significance and power as described above, a sample size of 1125 patients in each group was required. Thus, a sample size of 1337 and 1723 patients in the barbed and non-barbed suture groups was deemed adequate.

The sample size was calculated using WinPepi for windows version 11.63, copyright J.H. Abramson, May 15, 2016.

Categorical variables and outcomes of the two groups (barbed and non-barbed suture) were compared using Chi-square test or Fisher's exact test. *T* test was used to evaluate mean differences in continuous variables.

Logistic regression models were used to assess the relationship between the suture groups and binary outcomes adjusted for: age, body mass index, gestational age, CD group, rupture of membranes, pre-gestational diabetes

mellitus, antibiotics before CD, diabetes mellitus, endometriosis, gestational diabetes mellitus, full dilatation and operation duration, odds ratio (OR); 95% confidence interval (CI) and *p* value were presented. No collinearity was found among the independent variables, maximum VIF = 2.18 (antibiotics before CD).

As the duration of operation was not normally distributed, then median and 25th and 75th percentile were presented and Mann–Whitney test was used to compare between the two groups. The duration of operation was also dichotomized at  $<$  or  $\geq 30$  min (median value) and analyzed in a logistic regression model.

Statistical analysis was performed using the IBM SPSS Statistics for Windows, Version 24.0. Armonk, NY: IBM Corp.

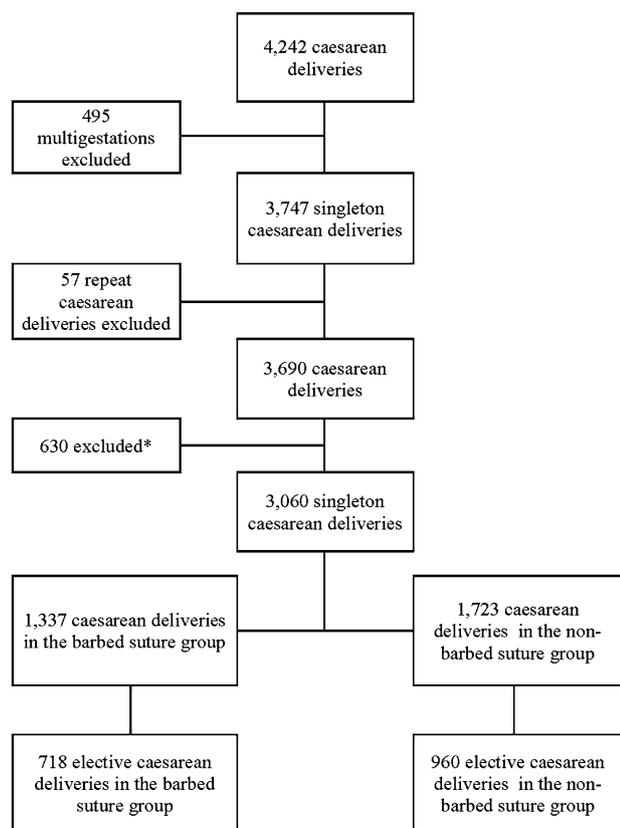
## Results

A total of 4242 CDs were performed using the non-barbed suture during 2015 and the barbed suture from January 1, 2016 to April 28, 2017 (Fig. 1). After excluding multiple pregnancies, patients that underwent more than one CD during the study period, preterm CDs, patients with pre or intrapartum fever, chorioamnionitis and placenta accreta, the cohort comprised 3060 patients. The barbed suture group included 1337 patients while the non-barbed suture 1723 patients.

Patient and caesarean deliveries characteristics are depicted in Table 1. There was no significant difference in baseline characteristics between the groups apart from the rate of prior CDs (46.6% in the barbed suture group, 50.8% in the non-barbed suture group;  $p=0.01$ ) as well as the primary indication for CD ( $p<0.001$ ). The rates of rupture of membranes prior to CD, rupture of membranes  $> 12$  h, complete dilatation of the cervix and use of antibiotics prior to the CD (attributed primarily to GBS prophylaxis) did not differ between groups. Neonatal weights and Apgar scores were similar.

