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Effectiveness of tourniquet with and without adjunctive misoprostol on haemorrhage during open myomectomy: A randomised controlled trial

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Abstract

Reducing intraoperative haemorrhage during open abdominal myomectomy is essential, as excessive bleeding is a major complication. This double-blind, randomised controlled trial, conducted at two tertiary hospitals in Nigeria between July 2020 and January 2021, compared the effect of combining misoprostol with a tourniquet versus a tourniquet alone on intraoperative blood loss. One hundred and forty consenting women were randomised in equal numbers to the intervention (tourniquet plus misoprostol) or the control (tourniquet only) group. The primary outcome was intraoperative blood loss, while secondary outcomes included duration of surgery, blood transfusion requirements, and adverse effects. Mean blood loss was significantly lower in the intervention group (678.2±42.4 ml) than in the control group (837.0±39.2 ml; P=0.042). There were no significant differences in transfusion rates, operative duration, or side effects between groups. The addition of misoprostol to a pericervical tourniquet effectively reduces intraoperative blood loss without increasing adverse events in women undergoing open abdominal myomectomy. *(Afr J Reprod Health 2026; 30 [13]: 33-44).*

Keywords: Haemorrhage, Misoprostol, Myomectomy, Tourniquet

Résumé

La réduction des hémorragies peropératoires lors d'une myomectomie abdominale par laparotomie est essentielle, car un saignement excessif constitue une complication majeure. Cet essai contrôlé randomisé en double aveugle, mené dans deux hôpitaux de soins tertiaires au Nigeria entre juillet 2020 et janvier 2021, a comparé l'effet de l'association du misoprostol et d'un garrot à celui d'un garrot seul sur les pertes sanguines peropératoires. Cent quarante femmes ayant donné leur consentement ont été réparties de manière aléatoire et équitable entre le groupe d'intervention (garrot et misoprostol) et le groupe témoin (garrot seul). Le critère de jugement principal était la perte sanguine peropératoire, tandis que les critères secondaires incluaient la durée de l'intervention, le recours à une transfusion sanguine et les effets indésirables. La perte sanguine moyenne était significativement plus faible dans le groupe d'intervention (678,2 ± 42,4 ml) que dans le groupe témoin (837,0 ± 39,2 ml ; P = 0,042). Aucune différence significative n'a été observée entre les groupes concernant les taux de transfusion, la durée de l'intervention ou les effets indésirables. L'ajout de misoprostol à un garrot péricervical réduit efficacement les pertes sanguines peropératoires sans augmenter la survenue d'effets indésirables chez les femmes subissant une myomectomie abdominale par laparotomie.*(Afr J Reprod Health 2026; 30 [13]:33-44).*

Mots-clés: Hémorragie, Misoprostol, Myomectomie, Garrot

Introduction

Uterine fibroids are the most common benign tumours of the uterus, primarily affecting women of reproductive age, with an increased prevalence among black women.[1-3] Women with large or submucous fibroids often present with complaints of menorrhagia, dysmenorrhea, urinary frequency, infertility, or recurrent pregnancy loss.[7-10] In Nigeria, symptomatic uterine fibroids account for about 20% of gynaecological outpatient consultations and 10% of admissions.[1-5,9] For women desiring future fertility or uterine preservation, myomectomy is the procedure of

choice.[16-17] Open (or abdominal) myomectomy is the most used method in low-income countries, due to limited access to endoscopic facilities and the large sizes of fibroids that patients often present with.[16] In many Nigerian hospitals, open myomectomy accounts for 43.7% to 97.4% of surgeries performed for uterine fibroids.[17-19]

A major challenge in open myomectomy is high intraoperative blood loss, potentially leading to significant anaemia, postoperative infections, febrile morbidity, the need for blood transfusions, and, in some cases, hysterectomy.[20-24] Consequently, practical strategies to reduce intraoperative blood loss during the procedure are critical. Various interventions have been explored to minimise bleeding, including mechanical and pharmacological methods.[25,26] Mechanical methods, such as pericervical tourniquets, have occluded the uterine blood vessels and reduced blood flow to the fibroids. Several studies have shown that this technique reduces intraoperative blood loss and transfusion rates without causing major complications. Despite its benefits, the pericervical tourniquet remains limited in its effectiveness, with reported intraoperative blood loss ranging from 313 to 700 ml and transfusion rates of 12.8% to 40.7%.[11-14,21,29,30] In addition, concerns about potential ischemic damage to the uterus and surrounding tissues persist.[17,18,26-30]

