Efficacy of Different Uterine Compression Sutures in Controlling Excessive Uterine Bleeding during Caesarean Section

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<u>Abstract</u>

Introduction : Obstetric hemorrhage remains the leading cause of maternal mortality in both developed and developing countries. Postpartum hemorrhage is blood loss more than 500 ml in vaginal delivery and more than 1000 ml within 24 h in cesarean section. The objective of this study is to compare the safety and efficacy of Nausicaa and B-Lynch compressive sutures to control excessive uterine bleeding during cesarean section.

Methods: The study included 60 women suffering from excessive uterine bleeding during cesarean section in Ain Shams University Maternity Hospital, a tertiary referral center in Cairo, Egypt with annual rate of seven thousand cesarean sections per year Participants were randomly assigned to Nausicaa suture and B-Lynch suture done. The primary outcome was emergency hysterectomy.

Results : Nausicaa suture achieved hemostasis and prevented hysterectomy in 80% of allocated patients compared to 96.7% in B-Lynch suture. B-Lynch suture required shorter procedure time (7.2 \pm 3.3 vs16.1 \pm 4.9, 95% CI 6.8-11.2, p<0.001) compared to Nausicaa suture, with less blood loss in B Lynch suture (1473.3 \pm 429.9 ml vs1886.7 \pm 620.2 ml, 95% CI (6.8–11.1, p<0.001) compared to Nausicaa suture.

Conclusion: B-Lynch suture is more effective than Nausicca suture in controlling excessive uterine bleeding and preventing emergency hysterectomy during cesarean section.

Keywords: B-Lynch –Nausicaa suture –excessive uterine bleeding.

Introduction

Postpartum hemorrhage (PPH) remains the leading cause of maternal mortality in both developed and developing countries 1. Postpartum hemorrhage is blood loss more than 500 ml in vaginal delivery and more than 1000 ml within 24 h cesarean section 2. First-line treatment for PPH consists of conservative management with the use of uterotonic agents, bimanual uterine massage and early replacement of blood 3. If conservative management fails, second-line therapy is available including intrauterine balloon tamponades, uterine compression sutures and ligation of the uterine artery/internal iliac artery, If all of the previous mentioned uterine preserving managements fail, then a hysterectomy should be done 4.

Many attempts are tried to introduce surgical conservative compressive sutures to avoid hysterectomy 5. Many compressive suture techniques were introduced as B-Lynch, Hayman, multiple square sutures and Nausicaa 6,7. Further studies are needed to compare efficacy of different compressive sutures 8.

The study objective is to compare the efficacy of Nausicaa versus B-Lynch compressive sutures to control excessive uterine bleeding during cesarean section, and avoiding life -saving hysterectomy.

Materials and Methods

The study included sixty women suffering from excessive bleeding during cesarean section after failed medical management and uterine massage and according to eligibility criteria.

The study was conducted between March 2022 through October 2022 Ain Shams University Maternity Hospitals, Cairo, Egypt.

The study was approved by Medical Ethics Committee of Obstetrics and Gynecology Department at Ain Shams University (FMASU MD 250 on 25 /8/ 2019) to ensure following the standard ethical principles governing research involving human subjects.

Eligibility Criteria

Patients thought to be at potential risk of excessive bleeding during cesarean section, as mentioned above, were approached preoperatively. The study was explained to patients for possible inclusion if excessive bleeding occurs and female patients willing to participate were asked to sign a written informed consent. Trans test and well training of the surgeons to master the technique of Nausicaa suture was done.

Inclusion criteria

Women suffering from excessive uterine bleeding during cesarean section despite uterine massage and medical interventions.

Exclusion criteria

Cases of severe hemodynamic instability needing immediate hysterectomy, Placenta accreta spectrum, patients with coagulopathy, receiving anticoagulant therapy, cases with thrombocytopenia or thrombasthenia, distorted uterus as unicornuate, bicornuate, fibroid uterus and adenomyosis uteri.

