Adjunctive Uterine Incision Compression Versus Tourniquet Alone for Reduction of Blood Loss During Abdominal Myomectomy: A Randomized Controlled Trial

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Summary

Introduction: The effectiveness of the uterine tourniquet alone for securing hemostasis during abdominal myomectomy remains debatable; however, its combination with uterine compression though popular has very scanty documented evidence of hemostatic efficacy. **Aim:** To determine the effect of uterine incision compression (UIC) combined with tourniquet on operative blood loss associated with abdominal myomectomy. **Materials and Methods:** A multicenter randomized double blind, controlled trial involving 184 participants randomized into two groups: 92 in the UIC and 92 in the control arm. UIC was administered in the interval from release of the uterine tourniquet to palpation of contraction. Data were analyzed using the Statistical Package for the Social Sciences (SPSS), version 21. **Results:** The mean intraoperative blood loss was lower in the UIC group (951.41 ± 362.32 mL) than in the control group (1051.30 ± 427.77 mL), but did not reach statistical significance (p = 0.125). The observed mean duration of myomectomy was, however, longer among the controls (152.95 ± 32.67 min, compared with 119.70 ± 23.96 min, p = 0.001). The control group also had significantly higher rates of deployment of additional hemostatic measures (OR = 4.68, 95% CI = 2.304–12.784, p = 0.001), occurrence of postoperative pyrexia (OR = 1.65, 95% CI = 1.256–2.154, p = 0.002), and greater mean postoperative blood loss (p = 0.003). **Conclusion:** Although no statistically significant difference occurred in intraoperative blood loss, adjunctive UIC was useful in reducing operating time and postoperative blood loss.

Keywords: Compression, Hemorrhage, Incision, Myomectomy, Tourniquet

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Introduction

Abdominal myomectomy is presently the commonest route for myomectomy globally (1). Late, often bizarre, presentations with huge masses and pressure complications make the abdominal route very important for myomectomy among African populations of women in the child bearing age that are desirous of fertility preservation (2). The abdominal approach remains the best option for complex and large fibroid masses (3).

Heavy intraoperative hemorrhage during myomectomy increases the risk of conversion to hysterectomy, thus negating the fertility preservation reason for the myomectomy in the first place. Excessive bleeding also increases the risk of intraoperative blood transfusion; as high as 20–58% intraoperative transfusion rates have been observed in patients undergoing abdominal myomectomy (4). Hemorrhage is also a recognized trigger for all the other complications of myomectomy, which include postoperative pyrexia, postoperative adhesions leading to intestinal obstruction, chronic low back pain, and infertility. Attempts to control heavy bleeding may result in injury to contiguous structures such as the ureter, bladder, and bowel. Hemorrhage may also prolong the duration of surgery and increase the risk of venous thromboembolism and complications of anesthesia (4). There is presently no consensus on the best method to reduce hemorrhage during myomectomy (5).

Tourniquet use for abdominal myomectomy remains a common practice in Nigerian hospitals (6, 7). The Foley catheter tourniquet which is commonly used is cheap, readily available, does not consume space and is easy to apply around the uterus at the level of the isthmus (6).

Studies on adjunctive hemostatic measures for myomectomy have continued to evolve globally, some adjunctive to tourniquets and others adjunctive to pharmacological agents. This is not unconnected with the low quality of evidence, the variations in methodologies, and contrasting results from research involving tourniquet use in ways that are cumbersome and not commonly practiced in the low resource settings where fibroids are prevalent and myomectomy is common (5, 8–10).

Although the tourniquet provides good hemostasis and a clear operating field during myoma enucleation, it is limited by its inability to produce continuous hemostasis after tourniquet removal because a variable lag in time from release of the tourniquet to uterine contraction exists. Uterine contraction is required for cessation of bleeding from the myoma bed from where fibroids have been removed. This time lag may be a critical determinant of blood loss with risk of blood transfusion, infection, adhesion formation, and even hysterectomy (11).

Uterine contractility is a very important phenomenon, required for cessation of bleeding. The vascular occlusion that stops bleeding depends largely on myometrial contraction against the vessels that run through the uterus in different fashion to achieve hemostasis. In myomectomy, uterine re-perfusion after tourniquet release precedes contraction, which is required for the living ligature to be set in action. Apart from filling up the myometrial microvasculature, re-perfusion also results in the delivery of endogenous oxytocin, platelets, and clotting factors. Reduced capillary hydrostatic pressure from the incision sites would lead to bleeding, until when this pressure becomes equal with or exceeds the re-perfusion pressure. This is what is aimed at when exogenous uterotonic agents, vasoconstrictors, and when uterine suturing is done during surgery on the uterus. Bimanual compression of the incision site would, in addition to enhancing platelet aggregation, sustain greater vascular hydrostatic pressure at the incision end of the re-perfusion cycle, allowing for contraction to occur and ultimately hemostasis. This is the principle applied during the brace (compression) sutures for the management of postpartum hemorrhage (12).

UIC is cheap, easy to apply, does not involve any drug, or does not require specialized training. Bimanual uterine compression is commonly done in the setting of this study, but claims of its effectiveness for hemostasis are largely anecdotal, as there is no literature description of a standardized method of application of this measure or its effectiveness in hemorrhage control during abdominal myomectomy.

This study therefore aims to determine the effect of adjunctive uterine incision compression (UIC) on blood loss, duration of surgery, and operative morbidities associated with abdominal myomectomy.