Apart from mechanical methods, pharmacological agents such as misoprostol, a prostaglandin E1 analogue, have been shown to reduce intraoperative blood loss during myomectomy. by induces myometrial contractions, which reduce uterine blood flow.[31-35] It is heat-stable and has a long shelf life, making it particularly suitable for low-resource settings. Although misoprostol is generally well tolerated, it is associated with side effects such as chills, nausea, and abdominal pain, which are typically dose-dependent and self-limiting.[36,37]

Despite the potential advantages of integrating mechanical and pharmacological strategies, few studies have investigated the combination of pericervical tourniquets and misoprostol compared with either alone to reduce intraoperative blood loss, underscoring the need for additional studies.[10,20] This approach utilises two techniques with different mechanisms, offering a chance to enhance effectiveness.

This study compared the effectiveness of combined rectal misoprostol and pericervical tourniquet with pericervical tourniquet alone during open myomectomy at two tertiary hospitals in Nigeria using intraoperative blood loss, blood transfusion requirements, surgery duration, and the number of adverse events as outcome measures. The null hypothesis is that there is no statistically significant difference in intraoperative blood loss between participants who received a combination of pericervical tourniquet and rectal misoprostol and those who received pericervical tourniquet alone during open myomectomy.

Methods

Study design

This was a two-centre, double-blinded, randomised controlled trial involving women undergoing open abdominal myomectomy. Participants were randomised to either the intervention arm, which received rectal misoprostol and a pericervical tourniquet, or the control arm, which received rectal placebo and a pericervical tourniquet. The primary outcome measure was intraoperative blood loss. Secondary outcome measures included blood transfusion, surgery duration, and adverse events associated with misoprostol. The study commenced 1st July 2020 and lasted for seven months.

Study settings

The study was conducted at two government-owned hospitals in Delta State, Nigeria: the Delta State University Teaching Hospital (DELSUTH) and Central Hospital Warri (CHW). These facilities are within 40 km of each other and follow similar clinical protocols in conducting myomectomies. DELSUTH and CHW are accredited by the National Postgraduate Medical College of Nigeria for postgraduate training in Obstetrics and Gynaecology. Both centres follow similar standard operating procedures for preoperative assessment, intraoperative techniques, and postoperative care of patients undergoing surgical procedures, including open myomectomy.

Study population

The study population consisted of all women with uterine fibroids attending the gynaecological clinics

in both study centres who had been scheduled to undergo open myomectomy. Eligible patients were those who satisfied the inclusion criteria.

Inclusion criteria

Participants included consenting women diagnosed with uterine fibroids, with uterine sizes equivalent to at least 12 weeks of gestation, who had no previous pelvic surgery.

Exclusion criteria

The study excluded women with a documented allergy to misoprostol, a family history of bleeding disorders, anticoagulant therapy, a haemoglobin concentration <10g/dL, pre-treatment with gonadotropin-releasing hormone analogues, large cervical or intra-ligamentous fibroids, or features suspicious for malignancy.

Sample size estimation

The minimum sample size was determined using the formula for calculating sample sizes of comparative intervention studies with quantitative outcomes.[42] The study was designed to have 80% power and a 5% significance level, using the study by Afolabi et al[28]. A minimum of 63 participants per group was required. With an attrition rate of 10%, an additional 7 women were recruited per study arm. Therefore, 140 participants were recruited.

Sampling, recruitment and allocation

A consecutive sampling method was employed to select study participants. All eligible patients admitted to the gynaecological wards and scheduled for open abdominal myomectomy during the study period were consecutively recruited until the calculated sample size was reached. Recruitment was conducted on a rolling basis, with an average of four or more participants enrolled weekly across both study centres. This continued until the target sample size of 140 participants was achieved.

An independent statistician generated 140 computer-generated three-digit random numbers.[43] Two identical copies of the allocation sequence were prepared: a labelled copy and a Master Copy. The Master Copy was kept securely and was accessible only to the designated pharmacist to ensure allocation concealment.

The placebo tablets were identical in size, shape, colour, and markings to the active misoprostol tablets (Cytotec®, Pfizer Limited, United Kingdom). A designated pharmacist, who was not involved in any other aspect of the study, used the Master Copy to randomly assign 70 of the 140 numbers to the intervention arm (misoprostol + tourniquet) and the remaining 70 to the control arm (placebo + tourniquet).