According to RCOG green top guidelines in prevention and management of postpartum hemorrhage 5 baseline full blood count, blood group, ultrasound and cross matching four units of packed red blood cells, fresh frozen plasma and platelets were prepared for potentially eligible patients. Patients were transferred to operative room, put in flat position, anesthetized and foley catheter to monitor urine output was inserted. Standard protocol of cesarean section was performed with transverse lower uterine segment incision.

Once excessive uterine bleeding was encountered during cesarean, continuous monitoring of vital data, intravenous fluid infusion of 500 cc saline, uterine massage, administration of uterotonics (5 iu oxytocin slowly intravenous, 40 IU oxytocin (syntocinon® Novartis, Egypt) on 500 cc saline at 125ml/hr, 0.5 mg Ergometrine (Methergin® Novartis, Egypt) intramuscular injection were administered unless contraindicated, until bleeding was controlled and misoprotol (Misotac® Sigma, Egypt) 800 µgm rectally.

Those cases, in whom the above mentioned

measures failed to control the bleeding, were included into either intervention groups.

Randomization & Allocation concealment

Randomization was done using computer generated random sequence. Allocation concealment was performed using sixty opaque envelopes that were numbered serially, each denoted the allocated group, according to randomization table. When the first patient was included, the first envelope was opened and the patient was allocated according to the letter inside and so on for the rest of the study population.

Blinding

Patients, outcome assessors, data analysts were blinded to group allocation. The surgeon was not due to the nature of the procedure.

Intervention Groups

Group (A) women allocated to this group had Nausicaa uterine compression suture done.

Group (B) women allocated to this group had B-Lynch uterine compression suture done.

Nausicaa suture was applied by using round bodied, 3/8 circle curved needle, 70mm with 2-metric polyglactan suture (Vicryl®, Ethicon, USA). The needle was inserted as lateral as possible from the uterine serosa to inside the uterine cavity. The needle was then threaded along horizontally inside the uterine cavity and emerged at the other side of the uterine serosa. The sutures penetrated the full thickness of the myometrium without suturing the anterior and posterior walls together. A flat surgical knot was then tied well. To achieve a better hemostatic effect, the assistant often needed to clench the sutured myometrium while the surgeon tied off the knots. Additional sutures were made 1.5-2 cm parallel to the previous sutures until bleeding stopped 7. (Figure1).

The technique of this type uterine compressive suture was first described by Shih et al., 7.



Fig.1 Nausicaa suture figure by Shih et al., ⁷.

B-Lynch suture was applied by using round bodied, 3/8 circle curved needle, 70mm with 2-metric polyglactan suture (Vicryl®, Ethicon, USA) by starting in the uterus 3 cm from the right lower edge of the uterine incision and 3 cm from the right lateral border, then passing through the uterine cavity to emerge at the upper incision margin, 3 cm above and approximately 4 cm from the lateral border. It was passed over to compress the uterine fundus, then the suture was passed posteriorly and vertically to enter the posterior wall of the uterine cavity at the same level as the upper anterior entry point. It was pulled under moderate tension assisted by manual compression exerted by the first assistant. The surgeon passed the suture through posteriorly and vertically over the fundus to lie anteriorly and vertically compressing the fundus on the left side as occurred on the right. The needle passed in the same manner on the left side through the uterine cavity and out approximately 3



cm anteriorly and below the lower incision margin on the left side. The suture was tight, assisted by bi-manual compression to minimize trauma and to achieve hemostasis, and then, surgical knot was made 9. (Figure 2).

This procedure followed the steps described by Matsubara et al., 6



Fig. 2 B-Lynch suture figure by Matsubara et al., ⁶.

If either uterine compressive sutures techniques failed to control bleeding, 3rd line procedures were then attempted (systemic pelvic devascularization), then emergency life- saving hysterectomy was done.

All surgical procedures were done by the same team led by a senior obstetrician, with a wide expertise in performing complicated cesarean sections and surgical management of excessive bleeding during cesarean section and emergency hysterectomy.