Materials and Methods

The study was a randomized double blind, controlled, clinical trial conducted at the three tertiary level hospitals in Ogun State, Nigeria namely, Babcock University Teaching Hospital (BUTH), Ilisan-Remo, Olabisi Onabanjo University Teaching Hospital (OOUTH), Sagamu and the Federal Medical Centre (FMC), Abeokuta. Participant recruitment, collection, and analysis lasted for 12 months.

The primary outcome variable was the mean intraoperative blood loss (IBL) in milliliters. In a randomized control trial (RCT) involving the application of pericervical uterine tourniquet for myomectomy by Taylor et al. (8), the standard deviations of the mean IBL obtained for the tourniquet group (362 mL) and 1241 mL for the control group were applied to the formula for estimation of sample size in clinical superiority parallel RCTs (13). The type I error was set at 0.05, corresponding to 1.96, while the type II error was set at 0.8. For the findings of this study to be attributable to UIC, the mean difference in IBL between intervention (UIC + tourniquet) and control (tourniquet alone) was set at 500 mL.

Thus

$$N = 2 \times \left(\frac{z_{1-\alpha} + z_{1-\beta}}{\delta - \delta_0} \right)^2 \times s^2$$

Thus, $N = 2 \times \left[\frac{1.645 + 0.845}{500} \right]^2 \times 362^2 + 1241^2$

$N = 165.8$.

Thus, to achieve the set objectives, the minimum sample size N for this study is 166 (intervention = 83, and control = 83).

To adjust for attrition due to withdrawals or dropouts, the prevalence (P) of uterine fibroid of 9.3% of all gynecologic admissions obtained in Ile-Ife (14), a similar town in southwestern Nigerian, was applied to the formula for sample size adjustment (15); thus

$N^* = N/(1 - P)$

$N^* = 166/0.907$

$N^* = 184$

Patients aged 18–45 years, with uterine fibroid necessitating abdominal myomectomy, were included, while the exclusion criteria were as follows: history of coagulopathy, heart disease, myocardial infarction, hypertension, endometriosis, diabetes, sickle cell disease, kidney disease, preoperative packed cell volume (PCV) <30%, patients with thromboembolic disease or on anticoagulants, previous myomectomy, and patients with a history of previous extensive pelvic surgery or features suggestive of pelvic adhesions. Patients with entirely subserous fibroid, not requiring myometrial incision, and those who have been treated with gonadotropin-releasing hormone (GnRH) analogs were also excluded from the study.

Ethical clearance was obtained from the institutional review board of the BUTH with protocol number: BUHREC002/21, and permissions obtained from the other two participating hospitals after review by their ethical review committees: FMCA/470/HREC/02/2021/02 (FMC) and OOUTH/HREC/391/2001/AP (OOUTH). The study was registered with the Pan African Clinical Trial Registry (PACTR) with protocol number: PACTR202106887906354.

The participants were informed about the study, using the participant information sheet and a signed informed consent obtained before recruitment. They were allocated into groups using computer-generated random sequence of numbers, obtained by a statistician, with a set coding for UIC, while another coded for the controls. Recruitment stopped when all of the code numbers for randomization had been used.

Protocol for abdominal myomectomy

The anterior abdominal wall was prepared aseptically after anesthesia had been administered, appropriate incision depending on the uterine size was made, and developed up to the peritoneal cavity, securing hemostasis along the way. The bowel loops were packed

with saline moistened and tagged abdominal towels. The uterus was then mobilized and delivered into the incision. A size 18-Fr Foley's catheter was then applied at the level of the uterine isthmus circumferentially, and tied anteriorly using one knot, to occlude the uterine arteries and a curved size No. 3 artery forceps was used to hold the two limbs of the catheter immediately distal to the knot, to aid easy release at hourly intervals. A modification of the tourniquet application methods by Ikechebelu et al. and Taylor et al., was thus used (6, 8). Uterine incision was made to aid easy enucleation of the fibroid nodules from the pseudo-capsule, while preference was given to anterior incisions. A myoma screw was used to aid dissection of the myomas off their beds and the dead spaces so created were closed in layers. Warm normal saline was instilled during dissection to prevent desiccation and used to lavage the peritoneum after completing the procedure, to remove tissue debris and prevent adhesion formation. The total volume of fluid used to wet the abdominal towels and for irrigation was subtracted from the measured IBL at the end of the surgery. Closure of the abdomen was done in layers. Perioperative prophylaxis for deep venous thrombosis was done with enoxaparin, with dosage depending on the patient weight. Antibiotic prophylaxis was done with a combination of co-amoxiclav and metronidazole for broad spectrum coverage. Postoperative analgesia was with a combination of diclofenac, pentazocine, and acetaminophen.

Protocol for UIC (the intervention)

Bimanual UIC was performed by applying the palmar aspect of both hands to cover all the uterine incisions and compressing the uterus at the same time. This was done immediately after completion of closure of dead spaces by repairing the myometrium in layers with absorbable sutures and release of the pericervical uterine tourniquet. The uterus was covered with a warm moist abdominal towel and grasped between the two hands of the surgeon such that the incisions are compressed as soon as the uterine hemostatic tourniquet was released. The pressure on the incisions was maintained until uterine re-perfusion (as evidenced by uterine contractions) was achieved, by palpating contractions around the incisions before the compressing hands were removed (Figure 1).