There was no significant difference in the primary outcomes between the groups. The red packed cell transfusion rate was found to be 2.5% in the barbed suture versus vs. 2.1% in the non-barbed suture groups;  $p=0.47$ ). The CMM rate was 3.8% vs. 4.8%, respectively;  $p=0.18$  (Table 2).

Among the different components of the CMM, only the rate of post-operative ileus differed between groups and was significantly lower in the barbed suture group compared with the non-barbed group (0.3% vs. 1.0%, respectively;  $p=0.02$ ). The difference remained significant after multivariate analysis adjusted for confounders (adjusted OR 0.22; 95% CI 0.06–0.75) (Table S1). Among the secondary outcomes, the duration of operation was significantly longer in the barbed suture group (31 vs. 29 min;  $p<0.001$ ). In the multivariate



**Fig. 1** The study group makeup is portrayed. From 01 January 2016 (introduction of the barbed suture) to 28 April 2017, all patients who underwent caesarean deliveries where barbed suture was used for myometrical closure were compared to all caesarean deliveries performed during the year 2015. Four hundred ninety five multigestation deliveries were excluded. Among the 57 patients who underwent more than one caesarean delivery during the study period, only the last one was included. \* 630 additional patients were excluded: 502 patients with deliveries before completion of 37 weeks of gestation; 118 patients with a diagnosis of chorioamnionitis, fever up to 72 h prior to or intrapartum; 47 patients with placenta accreta (46 patients had more than one reason for exclusion)

analysis this difference persisted (adjusted OR 1.22; 95% CI 1.04–1.42) (Table S1). There were also significantly fewer cases of UTI in the barbed suture group compared with the non-barbed suture group, but this difference did not persist after multivariate analysis.

In the analysis restricted to elective CDs only (Tables 3, S2, S3) we found no differences in the primary outcomes between the groups (red packed cells transfusion 1.1% in the barbed suture group vs. 1.3% in the non-barbed suture groups;  $p = 0.80$ ; CMM: 3.1% vs. 4.7%, respectively;  $p = 0.09$ ). The CMM components did not differ significantly between the groups. Similarly to the analysis of the entire cohort, the duration of operation was longer in the barbed suture group compared with the non-barbed group (27 vs. 26 min;  $p = 0.003$ ). This also persisted in the multivariate

analysis (adjusted OR 1.31; 95% CI 1.06–1.61) (table S3). Other secondary outcomes in the sub-analysis did not differ between groups.

## Discussion

In this retrospective cohort study of low risk, singleton pregnancies undergoing caesarean deliveries, we found no difference in the risk of haemorrhagic or infectious maternal morbidity with the use of barbed suture in comparison with the non-barbed suture. The use of barbed suture was associated with reduced risk of postoperative ileus and longer operation duration.

This study is subject to several limitations. First, although our rates of packed red cell transfusion were as expected, we did document relatively low rates of infectious morbidity. Though these rates are in line with current findings in the literature, they may have limited the ability to detect between groups differences. Second, we could not account for all cases presenting to other health services after discharge from our hospital. It should be noted, however, that our patients are strongly encouraged to present for follow up to our medical center in the six postoperative weeks as needed. Third, as this is a retrospective study, temporal changes in practice may possibly explain some of the findings, although no relevant departmental changes in practice were introduced during the study period. Fourth, the exact rate of cases requiring additional sutures for uterine closure in each group was not available.

The strengths of the study include among others, the large sample of participants, whose characteristics are similar to other industrialized countries. Due to the study group size, we were able to perform an analysis restricted to elective deliveries, thus eliminating a major risk factor for postpartum complications, while adjusting for confounding variables for infection. Third, we were able to rigorously collect and abstract data regarding maternal morbidity while enabling for proper identification of the study groups. Moreover, over 9000 deliveries occur annually at our department. The CDs in our cohort were performed by surgeons with variable experience, both residents and specialists. This large diversity of surgeons with variable surgical experience enhances the generalizability of our findings. Incidentally, this may have inversely contributed to the counterintuitive finding of shorter operative time with the non-barbed sutures.