In postoperative care, the patients were transferred to ICU or postpartum observation room with assessment of vital data every 15 minutes, postoperative hemoglobin, hematocrit level at 6 hours, day 1 and day 3 samples withdrawn 10, uterine contractility, urine output, vaginal bleeding were monitored.

The primary outcome was the need for

emergency hysterectomy. The secondary outcomes were the amount of blood loss assessed by number of soaked towels and suction titration), peripartum hemoglobin level drop (%) 6 hours post delivery and hematocrit value change (%), total blood loss (amount of blood loss included in soaked towels 'fill soacked 150 ml, half soacked 100ml' and suction titration number of received blood components (packed RBCsfresh frozen plasma and platelets), procedure time (minutes), need for devascularisation, ICU admission, venous thromboembolism (6weeks after delivery), postoperative fever (1week after delivery), hospital stay, number and cost of suture material used.

Statistical methods

Sample size justification

This is a pilot study, no previous published trials were retrieved from which power

calculation could be performed.

Arbitrary number of 60 cases will be included (30 cases in each group).

The collected data were coded, tabulated, and statistically analyzed using IBM SPSS statistics (Statistical Package for Social Sciences) software version 22.0, IBM Corp., Chicago, USA, 2013. Quantitative normally distributed data described as mean±SD (standard deviation) after testing for normality using Shapiro-Wilk test, then compared using independent t-test if normally distributed and Mann Whitney test if not normally distributed. Qualitative data described as number and percentage and compared using Chi square test and Fisher's Exact test for variables with small expected numbers. Logistic regression was used to find out factors affecting stress, depression and anxiety. The level of significance was taken at P value < 0.050 was significant, otherwise was non-significant

Results

The clinical characteristics of the patients

A total of 60 women were recruited in the current study, over the designated study

period, according to the shown participant flowchart (Figure 3).





Women in both groups were not different regarding their demographic and baseline characteristics as shown in Table (1).

Variables		Nausicaa (N=30)	B-Lynch (N=30)	P-value
Age	Mean±SD	26.3±3.7	27.0±3.6	0.500
(years)	Range	21.0-34.0	21.0-34.0	0.300
BMI (kg/m ²)	Mean±SD	26.8±1.7	27.9±2.9	0.467
	Range	23.7-38.2	24.5-35.8	
Parity	Median	2.0 (1.0-2.0)	2.0 (1.0-3.0)	0.735
	Range	0.0-5.0	0.0-4.0	
Previous	Median	1.0 (1.0-2.0)	1.0 (0.0-2.0)	0.836
CS	Rauge	0.0-5.0	0.0-3.0	
GA	Mean±SD	38.6±1.1	38.2±1.4	0.266
(weeks)	Range	35.0-40.0	35.0-40.0	
	DM	4 (13.3%)	3 (10.0%)	0.999
	GDM	3 (10.05)	2 (6.7%)	0.999
Comorbidities	HTN	4 (13.3%)	4 (13.3%)	0.999
	PIHTN	4 (13.3%)	4 (13.3%)	0.999
	Α	23 (76.7%)	23 (76.7%)	
Blood group	В	6 (20.0%)	5 (16.7%)	0.999
	AB	1 (3.3%)	2 (6.7%)	
RH	Positive	24 (80.0%)	7 (23.3%)	0.000
	Negative	6 (20.0%)	23 (76.7%)	0.999

Table (1): Baseline characteristics of the studied groups.

*DM:Diabetes mellitus *GA:Gestational age. *HTN:Hypertension. PIHTN: Pregnancy induced hypertension.