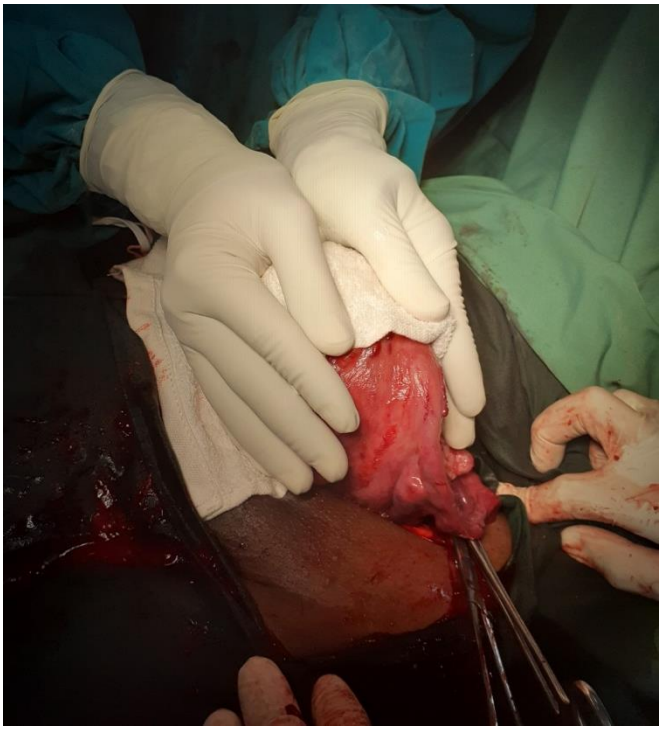

Figure 1. Method of application of the uterine incision compression for abdominal myomectomy.

The uterus was then observed for any more bleeding from the uterine incision sites. The control group had their usual myomectomy, but without compression of the incision site(s) after release of the uterine hemostatic tourniquets. All other aspects of the surgery, namely, prevention of adhesions and abdominal wall closure, was done in the usual way. Administration of uterotonic agents, or antifibrinolytic agents, or vasopressin, or placement of the extra figure of eight uterine sutures or other measures of securing hemostasis, including peritoneal drain placement, were determined by the presence of continued bleeding from the incision sites. Continued bleeding was defined as bleeding from the incision site despite UIC, observed after removal of the compressing hands, or after tourniquet removal in the control group. The presence of continued bleeding in the control group was managed by administration of uterotonic agents, or antifibrinolytic agents, or vasopressin, or placement of the extra figure of eight sutures and bimanual UIC if the above measures failed.

Uterine compression was applied for a further 5 min after tourniquet removal, if all measures above failed to achieve the desired hemostasis. UIC was also repeated for participants in the UIC group observed to start bleeding again after completion of the initial UIC. Hysterectomy in both groups was to be determined by the presence of persistent uterine bleeding despite the use of the usual measures for hemostasis during abdominal myomectomy. There was, however, no case of hysterectomy in this study.