Each of the 140 drug envelopes was labelled with one of the random numbers and filled with two tablets (400 µg total) of either misoprostol or placebo according to the allocation sequence. The envelopes were identical in appearance and were sealed to maintain blinding.

All 140 labelled drug envelopes, each containing two tablets, were returned to the Principal Investigator (IP) without the Master Allocation List, which identified which numbered envelopes contained the active drug or placebo. Consequently, treatment allocation remained concealed from the research team. These drug envelopes were stored in one of the shelves in the theatre.

The PI used the labelled copy of the 140 computer-generated numbers to prepare a randomisation kit. Each number was printed on a 5 × 5 cm sheet of paper and sealed in a small, identical, opaque brown envelope. All 140 envelopes were placed inside a larger envelope and stored in the theatre holding bay.

On the day of surgery, the circulating nurse invited the participant to draw a sealed envelope from the large envelope. The nurse opened it, and the number inside matched the corresponding drug envelope from the shelf. The participants, surgeons, and data collectors were all blinded to the treatment allocations. The designated pharmacist, who created the drug kits and maintained the Master Copy, had no further involvement in the trial until its conclusion, when it was unsealed to facilitate data analysis. A digital backup of the Master Copy was securely archived with the Chief Pharmacists in both Oghara and Warri centres.

Randomisation, allocation, and follow-up

Of the 161 women scheduled for myomectomy, 152 were assessed for eligibility, and 140 were randomised into two arms: intervention (Misoprostol & Pericervical Tourniquets, n=70) and

control (Pericervical Tourniquet & placebo, n=70). Seven participants did not receive their allocated intervention: 4 in the intervention arm (1 due to pelvic adhesion, 2 withdrew, 1 missed drug administration) and 3 in the control arm (2 due to pelvic adhesion, 1 withdrew). All were analysed according to their allocated arms (intention-to-treat).

Administration of misoprostol or a placebo

On the morning of surgery, written informed consent for participation in the study was obtained, and the circulating nurse allocated patients to the study arms as described above.

The two tablets in the envelope with the corresponding number picked by the participant were inserted rectally by the circulating nurse immediately after induction of anaesthesia. The selected number was immediately written on a copy of the collection pro forma in the participant's case note. The anaesthetist also recorded this number in the anaesthetic chart for identification.

Procedure for open myomectomy

The anaesthetic team, consisting of a consultant and residents, administered general or spinal anaesthesia. Surgery was performed by a consultant or senior registrar, with assistance from a resident. A bladder catheter was inserted, and the uterine size was recorded. The patient was placed in a supine position, and the surgical field was prepared with 0.5% chlorhexidine gluconate in 70% isopropyl alcohol, then dried with sterile gauze. The abdomen was draped with sterile towels.

The perioperative nurse weighed the laparotomy mops, which were used to cover the surgical field, absorb blood and prevent spillage. Myomectomy procedures followed a standard protocol with either a transverse, suprapubic, or midline incision. The uterus was exteriorised, inspected for myomas, and the pelvic organs assessed. A size-18 Foley catheter was inserted to occlude the uterine and ovarian vessels. The tourniquet was released for 15 seconds every 45 minutes to allow reperfusion.