Study Outcomes

Procedure time and Number of suture material

Both groups used one suture ampoule of suture material. The procedure time for Nausicaa suture ranged from 5 to 22 minutes $(mean 16.1 \pm 4.9),$ while the procedure time in B-Lynch suture ranged from 4-20minutes(mean7.2±3.3) (95%CI 6.8-11, p-value <0.001). This was statistically significant. It is noteworthy that prior to the formal recruitment of the study cases, the team conducting the study trained on the Nausicaa suture being a relatively new procedure. The formal enrollment of cases in the study was started after the team felt confident they mastered the maneuver and were capable of performing it within reasonable time.

Efficacy of interventions in controlling bleeding

As the primary outcome of the study, the success rate Nausicaa suture to achieve hemostasis and prevent hysterectomy was 80%, compared to 96.7% in B-Lynch suture (RR 5.99, 95%CI -27.4%–99.2%, p- value 0.103). This was statistically non -significant.

Although, there is an obvious difference in number, statistical significance was not reached. This is due to the fact this is a pilot study, where no previous data were available to adequately calculate the sample size to achieve power regarding this outcome.

However, there was a significant difference between both groups regarding the need for devascularisation, in the form of uterine and internal illiac artery ligation, which was done in 11 cases in Nausicca group(36.7%) compared to 4 cases in B-Lynch group (13.5%) (RR 2.75, 95%; CI -7.9%-89.6%. p-value 0.037).

Intraoperative Blood loss and the need for transfusion

The baseline hemoglobin was not different between both groups (11.3 \pm 0,4 gm/dl for both group A and B). However, there was a statistically significant difference in the postoperative hemoglobin measured 6 hours postoperatively (8.9 gm/dl \pm 1.0 for group A versus 0.4 g/dl \pm 0.7 for group B, p=0.034).

Furthermore, the hemoglobin drop was more pronounced for group A (2.5 gm/ dl \pm 0.8) compared to group B (1.9 gm/ dl \pm 0.6). This difference reached statistical significance (p=0.004).Similar findings were also observed for the hematocrit values. Intraoperative blood loss was significantly higher among Nausicaa group than among B-Lynch group.

Blood loss ranged from 1000-3800ml in

Nausicaa suture and ranged from 800-2500 ml in B-Lynch suture (95% CI 137.6-689.1, p-value<0.001).

This was reflected on the need for blood transfusion. Fourteen cases (46.7%) of group A needed transfusion of blood products while six cases (6%) needed such transfusion in group B. This was statistically different (RR 2.33, 95%CI -1.6-83.7, p-value 0.028).

Regarding ICU admission, four cases (13.3%) required ICU admission in Nausicca suture group, while one case (3.3%) required ICU admission in B-Lynch group (RR 4, 95%; CI-122.9-98.9%). No cases of venous thromboembolism in both groups were encountered over a six week postpartum follow up period. Longer days of hospital stay was needed for Nausicaa group compared to B-Lynch group (Mean3.2 versus 2.2,95%; CI 0.4-1.5, p-value 0.001). However, there was no significant difference in both groups regarding postoperative fever (3 patients 10% in group A, versus 2 patients 6.7% in group B) (RR 1.5, 95%CI -370.7-92%, pvalue 0.999) (Table2).

Outcome	Nausicaa group	B-Lynch group	95% CI	P-value
Procedure time	mean16.1±4.9	mean7.2±3.3	6.8–11.1	< 0.001
Hysterectomy	6 (20.0%)	1 (3.3%)	-27.4%-99.2(RR5.99)	0.103
Devascularisation	11(36.7%)	4 (13.5%)	-7.9%-89.6(RR2.75)	0.037
Blood loss	1000-3800	800-2500	137.6-689.1	< 0.001
Hemoglobin drop	1.3–5.2	1.0-3.4	0.2–0.9	0.004
Hematocrit drop	3.8–15.2	2.9-10.0	0.5–2.7	0.005*
Blood transfusion	14 (46.7%)	6(6%)	-1.6-83.7(RR2.33)	0.028
ICU admission	4(13.3%)	1(3.3%)	-122.9-98.9(RR4)	0.353
Hospital Stay	Mean3.2	Mean2.2	0.4-1.5	0.001
Postoperative fever	3(10%)	2(6.7%)	-370.7-92	0.999

Table (1): Study Outcomes

Discussion

Obstetric hemorrhage remains the leading cause of maternal mortality worldwide 11. Most cases of excessive bleeding during cesarean section are controlled by conservative measures as uterotonics and uterine massage 12.