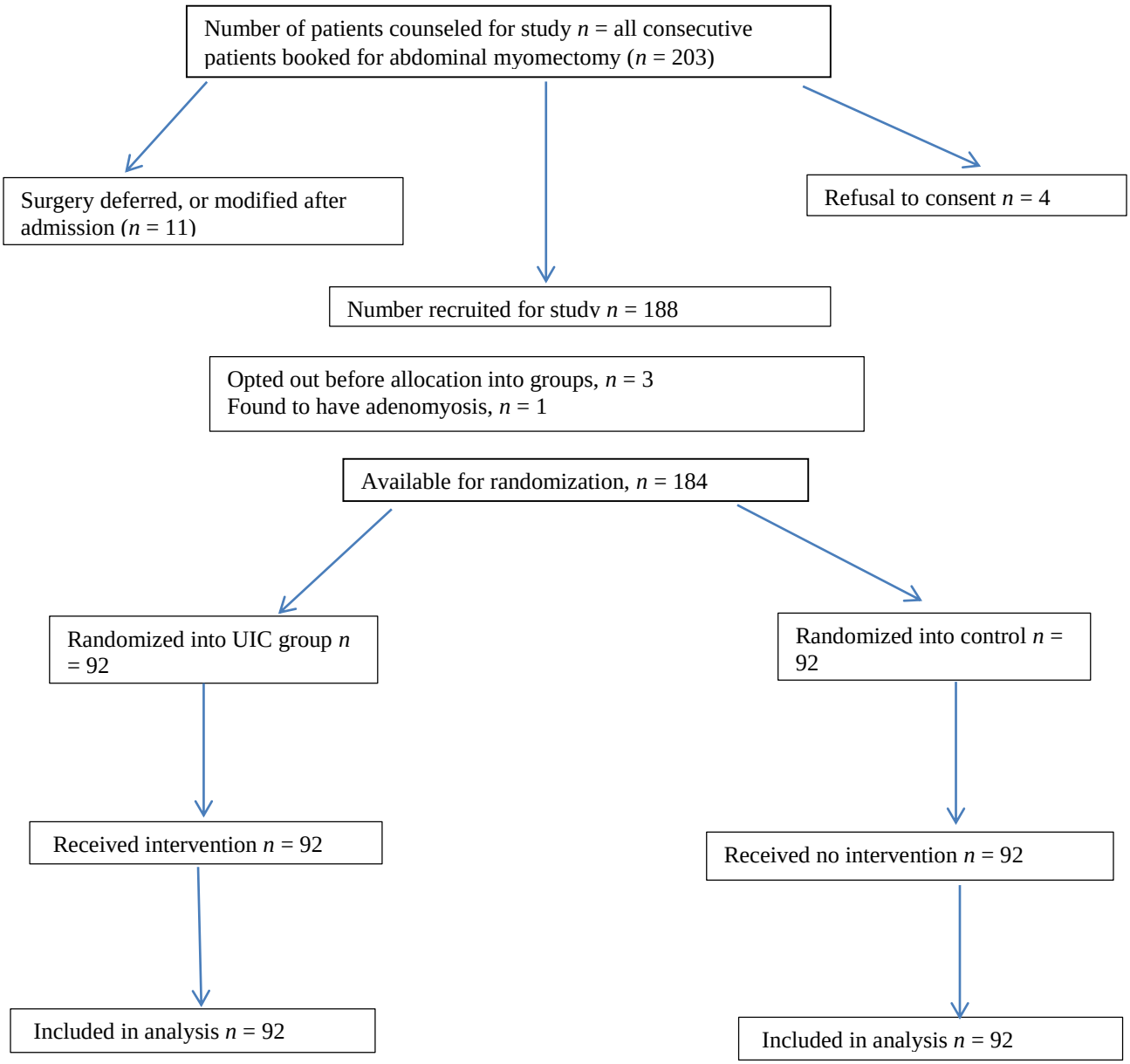

Figure 2. Consort flow chart.

The data of participants who had additional hemostatic measures were retained and included in the final analysis. The intervention was administered by investigators at the level of consultant or senior registrar at all the sites. Meetings were held before the commencement of the study and then 2–4 weekly during the study; this included trainings to harmonize the method of uterine incision closure to prevent dead space at myomectomy, participant recruitment, and outcome measure assessment.

A co-principal investigator (co-PI) at the level of consultant from each study site was identified and they ensured that the study protocols for myomectomy and UIC were followed.

Table 1. Comparing the UIC and the control groups with respect to preoperative findings

Sociodemographic characteristics				
Findings	**UIC (*n* = 92)**	**Control (*n* = 92)**	**X^2**	***p* value**
Educational attainment			0.365	0.325
Secondary(*n* = 72)	38 (52.8%)	34 (47.2%)		
Tertiary (*n* = 112)	54 (48.2%)	58 (51.8%)		
Employment status			0.423	0.747
Unemployed (*n* = 10)	4 (40.0%)	6 (60.0%)		
Employed (*n* = 174)	88 (50.6%)	86 (49.4%)		
Marital status				
Currently married (*n* = 168)	85 (50.6%)	83 (49.4%)	0.274	0.397
Currently single (*n* = 16)	7 (43.8%)	9 (56.2%)		
Parity			2.577	0.294
0 (*n* = 137)	73 (53.5%)	64 (46.7%)		
1 (*n* = 43)	17 (39.5%)	26 (60.5%)		
≥2 (*n* = 4)	2 (50.0%)	2 (50.0%)		
Phase of cycle			0.877	0.373
Follicular (*n* = 161)	83 (51.6%)	78 (48.4%)		
Luteal (*n* = 22)	9 (40.9%)	13 (59.1%)		
Menorrhagia				
Yes (*n* = 119)	63 (52.9%)	56 (47.1%)	1.166	0.355
No (*n* = 65)	29 (44.6%)	36 (55.4%)		
Abdominal mass				
Yes (*n* = 139)	70 (50.4%)	69 (49.6%)	0.029	1.000
No (*n* = 54)	22 (48.9%)	23 (51.1%)		
Infertility/subfertility				
Yes (*n* = 156)	77 (49.4%)	79 (50.6%)	0.168	0.838
No (*n* = 28)	15 (53.6%)	13 (46.4%)		

Clinical characteristics			
Finding (mean ± SD, years)	**Study group**		**Sig. (2-tailed)**
	UIC (*n* = 92)	**Control (*n* = 92)**	
Age[a] (years)	36.28 ± 4.92	36.95 ± 4.85	0.466[a]
BMI (kg/m²)	25.82 ± 3.52	25.79 ± 2.44	0.853
MAP (mmHg)	95.54 ± 9.87	95.51 ± 12.49	0.981
Temp (°C)	36.53 ± 0.40	36.59 ± 0.32	0.278
PCV (%)	35.23 ± 2.87	35.04 ± 3.06	0.668
Clinical estimated uterine size (weeks)	20.18 ± 4.93	20.07 ± 5.05	0.879

[a]The Mann–Whitney U test was used to compare the variable.

Abbreviations: *PCV*, packed cell volume; *UIC*, uterine incision compression.

The primary outcome measure was the IBL, which was defined as a summation of the blood loss obtained in the suction bottle and that from gauzes, sponges, towels, and drapes. Blood loss was obtained from the difference between the wet weight and the dry weight of the items used (1 g ≈ 1 mL). Postoperative blood loss was obtained from the abdominal drain bag (10). Other outcome measures were duration of abdominal myomectomy in minutes, postoperative pain assessment, occurrence of fever, and the duration of postoperative hospital stay.

There was no placebo in this study, and the patients were blinded to the intervention and outcome assessment, to prevent biased outcomes such as biased reporting of visual analog pain scores and dropouts or patient-influenced protocol deviations (16). The surgeon who administered the intervention was also blinded to the outcome assessment until after data entry and analysis, thus achieving double blinding.