Only two previous studies compared knotless barbed suture to non-barbed suture for uterine closure in CDs. Zayed et al. reported that blood loss, length of hospital stay after CDs and operation time did not differ between the groups whereas the uterine closure time was significantly shorter in the barbed suture group [12]. Peleg et al. reported that uterine closure time was shorter and estimated blood loss

**Table 1** Maternal pregnancy and caesarean deliveries characteristics

	Barbed suture ( <i>n</i> = 1337)	Non-barbed suture ( <i>n</i> = 1723)	<i>p</i> value
Age (years)	33.62 ± 5.43	33.99 ± 5.49	0.07
BMI (kg/m <sup>2</sup> ) median	28.44 (25.65–32.00)	28.91 (26.11–32.27)	0.10
BMI (kg/m <sup>2</sup> ) groups			0.05
< 25	279 (21.1)	296 (17.4)	
25–30	517 (39.1)	726 (42.7)	
30–40	481 (36.4)	619 (36.4)	
≥ 40	46 (3.5)	59 (3.5)	
Number of prior deliveries	1.0 (0.0–2.0)	1.0 (0.0–2.0)	0.05
Prior CDs	619 (46.4)	875 (50.8)	0.01
Medical comorbidities			
Pre-gestational diabetes mellitus	13 (1.0)	9 (0.5)	0.20
Chronic hypertension	10 (0.8)	21 (1.2)	0.20
Endometriosis	16 (1.2)	14 (0.8)	0.36
Gestational comorbidities			
Gestational diabetes mellitus	186 (14.0)	259 (15.1)	0.41
GH or PET	46 (3.5)	70 (4.1)	0.39
Gestational age during CD	38.7 (38.1–39.7)	38.7 (38.1–39.4)	0.48
Mode of delivery initiation			< 0.001
Spontaneous	124 (9.3)	170 (9.9)	
Induction	167 (12.5)	181 (10.5)	
SROM	58 (4.3)	19 (1.1)	
Caesarean delivery	971 (72.6)	1322 (76.7)	
Other	17 (1.3)	31 (1.8)	
ROM before CD	350 (30.4)	437 (29.1)	0.47
ROM > 12 h	107 (9.3)	129 (8.6)	0.54
Full dilatation before CD	56 (4.2)	62 (3.6)	0.45
Antibiotics before CD	110 (8.2)	132 (7.7)	0.59
Urgency of CD			0.10
Elective	764 (57.1)	1050 (60.9)	
Emergent	537 (40.2)	628 (36.4)	
Unknown	36 (2.7)	45 (2.6)	
Primary indication for CD			< 0.01
Previous CD	533 (39.9)	775 (45.0)	
Maternal request	91 (6.8)	108 (6.3)	
Abnormal presentation	203 (15.2)	231 (13.4)	
NRFHR	212 (15.9)	191 (11.1)	
Failure to progress	108 (8.1)	129 (7.5)	
Other	162 (12.0)	247 (14.3)	
Unknown	28 (2.1)	42 (2.4)	

Data are mean ± standard deviation, *n* (%), or median (interquartile range). Percentages may not total 100 because of rounding

*SD* standard deviation, *BMI* body mass index at the time of caesarean delivery, *GH* gestational hypertension, *PET* preeclampsia, *CD* caesarean delivery, *SROM* spontaneous rupture of membranes, *ROM* rupture of membranes (before or during delivery, either spontaneous or artificial), *NRFHR* non-reassuring fetal heart rate

during incision closure was lower in the barbed suture group whereas total operating time did not differ between groups [13]. The aforementioned studies were of a relatively small sample size and their report about postoperative complications was limited. Our study adds to these previous works by

reporting extensively regarding postoperative haemorrhagic and infectious maternal morbidity.