If excessive bleeding during cesarean section is still encountered, uterine compressive sutures with or without devascularization are done. However, if there is still ongoing bleeding the last resort will be life-saving cesarean hysterectomy 13.

The B-Lynch uterine compressive suture to control excessive uterine bleeding was first described by Christopher B-Lynch in 1997 and after that B-Lynch compressive suture became a popular surgical technique to control excessive uterine bleeding 14. A new compressive suture termed Nausicaa suture was first described by Shih et al. 7. who reported its efficacy in controlling postpartum hemorrhage. Few studies compared this type of uterine compressive suture to the other types. The current study was performed to compare Nausicaa suture and B-Lynch suture in their efficacy in controlling excessive bleeding during cesarean section.

Those women were randomized into one of 2 groups: Group (A) had Nausicaa suture applied while group (B) had B-Lynch suture applied.

To the best of our knowledge, there are no published studies comparing Nausicaa vs B-Lynch in controlling excessive bleeding during cesarean section. The available publishes studies mainly address B-Lynch suture and there is relative paucity of trials involving Nausicaa suture.

The study was performed in Ain Shams University Maternity Hospital during the period from March 2022 to October 2022. The study included sixty women who suffered from excessive uterine bleeding during cesarean section, not responding to uterine massage or maximum dose of ecbolics. In the current study there was no significant difference regarding age, BMI, gestational age number of previous caesarean sections or associated comorbidities between the 2 groups.

Our results showed that Nausicaa suture group achieved hemostasis and prevented hysterectomy in 80% of women compared to in 96.7% in B-Lynch suture group contrary to our results, Nausicaa suture prevented hysterectomy in 97% of participating women by Shih et al. 7 who first described this procedure may be due to difference in eligibility criteria as the cases of placenta accreta spectrum were not included in the current study. Similar to our results, B-Lynch suture achieved hemostasis and prevented hysterectomy in 100% and 96.8% of participating women in the study by Kalkal et al. 15 and Harma et al. 16 respectively.

In the current study, 36.7% of women Nausicaa suture in group required devascularization, while 4% of women in B-Lynch group required devascularization. No published studied was found mentioning the need for devascularization with Nausicaa suture. Conversely, 20% of women participating in B-Lynch group suture in the study by Sentilhes et al. 17 needed devascularization. This could be attributed to the difference in skills or indications of devascularization procedure.

We found that procedure duration was significantly longer among Nausicaa group than among B-Lynch group. Duration to perform B-Lynch suture in this study ranged from 4 to 20 minutes compared to procedure time of 5 to 22 minutes to perform Nausicaa suture. On the other hand, procedure time to perform B-Lynch suture was about 35 minutes by Abdelfatah et al. 18 and 4.7 minutes to 7.9 minutes by Karena et al. 19 this may be explained by the difference in training and skills for suture application. Procedure time to perform Nausicaa suture was about 20 minutes by Shih et al.7 which is close to our study.

The Blood loss in women who had Nausicaa suture in this study ranged from 1000-3800 ml compared to 800-2500 ml in women participating in B-Lynch suture group. On the other side, the blood loss in women who had Nausicaa suture done was 500-4100 in Shih et al. 7 Women had B-Lynch suture done in the studies of Gadappa et al. 20 and Tariq et al. 21 had blood loss of 1000-1500 ml. The difference in amount of blood loss may be attributed to the time of the decision of compression suture application. The time taken till decision for suture application plays a major role in the amount of blood loss consequently, the amount of blood transfused to the patients.