Table 2. Comparing the intraoperative findings and surgical procedure between the UIC and the control groups

Operative characteristics				
Findings[a] (mean ± SD)	**Study group**		**Sig.**[a] **(2-tailed)**	
	UIC (*n* = 92)	**Control (*n* = 92)**		
Uterine size (weeks)	19.85 ± 4.70	19.91 ± 4.83	0.905	
No. of fibroid nodules	12.55 ± 6.72	12.59 ± 6.39	0.847	
Total weight of all fibroids (g)	790.30 ± 669.65	896.20 ± 816.36	0.690	
Diameter of largest nodule (cm)	10.73 ± 4.98	10.09 ± 4.11	0.565	
Total tourniquet duration (min)	72.98 ± 25.88	73.12 ± 23.24	0.880	
No. of uterine incisions	6.67 ± 2.15	6.93 ± 1.66	0.358	
Operative procedure				
Procedure	**UIC (*n* = 92)**	**Control (*n* = 92)**	**X^2**	***p* value**
Anesthesia regimen				
GA (*n* = 139)	69 (49.6%)	70 (50.4%)	0.029	1.000
SAB (*n* = 45)	23 (51.1%)	22 (48.9%)		
Skin incision type				
Longitudinal (*n* = 108)	49 (45.4%)	59 (54.6%)	2.242	0.178
Transverse (*n* = 76)	43 (56.6%)	33 (43.4%)		
Tourniquet reapplied				
Yes (*n* = 121)	61 (50.4%)	60 (49.6%)	0.001	1.000
No (*n* = 63)	31 (49.2%)	32 (50.8%)		
Hydrofloatation				
Yes (*n* = 27)	18 (66.7%)	9 (33.3%)	3.516	0.094
No (*n* = 157)	74 (47.1%)	83 (52.9%)		
Endometrium entered				
Yes (*n* = 126)	64 (50.8%)	62 (49.2%)	0.101	0.874
No (*n* = 58)	28 (48.3%)	30 (51.7%)		

[a]The Mann–Whitney U test was used to compare the variables.

Abbreviations: *GA,* general anesthesia; *SAB,* subarachnoid block; *UIC,* uterine incision compression.

The IBL was assessed by the anesthetist registrar from a team that was not involved in the myomectomy. The secondary outcome measures, which included postoperative vital signs, postoperative blood loss, and visual analog pain scores, were obtained by the gynecological ward nursing staff, using a case records form.

Data analysis was done with the "intention to treat model"; there was, however, no dropout after randomization. The participants in the control group who received bimanual UIC for the control of continued intraoperative hemorrhage had their data retained and included in the final analysis.

Data were analyzed using the Statistical package for the Social Sciences (SPSS), version 21. Frequency tables were drawn and numerical data expressed as mean ± standard deviation, while for bivariate analysis, categorical variables were compared using the Chi-square test (or the Fisher's exact test where the cell permits) and odds ratios thus generated. The continuous variables were compared using Student's *t*-test (the Mann–Whitney U test, where the data were not normally distributed) and the 2-tailed significance values were

taken. The 95% confidence interval was used throughout the data analysis and the level of statistical significance was set at a *p* value of <0.05.

The duration of abdominal myomectomy was considered as the time interval (in minutes) from skin incision to skin closure.

Fever was defined as temperature ≥37.5°C taken with a mercury thermometer from the axilla (17).

The duration of hospitalization was considered as the interval (in number of days) from the day of surgery to discharge home.

Intraoperative hemorrhage was defined as intraoperative bleeding ≥1000 mL or requiring blood transfusion. Massive intraoperative hemorrhage was defined as IBL >25% of the blood volume or that required emergency intervention such as hysterectomy (18).

Table 3. Comparing the operative blood loss and duration of myomectomy between the UIC and control groups

Outcome[a] (mean ± SD, min)	**Study group (mean ± SD)**		**Sig.**[a] **(2-tailed)**
	UIC (*n* = 92)	**Control (*n* = 92)**	
Intraoperative blood loss (mL)	951.41 ± 362.32	1051.30 ± 427.77	0.125
Postoperative blood loss (mL)	64.673 ± 120.56	127.55 ± 153.35	0.003
Total operative blood loss (mL)	1016.52 ± 453.64	1162.01 ± 540.63	0.078
Duration of myomectomy (min)	119.70 ± 23.96	152.95 ± 32.67	0.001
Tourniquet removal—skin closure interval (min)	32.79 ± 11.39	61.89 ± 21.91	<0.001
Duration of UIC	4.80 ± 1.6 Range = 1–9	NA	NA

Outcome	**Study group (*n* = 92)**	**Control (*n* = 92)**	***p* value (OR)**	**95% CI**	
				Lower	**Upper**
Intraoperative hemorrhage (≥1000 mL)					
Yes (*n* = 68)	29 (42.6%)	39 (57.4%)	0.169		
No (*n* = 116)	63 (54.3%)	53 (45.7%)	OR = 1.59	0.874	2.723
Total operative blood loss ≥1000 mL					
Yes (*n* = 80)	34 (42.5%)	46 (57.5%)	0.102		
No (*n* = 104)	58 (55.8%)	46 (44.2%)	OR = 0.77	0.578	1.024
Intraoperative transfusion					
Yes (*n* = 75)	36 (48.0%)	39 (52.0%)	0.764		
No (*n* = 109)	56 (51.4%)	53 (48.6%)	OR = 1.15	0.635	2.062
Duration of myomectomy ≥120 min					
Yes (*n* = 124)	54 (43.5%)	70 (56.5%)	0.018		
No (*n* = 60)	38 (63.3%)	22 (36.7%)	OR = 2.24	1.183	4.220

[a]The Mann–Whitney U test was used to compare the variables.