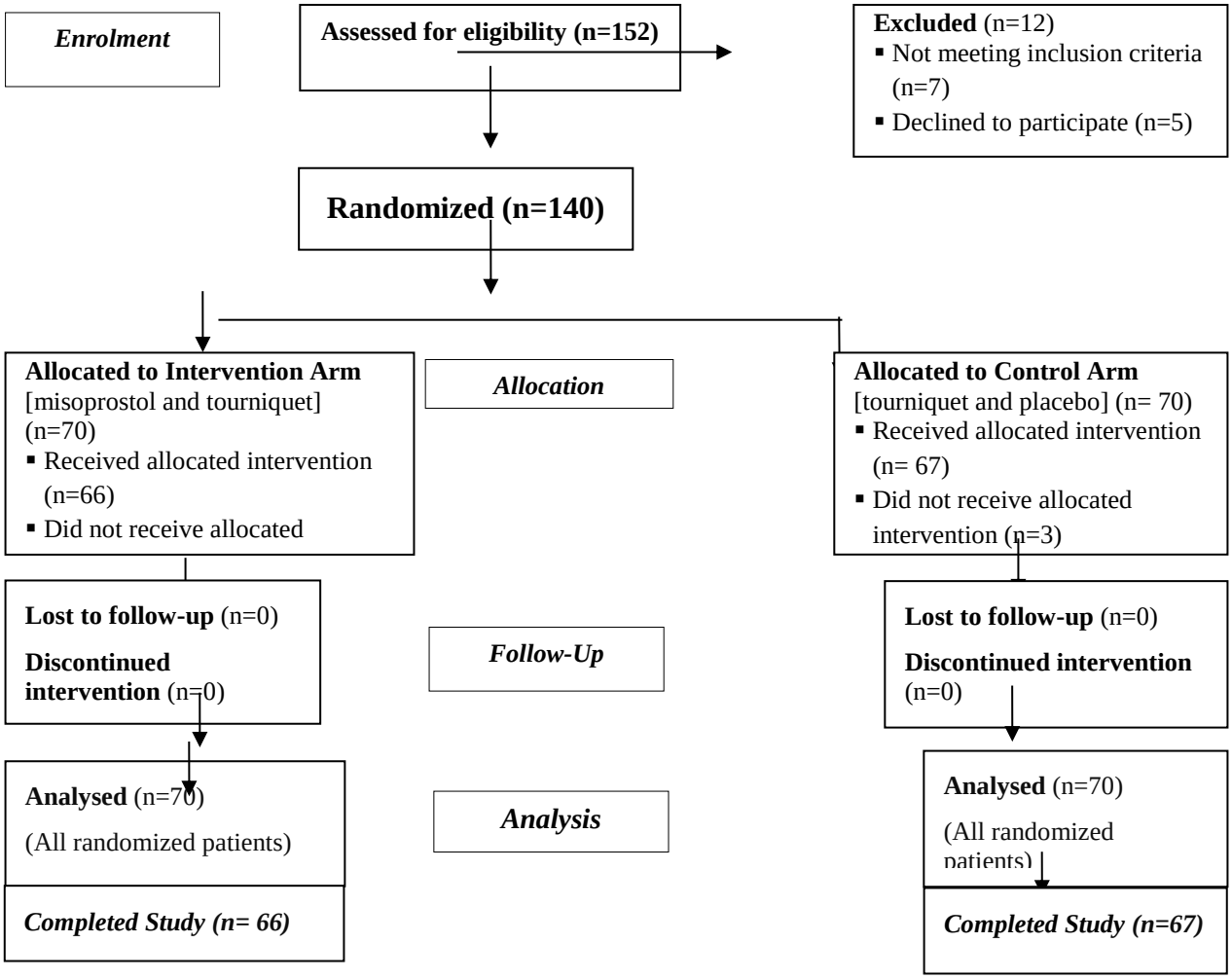
The uterine incision was made over the fibroid, and the fibroid was enucleated using myoma-screws or forceps. Additional incisions were made as needed for posterior or smaller fibroids. Pedunculated fibroids were removed by ligating their pedicles. The uterine defect was closed with continuous polyglactin sutures, and the Foley catheter tourniquet was removed after reconstruction.

Haemostasis was secured with polyglactin sutures, and the peritoneal cavity was irrigated and suctioned. Mops and instruments were counted. The abdominal layers were closed, and the wound was dressed. Blood transfusion was considered if haemorrhage was significant, indicated by hypovolaemia or intraoperative blood loss exceeding the acceptable limit. The acceptable blood loss limit was estimated{TBV× {Hb−8}/ Hb [45-46]; where TBV is the patient's total blood volume (approximately 65ml per kg); Hb is the preoperative haemoglobin concentration in g/dL, and 8 is the acceptable haemoglobin threshold of 8g/dL.

Postoperative management

Participants were asked about side effects such as chills, nausea, vomiting, headache, vertigo, abdominal pain, and diarrhoea. Most of misoprostol's side effects were self-limiting; however, persistent symptoms were managed according to standard protocol.