In the current study, hemoglobin drop was more significant in Nausicaa suture group compared to B-Lynch suture group. (2.5 gm%) which was in compared to (1.9 gm%) for women in B-Lynch group. This results go in agreement with Shih et al. 7 (hemoglobin drop for Nausicaa suture was 2.5 gm%) and Kalkal et al. 15 (hemoglobin drop for B-Lynch suture group was 2 gm%).

In our study, 14% of participating women in Nausicaa suture group required blood transfusion compared 20% of participating women in B-Lynch suture group. Contrary to our findings, 38% of women who had in Nausicaa suture in the study of Shih et al. 7 and 29% of women who had B-Lynch sutures in the study by Koh et al.22. Received blood transfusion. This may be due to difference in protocol of initiation of blood transfusion in different centres.

In the current study, four women (13%) in Nausicaa suture group required ICU admission compared to one woman (3.3%) in B-Lynch group. On the other hand, eight women (11%) required ICU admission in Shih et al. 7 and three women required ICU admission in B-Lynch group (17%) in Harma et al, 16 study. This may be due to difference in protocol of ICU admission among different hospitals. Based on the results of this study, B-Lynch suture seems more effective than Nausicca suture in controlling excessive uterine bleeding during cesarean section and avoiding the need of hysterectomy. Also, B-Lynch suture requires shorter procedure time with less blood loss compared to Nausicca suture, which is of critical value during these life threatening situations.

Among the points of strength of the current study is its randomized controlled design that it was strictly adherent to during its performance.

Additionally, it was conducted at a tertiary center, well equipped to deal with such complex and emergent cases.

Furthermore, it is the only published trial. According to our latest literature search comparing Nausicaa compressive suture to the widely spread B-Lynch suture.

Points of limitations include its single center performance, for which we hope to recruit other centers in a multicenter trial. Also, the study was powered to detect the primary outcome of achieving hemostasis and avoidance of hysterectomy, but not to detect other rare outcomes as maternal mortality. Lastly, Long term impact of other morbidities and effect of such compressive sutures on fertility needs longer follow up. Also it is a pilot study and there were no available published results to calculate the needed sample size upon. So, an arbitrary number of 30 cases per group was adopted. Based on the findings of our study, we suggest that adequately powered studies be conducted based on sufficient sample size calculation. These points should be considered before generalizability of our findings to be implemented.

Conclusion

B-Lynch suture is more effective than Nausicca suture in controlling excessive uterine bleeding during cesarean section and avoiding the need of hysterectomy. Also, B-Lynch suture needs shorter procedure time with less blood loss compared to Nausicca suture, which is of critical value during these life threatening situations.

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Author Contributions

Conception of ideas and study design & study design by Mohamed Hamed Salama, (Orcid ID : 0000-0002-3951-6499) performance of surgical interventions by Ahmed Mohamed Zeinhom (Orcid ID : 0009-0006-3195-3885), Ahmed Mohammed Selim (Orcid :0009-0009-9494-2456) and Amany Salah eldin Abdelhafeez abdelhady, Manuscript preparation Mohamed Hamed Salama & Amany Salah eldin Abdelhafeez abdelhady (Orcid ID : 0009-0008-7422-5954) under supervision of Amr El Helaly (Orcid ID: 0000-000304134-1146) and Noha Rabie(Orcid ID : 0000-00030202-2679).

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Protocol Registration

The study protocol was registered at clinicaltrials.gov (NCT 05270473).

Availability of Data and Materials

All data generated or analyzed during this study are included in this article and supplementary information file. Data sets are available on Harvard Dataverse <u>https://doi.org/10.7910/DVN/KVMW95.</u>

Declarations

Ethical Approval and consent to participate

The study was approved by Medical Ethics Committee of Obstetrics and Gynecology Department at Ain Shams University (ID: MD250/2019) to ensure following the standard ethical principles governing research involving human subjects. Written and oral informed consent was obtained from all individual participants included in the study.

Consent for publication

The manuscript is approved by all authors for publication.

Competing interests

No conflict of interest for all authors.

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