Abbreviations: *NA*, not applicable; *UIC*, uterine incision compression.

Results

There were a total of 203 patients admitted for myomectomy in all the study sites. Nineteen, however, did not get randomized for reasons which included surgeries being modified, postponed, refusal to consent, or later found with an exclusion criterion on imaging. All of the participants that were randomized completed the study and had their data (*n* = 184) included in the analysis (Figure 2).

The participants in the UIC and the control groups were comparable with respect to age (*p* = 0.466), parity (*p* = 0.294), menorrhagia (*p* = 0.355), abdominal mass (*p* = 1.000), infertility (*p* = 0.838), and clinical estimated uterine size (*p* = 0.879) (Table 1).

The participants in the two study groups were not significantly different with respect to uterine size (p = 0.905), number of fibroid nodules (p = 0.847), the mean total duration of tourniquet application (p = 0.969), anesthesia regimen (p = 1.000), and rates of entry into the endometrium (p = 0.874) (Table 2).

The patients in the UIC group had less (951.41 ± 362.32 mL) measured IBL than the patients in the control group (1051.30 ± 427.77 mL); this finding, however, did not reach statistical significance (p = 0.125). The postoperative blood loss was, however, significantly greater in the control group (p = 0.003). The observed mean duration of myomectomy was significantly longer among the patients in the controls (152.95 ± 32.67 min), than the 119.70 ± 23.96 min observed in the UIC group (p = 0.001). The mean interval from tourniquet removal to skin closure among the patients in the control group (61.89 ± 21.91 min) was longer than the 32.79 ± 11.39 min observed among those in the UIC group and this was significant (p = 0.001). There was also a significantly greater risk for myomectomy duration at ≥120 min among the control group (OR = 2.24, 95% CI = 1.18–4.22, p = 0.018). There was, however, no significant difference in the risk of intraoperative hemorrhage at ≥1000 mL (p = 0.169). The mean duration of UIC was 4.80 ± 1.6 min with a range of 1–9 min (Table 3).

The risks for deployment of additional hemostatic measures (OR = 4.68, 95% CI = 2.304–12.784, p = 0.001), peritoneal drain placement (OR = 1.63, 95% CI = 1.231–2.155, p = 0.001), occurrence of postoperative fever (OR = 1.65, 95% CI = 1.256–2.154, p = 0.002), and longer duration of hospitalization (p < 0.001) were significantly greater among the controls (Table 4).

The risks of use of sutures, which was the commonest additional hemostatic measure (OR = 1.921, 95% CI = 1.200–3.075, p = 0.037), and application of salvage uterine compression (OR = 1.799, 95% CI = 1.273–2.542, p = 0.001,) were significantly more among the controls (Table 5).

Table 4. Comparing the requirements for additional hemostatic measures, drain placement and postoperative morbidity between the UIC and control groups

Outcome	**Study group**		***p* value (OR)[a]**	**95% CI**	
	UIC (*n* = 92)	**Control (*n* = 92)**		**Lower**	**Upper**
Use of additional hemostatic measures					
Yes (*n* = 128)	50 (39.1%)	78 (60.9%)	0.001		
No (*n* = 56)	42 (75.0%)	14 (25.0%)	OR = 4.68	2.304	12.784
Drain placement					
Yes (*n* = 70)	24 (34.3%)	46 (65.7%)	0.001		
No (*n* = 114)	68 (59.6%)	46 (40.4%)	OR = 1.63	1.231	2.155
Occurrence of fever (temp ≥ 37.5°C)					
Yes (*n* = 34)	9 (26.5%)	25 (73.5%)	0.002		
No (*n* = 150)	83 (55.3%)	67 (44.7%)	OR = 1.65	1.258	2.154
Readmission					
Yes (*n* = 15)	5 (33.3%)	10 (66.7%)	0.281		
No (*n* = 169)	87 (51.5%)	82 (48.5%)	OR = 1.37	0.930	2.080

Outcome (mean ± SD)	**Study group**		**Sig. (2-tailed)**
	UIC (*n* = 92)	**Control (*n* = 92)**	
Day 2 pain score	6.29 ± 1.57	6.82 ± 1.27	0.014
Discharge day pain score	4.21 ± 2.05	4.28 ± 1.73	0.785
Duration of hospital stay (days)	6.73 ± 1.33	8.02 ± 1.96	<0.001

[a]The calculated OR are for the risk of controls > UIC groups.

Abbreviation: *UIC*, uterine incision compression.

Table 5. Comparing the specific additional hemostatic measures for controlling blood loss between the UIC and the control groups

Hemostatic measure[a]	Study group		*p* value (OR)[b]	95% CI	
	UIC (*n* = 50)	Control (*n* = 78)		Lower	Upper
Suture placement					
Yes (*n* = 118)	43 (36.4%)	75 (63.6%)	0.037		
No (*n* = 10)	7 (70.0%)	3 (30.0%)	OR = 1.921	1.200	3.075
Uterotonic agents					
Yes (*n* = 65)	21 (32.3%)	44 (67.7%)	0.147		
No (*n* = 63)	29 (46.0%)	34 (54.0%)	OR = 0.560	0.237	1.339
Tranexamic acid					
Yes (*n* = 7)	5 (71.4%)	2 (28.6%)	0.109		
No (*n* = 121)	45 (37.2%)	76 (62.8%)	OR = 1.921	1.139	3.239
Salvage/repeat uterine compression					
Yes (*n* = 75)	19 (25.3%)	56 (74.7%)	0.001		
No (*n* = 53)	31 (25.3%)	22 (41.5%)	OR = 1.799	1.273	2.542

aCombinations of hemostatic measures were possible.
bCalculated ORs were for risk of cohort "controls" > UIC.
Abbreviation: UIC, uterine incision compression.