All participants received intravenous antibiotics (ceftriaxone 1g every 12 hours, metronidazole 500mg every 8 hours) for 48 hours, followed by oral cefuroxime 500mg twice daily and metronidazole 400mg three times daily for five days. Adequate analgesia was provided, and a liquid diet began within 12 hours. The urethral catheter was removed after 24 hours. Blood transfusion was considered if post-operative haemoglobin was <8g/dL at 48 hours or in cases of significant bleeding. The wound was inspected on the third postoperative day, and participants were discharged



Flow chart

was after meeting specific criteria: good general condition, stable vital signs, post-operative haemoglobin ≥8g/dL, and no complications. If these criteria were not met, the participant remained hospitalised. Discharged participants were followed up at the gynaecological outpatient clinic two weeks later.

Data collection

The information extracted included age, parity, education level, weight, height, BMI, presenting symptoms, uterine size, and preoperative haemoglobin. Intraoperative data included myoma location, number, weight ,intraoperative blood loss , blood transfusion, and surgical duration. The type of anaesthesia, the surgeon's rank, and the type of skin incision were also noted. The postoperative myoma location was documented, and its weight and count were recorded using a digital scale. Intraoperative blood loss was estimated by weighing mops and measuring suctioned blood. Blood absorbed by surgical mops was estimated gravimetrically. Suctioned blood was calculated by subtracting 500 ml of irrigation fluid. Total intraoperative blood loss was the sum of these two volumes. The duration of surgery was recorded from skin incision to final stitch.

Postoperative data included blood transfusion and adverse events. Total transfusion comprised the sum of intraoperative and postoperative blood transfusions. Postoperative haemoglobin levels were measured 48 hours after surgery. Adverse events associated with

misoprostol included chills, nausea, vomiting, headache, vertigo, abdominal pain, and diarrhoea.

Data analysis

Data were entered and analysed using SPSS version 21 (IBM® Inc., Chicago, USA). After data entry, the study arms were unveiled. Analysis was conducted based on the intention-to-treat principle. Descriptive statistics were presented as frequency tables. Categorical variables were expressed as frequencies and percentages; normally distributed continuous variables as means ± SD, and non-normally distributed variables as medians with interquartile ranges. Baseline characteristics and outcome measures were compared using Chi-square and Student's t-tests. Statistical significance was set at $P < 0.05$.

Ethical considerations

Ethical approval for this study was obtained from the Health Research Ethics Committee (HREC) of Delta State University Teaching Hospital, Approval Number HREC/PAN/2019/073/0325, dated 21st January 2020, and from the Ethics and Research Committee of the Delta State Hospital Management Board, Warri Medical Zone, Protocol Number CHW/ECC VOL 1/204, dated 30th January 2020. The study was conducted in accordance with established ethical principles for research involving human participants. Written informed consent was obtained from all participants after an adequate explanation of the study objectives, procedures, potential benefits, and the voluntary nature of participation. Participants were informed of their right to withdraw from the study at any stage without any consequences. Confidentiality and privacy were maintained throughout the study by anonymising participant information and restricting data access to the research team only. All collected data were securely stored and used strictly for research purposes.

Results

Baseline characteristics

The baseline characteristics of participants are presented in Table 1. The average age was 37.5±7.1 years, with 57.9% aged 30–39. Parity ranged from 0 to 6, and 52.9% were nulliparous. Mean BMI was 26.3±4.9 kg/m², with 22.1% classified as obese. Uterine size averaged 21.6 weeks. Mean preoperative haemoglobin was 11.9±1.5 g/dL, with 70.7% falling within the 10–10.9 g/dL range. No significant baseline differences were found between study arms.

Table 2 summarises operative characteristics. Consultants led most surgeries (82.9%). Spinal anaesthesia was used in 75.7% of cases, and midline incisions were most common (60.0%). The number of fibroids enucleated ranged from 1 to 40 (mean 10.16), with 87.1% located at multiple depths. The mean fibroid weight was 491 g, and 46.0% exceeded 500 g. No significant differences were observed between the intervention and control groups. Table 3 presents the study outcomes.

The mean intraoperative blood loss was ±91.4 ml overall, significantly lower in the intervention arm (678.2±42.4 ml) than in the control group (837.0±39.2ml; P=0.042).

Blood transfusion was required in 17.4% of participants in the intervention group compared to 28.2% in the control group, although this difference was not statistically significant (P=0.4). Most transfused participants received 2–5 units (60.5%). The mean duration of surgery was 103.5±6.9 minutes overall, 104.3±7.2 in the intervention group, and 112.5±7.3 in the control group, with no significant difference (P=0.9). Nine participants (6.4%) experienced mild adverse effects (chills, nausea), which were evenly distributed across both groups. No mortality was recorded.