No difference in packed red cell transfusion rates between the barbed and the non-barbed suture groups was found. Zayed et al. found no difference in transfusion rates albeit

**Table 2** Maternal outcomes

	Barbed suture ( <i>n</i> = 1337)	Non-barbed suture ( <i>n</i> = 1723)	<i>p</i> value
<b>Primary outcomes</b>			
Red packed cells transfusion total	34 (2.5)	37 (2.1)	0.47
Red packed cells transfusion during CD	7 (0.5)	9 (0.5)	> 0.99
Red packed cells transfusion after CD	28 (2.1)	32 (1.9)	0.69
CMM	51 (3.8)	83 (4.8)	0.18
<b>CMM components</b>			
Endometritis	8 (0.6)	4 (0.2)	0.14
Abdominopelvic abscess	5 (0.4)	5 (0.3)	0.76
Post-operative ileus	4 (0.3)	18 (1.0)	0.02
OVT	2 (0.1)	1 (0.1)	0.58
Wound infection	27 (2.0)	50 (2.9)	0.13
Fever	25 (1.9)	24 (1.4)	0.31
<b>Secondary outcomes</b>			
Duration of operation (min)	31 (24–39)	29 (22–38)	< 0.001
Post-operative antibiotics for infectious morbidity	67 (5.0)	97 (5.6)	0.47
UTI	6 (0.4)	21 (1.2)	0.03
Pneumonia or URTI	1 (0.1)	1 (0.1)	> 0.99
Fever due to other etiologies	2 (0.1)	1 (0.1)	0.58
Haemoglobin difference before-after CD	1.41 ± 1.24	1.39 ± 1.20	0.62
Re-laparotomy	3 (0.2)	7 (0.4)	0.52
Length of stay (days)	4.7 (4.0–5.2)	4.7 (4.0–5.2)	0.22
ER visit after discharge	144 (10.8)	159 (9.2)	0.16
Readmission to hospital	28 (2.1)	23 (1.3)	0.12
Readmission to hospital—OBGYN only	20 (1.2)	25 (1.9)	0.13

Data are *n* (%), mean ± standard deviation or median (inter quartile range)

*CMM* composite maternal morbidity including one or more of the following: endometritis, abdominopelvic abscess, post-operative ileus, ovarian vein thrombosis, wound infection or fever, *OVT* ovarian vein thrombosis, *CD* caesarean delivery, *UTI* urinary tract infection, *URTI* upper respiratory tract infection, *ER* emergency room

only one patient was transfused in the control group. Peleg et al. reported a difference of 50–100 ml in the estimated intraoperative blood loss between the two suture types, a finding of questionable clinical significance and in line with our findings [13]. We decided to evaluate red packed cells transfusion as a haemorrhagic outcome as it is of clinical significance and found transfusion rates that were in line with the current literature regarding CDs.

We documented a relatively low rate of postpartum endometritis (0.2–0.7%), in line with the recent publications [12, 15]. The relatively low incidence might be attributed to the use of strict defining criteria in our study, adherence to hospital protocol consisting of prophylactic antibiotic use during CDs as well as uniform and monitored surgical site and vaginal preparations.

It has been previously shown that the use of barbed sutures may reduce operative time and that the suturing technique is easy to learn [16]. Yet, we found slightly shorter operating times with the non-barbed suture. This finding

may be due to the inclusion of multiple surgeons with variable experience in both study groups as well as our definition of operation duration which was defined from the time of delivery to completion of skin closure.

Previous publications suggested that the proximity of the sharp barbs to bowel loops might cause obstruction or perforation [16]. We found that the risk of postoperative ileus was significantly lower in the barbed suture group. Fewer ileus cases may suggest lower inflammatory reaction with barbed sutures, promotion of wound healing, and positive affect on patient pain and recovery, in contrast to these previous publications [17, 18]. It must be noted, however, that the absorption time of the barbed suture is approximately three times longer than the non-barbed suture (180 vs. 56–70 days, respectively), causing potentially a longer and more robust inflammatory reaction [6]. Longer follow-up times may be needed in future studies in order to determine whether there is a difference in intestinal complication rates between the two suture types.