Discussion

The presently low quality of evidence available for strategies aimed at reducing blood loss during myomectomy is majorly due to issues relating to the number and quality of the appropriate prospective studies from which inferences can be made to influence clinical practice. Issues relating to sample size, variability in inclusion criteria, uterine size, blood estimation methods, and inclusion of studies involving diverse routes of myomectomy may have led to the present conclusions from systematic reviews. The use of the uterine tourniquet remains popular in low-income countries despite the foregoing, mainly because of its ready availability, low cost, ease of application, and the relative biochemically inert nature which precludes adverse reactions and its applicability in a wide range of patients, irrespective of premorbid status (6, 7, 14). This study therefore presents evidence for the use or rejection of UIC to improve outcomes of abdominal myomectomy done with the use of the pericervical tourniquet as primary hemostatic measure.

The sociodemographic features (age, parity, and clinical presentation), in addition to the operative findings (vital signs, uterine size, number fibroid nodules), procedure for myomectomy (anesthesia regimen, skin incision, tourniquet application duration, and the number of uterine incisions) were similar between the intervention (UIC) and the control groups. Therefore, differences in outcomes between the two groups may be attributable to the administered intervention.

Although the measured IBL was greater among the controls, this difference did not reach statistical significance. This lack of difference may be a result of higher incidence of use of additional hemostatic measures among the controls with more than a fourfold risk for these salvage measures.

Another important reason for the lack of difference in IBL is the finding of significantly longer mean duration of myomectomy among the control group ($p = 0.001$). The participants in the control group were also observed to have more than twice the risk of the UIC group for myomectomy duration lasting for ≥120 min. This time was spent essentially in the interval between the release of the tourniquet and skin closure, a duration that was also significantly longer among the control group ($p < 0.001$). The higher rates of application of additional hemostatic measures among the controls suggest that this extra time interval was spent securing hemostasis.

Hemorrhage is known to prolong the duration of surgery and increase the risk of use of salvage hemostatic measures (4, 11). Thus attainment of efficient hemostasis in the control group occurred at the expense of operating time.

Intraoperative bleeding could also result in postoperative bleeding (which was significantly more in the control group): when peritoneal blood is not completely evacuated, when hemostatic measures are inadequate, or when coagulopathy sets in (4, 19). The main contribution to estimated postoperative blood loss in this study was obtained from the peritoneal drainage tubes. Higher rates of drain placement were observed among the participants in the control group than in the UIC group (p = 0.001, OR = 1.63). The greater postoperative blood loss may actually be a reflection of a greater tendency to bleed or an apparently greater IBL among the control group.

The measured IBL among the controls in this study at 1051.30 ± 427.77 mL is comparable to the 998.72 ± 607.21 mL obtained in an RCT by Abdul et al. in Ilorin, but higher than the 515.7 ± 292.8 mL obtained by Ikechebelu et al. using a similarly applied tourniquet in a non-RCT comparative study. It is also higher than the 489 ± 362 mL among the tourniquet arm of an RCT by Taylor et al. done in the United Kingdom, and the 467.9 ± 74.5 mL by Dutta et al. in India. Their observed lower IBL compared with this present study may be due to the exclusion of patients with uterine size >16 weeks, exclusion of patients with the number of fibroid nodules >3, and a small sample size (6, 8, 10, 20). Fibroid size is a significant determinant of IBL (4, 19).

The mean operating time obtained from the tourniquet alone arm of this study is, however, comparable to what has earlier been obtained in southwestern Nigeria by Oladapo et al. (145.5 ± 46.4 min) and Okogbo et al. (127 ± 27 min) (14, 19).

There have also been variations in tourniquet application methods, based mainly on achieving a balance between adequate hemostasis and the effect on ovarian reserve and uterine function; only the pericervical tourniquet was used, in this study. In addition, the tourniquet was released at 60-min intervals. Earlier studies have shown this interval to be safe (21, 22). Taylor et al. applied tourniquets to the infundibulo-pelvic ligaments and the uterine isthmus; their study demonstrated that it was safe to leave an absorbable pericervical tourniquet permanently in place after completion of the myomectomy (8).

The higher rates of fever observed in the control group may be a consequence of the use of additional suture materials, drain placement, longer operating time, and higher blood transfusion rates, also reported in an earlier study (23). Although the incidence (18.5%) of postoperative pyrexia is comparable, the rate of peritoneal drain placement is, however, higher than obtained in earlier studies in Nigeria (6, 7, 14).

The entire process of UIC lasted for a mean duration of less than 5 min. This relatively short procedure of bimanual UIC reduced the duration of myomectomy by a mean difference of 33 min. The extra time was spent applying extra measures for hemostasis, especially suturing, which significantly increased the risk for postoperative fever, pain, and longer hospital stay.