Table 1: Baseline biodemographic and clinical characteristics of participants

Variable	Total (N=140) n (%)	Intervention (n=70) n (%)	Control (n=70) n (%)	Test Statistic	p-value
Study Centre					
Centre 1	124 (88.6)	63 (90.0)	61 (87.1)		
Centre 2	16 (11.4)	7 (10.0)	9 (12.9)		
Age (years)				$\chi^2 = 1.2$	0.5
20–29	11 (7.9)	7 (10.0)	4 (5.7)		
30–39	81 (57.9)	38 (54.3)	43 (61.4)		
≥ 40	48 (34.4)	25 (35.7)	23 (32.9)		
Mean ± SD	37.5 ± 7.1	37.2 ± 7.5	37.8 ± 6.7	t = 0.9	0.1
Marital Status				$\chi^2 = 4.2$	0.4
Single/Cohabiting	30 (21.4)	16 (22.9)	14 (20.0)		
Married	88 (62.9)	40 (57.1)	48 (68.6)		
Separated	15 (10.7)	10 (14.3)	5 (7.1)		
Divorced	6 (4.3)	4 (5.7)	2 (2.9)		
Widow	1 (0.7)	0 (0.0)	1 (1.4)		
Educational Status				$\chi^2 = 4.4$	0.2
None	6 (4.3)	4 (5.7)	2 (2.9)		
Primary	25 (17.9)	16 (22.9)	9 (12.9)		
Secondary	64 (45.7)	32 (45.7)	32 (45.7)		
Tertiary	45 (32.1)	18 (25.7)	27 (38.6)		
Parity				$\chi^2 = 1.600$	0.449
Para 0	74 (52.9)	36 (51.4)	38 (54.3)		
Para 1–4	44 (31.4)	25 (35.7)	19 (27.1)		
Para ≥5	22 (15.7)	9 (12.9)	13 (18.6)		
BMI (kg/m²)				$\chi^2 = 5.064$	0.079
< 26	40 (28.6)	26 (37.1)	14 (20.0)		
26–30	69 (49.3)	30 (42.9)	39 (55.7)		
> 30	31 (22.1)	14 (20.0)	17 (24.3)		
Mean ± SD	26.3 ± 4.95	26.05 ± 4.80	26.62 ± 5.12	t = -0.684	0.495
Indication for Surgery				$\chi^2 = 3.303$	0.508
Abdominal swelling	25 (17.9)	14 (20.0)	11 (15.7)		
HMB	46 (32.9)	26 (37.1)	20 (28.6)		
Dysmenorrhoea	38 (27.1)	15 (21.4)	23 (32.9)		
Infertility	28 (20.0)	13 (18.6)	15 (21.4)		
Recurrent miscarriage	0 (0.0)	0 (0.0)	0 (0.0)		
Pressure symptoms	3 (2.1)	2 (2.9)	1 (1.4)		
Uterine Size (weeks)				$\chi^2 = 1.457$	0.483
< 16	43 (30.7)	20 (28.6)	23 (32.9)		
16–30	61 (43.6)	34 (48.6)	27 (38.6)		
> 30	36 (25.7)	16 (22.9)	20 (28.6)		
Mean ± SD	21.59 ± 6.02	21.83 ± 5.67	21.36 ± 6.34	t = 0.462	0.645
Preoperative Haemoglobin (g/dL)				$\chi^2 = 5.766$	0.192
> 12	3 (2.1)	0 (0.0)	3 (4.3)		
11–11.9	38 (27.2)	16 (22.9)	22 (31.4)		
< 11	99 (70.7)	54 (77.1)	45 (64.3)		
Mean ± SD	11.8 ± 1.54	11.79 ± 1.47	11.87 ± 1.64	t = 2.192	0.050

Note:Values are presented as n (%).

BMI = body mass index; HMB = heavy menstrual bleeding; SD = standard deviation; χ^2 = Pearson chi-square test; t = Student's t-test.