**Table 3** Maternal outcomes, elective caesarean deliveries

	Barbed suture ( <i>n</i> = 718)	Non-barbed suture ( <i>n</i> = 960)	<i>p</i> value
<b>Primary outcomes</b>			
Red packed cells transfusion total	8 (1.1)	12 (1.3)	0.80
Red packed cells transfusion during CD	4 (0.6)	2 (0.2)	0.41
Red packed cells transfusion after CD	4 (0.6)	11 (1.1)	0.21
CMM	22 (3.1)	45 (4.7)	0.09
<b>CMM components</b>			
Wound infection	12 (1.7)	27 (2.8)	0.13
Fever	11 (1.5)	14 (1.5)	0.90
Endometritis	5 (0.7)	3 (0.3)	0.30
Abdominopelvic abscess	2 (0.3)	3 (0.3)	> 0.99
OVT	2 (0.3)	1 (0.1)	0.58
Post-operative ileus	1 (0.1)	7 (0.7)	0.15
<b>Secondary outcomes</b>			
Duration of operation (min)	27 (22–34)	26 (21–33)	0.003
Post-operative antibiotics for infectious morbidity	29 (4.0)	47 (4.9)	0.40
UTI	1 (0.1)	9 (0.9)	0.05
Re-laparotomy	2 (0.3)	4 (0.4)	> 0.99
Pneumonia or URTI	0	1 (0.1)	> 0.99
Fever of due to other etiologies	2 (0.3)	1 (0.1)	0.58
Haemoglobin difference before and after CD (g/dL)	1.0 ± 1.0	1.0 ± 1.0	0.80
Length of stay (days)	4.1 (3.9–4.8)	4.1 (3.9–4.8)	0.12
ER visit after discharge	74 (10.3)	90 (9.4)	0.53
Readmission to hospital	15 (2.1)	14 (1.5)	0.33
Readmission to hospital- OBGYN only	13 (1.8)	12 (1.3)	0.35

Data are *n* (%), mean ± standard deviation or median (inter quartile range) where specified

*CMM* composite maternal morbidity including one or more of the following: endometritis, abdominopelvic abscess, post-operative ileus, ovarian vein thrombosis, wound infection or fever, *OVT* ovarian vein thrombosis, *CD* caesarean delivery, *UTI* urinary tract infection, *URTI* upper respiratory tract infection, *ER* emergency room

In Israel the barbed suture is approximately three times more expensive than the non-barbed one. Thus, using the barbed suture may be unjustified economically due our findings of similar haemorrhagic and infectious morbidity. The shorter operation duration with the non-barbed suture may be of no economical consequence.

## Conclusion

We found similar rates of maternal morbidity in CDs where uterine closure was performed with barbed type sutures, in comparison with CDs performed with non-barbed sutures. CDs performed with barbed sutures were associated with lower rate of postoperative ileus and longer operation time. Further, prospective studies are needed to evaluate the effect of barbed sutures on short and long term outcomes following CDs, considering the

current price difference between the sutures. Complications including adhesions formation, abnormal placental implantation and rate of uterine rupture should be studied.

**Author contributions** RM: project development, data collection and management, data analysis, manuscript writing and editing. NS: project development, data collection and management, manuscript editing. ES: project development, manuscript editing. MFB: project development, data management, manuscript editing. AK: project development, data collection, manuscript editing. ED: project development, data management, data analysis, manuscript editing. AA: project development, data collection, manuscript editing. AA: project development, manuscript editing. AS: project development, data collection and management, data analysis, manuscript writing and editing.

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## Compliance with ethical standards

**Conflict of interest** The authors report no conflict of interest.

**Ethical approval** The study was approved by the local institutional review board of the Sheba Medical Center, #3676-16-SMC, December 2016.

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