The strengths of this study include its prospective nature, an RCT, and included fibroid sizes and number that are usually encountered in the practice setting of fibroid-prevalent areas. However, the inability to maintain the same temperature of fluid used to moisten the abdominal towel used for UIC, has the potential for varying degrees of stimulation of uterine contraction and attainment of hemostasis. The difference in skills of the surgeons also had the potential to affect the administration of the intervention and outcomes. This effect was, however, minimized with the use of a standardized protocol for myomectomy and UIC in all study sites.

Conclusion

UIC was associated with a significant reduction in operating time, postoperative blood loss, and requirement for additional hemostatic measures, although there was no significant difference in the IBL.

Author contributions

JOI led in conceptualization, funding acquisition, investigation, methodology, software, supervision and writing of the original draft; OML led in Project

administration and OW led in validation and visualization. All authors equally contributed to data curation, formal analysis, resources and in reviewing & editing of the original draft.

References

1. Akbaba E, Sezgin B, Sivaglioglu A, et al. Can the application of a temporary uterine tourniquet during an abdominal myomectomy reduce bleeding? J Turk Ger Gynecol Assoc. 2022; 23: 111-16.
2. Igboeli P, Walker W, McHugh A, et al. Burden of uterine fibroids: an African perspective, a call for action and opportunity for intervention. Curr Opin Gynecol Obstet. 2019; 2: 287-94.
3. Chen R, Su Z, Yang L, et al. The effects and costs of laparoscopic versus abdominal myomectomy in patients with uterine fibroids: a systematic review and meta-analysis. BMC Surg. 2020; 20: 1-9.
4. Pundir J, Krishnan N, Siozos A, et al. Perioperative morbidity associated with abdominal myomectomy for very large uterine fibroids. Eur J Obstet Gynecol Reprod Biol. 2013; 167: 219-24.
5. Kongnyuy EJ, Wiysonge CS. Interventions to reduce haemorrhage during myomectomy for fibroids. Cochrane Database Syst Rev. 2014: CD005355.
6. Ikechebelu J, Ezeama C, Obiechina N. The use of torniquet to reduce blood loss at myomectomy. Niger J Clin Pract. 2010; 13: 154-58.
7. Adesina K, Owolabi B, Raji H, et al. Abdominal myomectomy: a retrospective review of determinants and outcomes of complications at the University of Ilorin Teaching Hospital, Ilorin, Nigeria. Malawi Med J. 2017; 29: 37-42.
8. Taylor A, Sharma M, Tsirkas P, et al. Reducing blood loss at open myomectomy using triple tourniquets: a randomized controlled trial. BJOG. 2005; 112: 340-45.
9. Mehdizadehkashi A, Tahermanesh K, Rokhgireh S, et al. Uterine isthmus tourniquet during abdominal myomectomy: support or hazard? A randomized double-blind trial. Gynecol Obstet Invest. 2020; 85: 396-404.
10. Dutta S, Samanta S, Lahiri S, et al. A comparative study to assess blood loss during abdominal myomectomy by tourniquet application versus intramyometrial vasopressin injection. Int J Sci Stud. 2019; 6: 87-92.
11. Sch€uring A, Garcia-Rocha G, Schl€osser H, et al. Perioperative complications in conventional and microsurgical abdominal myomectomy. Arch Gynecol Obstet. 2011; 284: 137-44.
12. Baskett T. Uterine compression sutures for postpartum hemorrhage: efficacy, morbidity, and subsequent pregnancy. Obstet Gynecol. 2007; 110: 68-71.
13. Zhong B. How to calculate sample size in randomized controlled trial? J Thorac Dis. 2009; 1: 51-54.
14. Okogbo F, Ezechi O, Loto O, et al. Uterine leiomyomata in South Western Nigeria: a clinical study of presentations and management outcome. Afr Health Sci. 2011; 11: 271-78.
15. Bolarinwa O. Sample size estimation for health and social science researchers: the principles and considerations for different study designs. Niger Postgrad Med J. 2020; 27: 67-75.
16. Karanicolas P, Farrokhyar F, Bhandari M. Blinding: Who, what, when, why, how? Can J Surg. 2010; 53: 345-48.
17. Mackowiak P, Chervenak F, Grunebaum A. Defining fever. Open Forum Infect Dis. 2021; 8: ofab161.
18. Santoso J, Saunders B, Grosshart K. Massive blood loss and transfusion in obstetrics and gynaecology. Obstet Gynecol Surv. 2005; 60: 827-37.
19. Oladapo O, Akinsanya A. Relative morbidity of abdominal myomectomy for very large uterine fibroids in a developing country hospital. Arch Gynecol Obstet. 2011; 283: 825-30.
20. Abdul I, Amadu M, Adesina K, et al. Adjunctive use of tranexamic acid to tourniquet in reducing haemorrhage during abdominal myomectomy: a randomized controlled trial. Eur J Obstet Gynecol Reprod Biol. 2019; 242: 150-58.
21. Nnang Essone J, Ovono Abessolo F, Tsagoulela A, et al. Uterine reperfusion ischemia and use of elastic tourniquet. J Biosci Med. 2019; 7: 98-119.
22. Adachi M, Kisu I, Nagai T, et al. Evaluation of allowable time and histopathological changes in warm ischemia of the uterus in cynomolgus monkey as a model for uterus transplantation. Acta Obstet Gynecol Scand. 2016; 95: 991-98.
23. Ndububa V. Uterine fibroids: Experience with 100 myomectomies in Orlu, South East Nigeria. PH Med J. 2016; 10: 124-29.