Table 2: Operative characteristics of participants

Variable	Total (N=140) n (%)	Intervention (n=70) n (%)	Control (n=70) n (%)	Test Statistic	p-value
Cadre of Surgeon				$\chi^2 = 3.995$	0.677
Consultants	116 (82.9)	60 (85.7)	56 (80.0)		
Senior Registrar	24 (17.1)	10 (14.3)	14 (20.0)		
Type of Anaesthesia				$\chi^2 = 0.804$	0.669
Spinal	108 (75.7)	55 (78.6)	51 (72.9)		
Spinal/Epidural	19 (13.6)	9 (12.9)	10 (14.3)		
Epidural	0 (0.0)	0 (0.0)	0 (0.0)		
General	15 (10.7)	6 (8.6)	9 (12.9)		
Type of Skin Incision				$\chi^2 = 1.905$	0.168
Midline	84 (60.0)	46 (65.7)	38 (54.3)		
Transverse	56 (40.0)	24 (34.3)	32 (45.7)		
Location of Myomas				$\chi^2 = 7.011$	0.072
Subserous	5 (3.6)	2 (2.9)	3 (4.3)		
Intramural	9 (6.4)	2 (2.9)	7 (10.0)		
Submucous	4 (2.9)	4 (5.7)	0 (0.0)		
Mixed	122 (87.1)	62 (88.6)	60 (85.7)		
Weight of Myomas (g)				$\chi^2 = 0.794$	0.672
< 250 g	14 (10.0)	7 (10.0)	7 (10.0)		
250–500 g	61 (43.6)	28 (40.0)	33 (47.1)		
≥ 500 g	65 (46.4)	35 (50.0)	30 (42.9)		
Mean ± SD	491.43 ± 182.11	505.57 ± 189.94	477.29 ± 174.15	t = 0.918	0.360
Number of Fibroids				$\chi^2 = 1.979$	0.372
1–10	70 (50.0)	39 (55.7)	31 (44.3)		
11–20	67 (47.9)	30 (42.9)	37 (52.9)		
> 20	3 (2.1)	1 (1.4)	2 (2.9)		
Mean ± SD	10.16 ± 4.64	9.69 ± 4.84	10.63 ± 4.64	t = -1.175	0.242

Note: Values are presented as n (%).
SD = standard deviation; χ^2 = Pearson chi-square test; t = Student's t-test

Table 3: Study outcome measures

Outcome Variable	Total (N=140) Mean ± SD	Intervention (n=70) Mean ± SD	Control (n=70) Mean ± SD	Test Statistic	p-value
Intraoperative Blood Loss (ml)	757.60 ± 91.4	678.2 ± 42.38	837.0 ± 39.2	t = -23.1	0.042*
Duration of Surgery (min)	103.53 ± 6.9	104.33 ± 7.2	112.5 ± 7.3	t = 6.7	0.1
Requirement for Blood Transfusion				$\chi^2 = 0.9$	0.4
Yes	32 (22.9)	12 (17.4)	20 (28.2)		
No	108 (77.1)	57 (82.6)	51 (71.8)		
Number of Units Transfused (N=43)				$\chi^2 = 0.3$	0.9
1	4 (9.3)	1 (6.3)	3 (11.1)		
2–5	26 (60.5)	10 (62.5)	16 (59.3)		
> 5	13 (30.2)	5 (31.3)	8 (29.6)	t = 0.9	0.5
Adverse Events (N=9)				$\chi^2 = 1.3$	0.3
Chills	3 (33.3)	3 (60.0)	0 (0.0)		
Nausea	6 (66.7)	2 (40.0)	4 (100.0)		
Headache	0 (0.0)	0 (0.0)	0 (0.0)		
Vomiting	0 (0.0)	0 (0.0)	0 (0.0)		
Vertigo	0 (0.0)	0 (0.0)	0 (0.0)		
Abdominal pain	0 (0.0)	0 (0.0)	0 (0.0)		
Diarrhoea	0 (0.0)	0 (0.0)	0 (0.0)		

Discussion

Baseline biodemographic and clinical characteristics were comparable between the intervention and control groups, with no statistically significant differences. This confirms that randomisation was effective and minimised the risk of confounding.

Similarly, operative characteristics (Table 2), including the surgeon's cadre, type of anaesthesia, type of incision, number and location of fibroids, and fibroid weight, were comparable between the two groups. These factors are well-recognised determinants of intraoperative blood loss and surgical complexity. Their similarity across study arms strengthens the study's internal validity and supports the conclusion that the observed differences in outcomes are attributable to the intervention rather than procedural variability.

The primary finding of this study is that combining rectal misoprostol with a pericervical tourniquet significantly reduces intraoperative blood loss during myomectomy compared with a tourniquet alone. The mean blood loss in the intervention group was substantially lower than in the control group, representing a clinically meaningful reduction. This finding aligns with previous studies and supports the additive benefit of combining pharmacological and mechanical haemostatic strategies.

The mechanism underlying this effect is likely due to the complementary actions of both interventions. Misoprostol, a prostaglandin E1 analogue, promotes uterine contraction and vasoconstriction, thereby reducing uterine blood flow. The pericervical tourniquet, by contrast, mechanically occludes the uterine arterial supply. The combined use of these approaches likely produces a synergistic haemostatic effect during myometrial incision and fibroid enucleation.

These findings are consistent with those reported by Nnagbo *et al*[10] and Agyabeng *et al*.[20] both of whom demonstrated improved haemostatic outcomes with the combined use of misoprostol and tourniquet application. Furthermore, a systematic review by Wali et al[23]. supports the role of misoprostol in reducing intraoperative blood loss and haemoglobin drop in open myomectomy.

In the present study, most participants had multiple fibroids at varying depths, and nearly half had large fibroid burdens (≥500 g). Despite this, the intervention remained effective, suggesting that the benefit of combining misoprostol with a tourniquet persists even in complex surgical cases.

Although the proportion of participants requiring blood transfusion was lower in the intervention group, this difference was not statistically significant. This finding is consistent with previous studies by Nnagbo *et al*[10] and Agyabeng *et al*[20] and may reflect limited statistical power to detect differences in secondary outcomes. Additionally, transfusion decisions are influenced by several clinical factors, including baseline haemoglobin levels and clinician judgement, which may not directly correlate with measured intraoperative blood loss.

The duration of surgery was shorter in the intervention group; however, this difference did not reach statistical significance. This suggests that while the intervention may improve surgical efficiency, the magnitude of this effect is modest. Importantly, the findings indicate that adding misoprostol does not prolong operative time or increase procedural complexity. This trend is consistent with the meta-analysis by Wali *et a*l.[23]

Adverse events were minimal, limited to mild symptoms such as chills and nausea, and there was no significant difference between the two groups. No severe complications or mortality were recorded. These findings support the established safety profile of misoprostol, with side effects that are generally mild and self-limiting.

Conclusion

In conclusion, the combined use of rectal misoprostol and a pericervical tourniquet significantly reduces intraoperative blood loss during myomectomy without prolonging operative time or increasing adverse outcomes. This strategy is safe, effective, and feasible, and holds particular promise for improving surgical outcomes in resource-constrained settings.

Strengths and limitations

A major strength of this study is its randomised design, which is widely regarded as the most robust method for minimising selection bias and ensuring comparability between study groups. In addition,

the blinding of participants, healthcare providers, and data analysts reduces the risk of performance and detection bias, thereby enhancing the reliability of the findings.

Another important strength is the comparability of operative characteristics across groups, which minimises the influence of surgical variability on study outcomes. This is particularly relevant in open abdominal myomectomy, where factors such as fibroid size, number, and location can significantly affect intraoperative blood loss.

However, some limitations should be acknowledged. First, the estimation of intraoperative blood loss is inherently imprecise and subject to observer variability, despite the use of a standardised method across both groups. Second, longer-term outcomes were not assessed, limiting the evaluation of the intervention's full clinical impact.

Implications for clinical practice and policy

The findings of this study have significant implications for clinical practice and health policy, particularly in resource-limited settings. The combination of rectal misoprostol and a pericervical tourniquet provides a simple, safe, and cost-effective strategy to reduce intraoperative blood loss during open abdominal myomectomy.

In clinical practice, this approach may reduce the need for blood transfusion, thereby minimising the risks associated with transfusion, including transfusion reactions and the transmission of infections. It may also improve surgical outcomes for patients with large or multiple fibroids, who are at higher risk of significant intraoperative blood loss.

From a policy perspective, the use of readily available, inexpensive interventions such as misoprostol aligns with strategies to improve surgical safety and reduce healthcare costs in low- and middle-income countries. Incorporating this combined approach into clinical guidelines and standard surgical protocols could enhance the quality of care and optimise resource utilization.

Recommendations

The combined use of misoprostol and a pericervical tourniquet is recommended as a routine haemostatic strategy in open abdominal myomectomy, particularly in resource-limited settings where blood transfusion

services may be inadequate. Further multicentre studies with larger sample sizes are recommended to validate these findings and assess long-term outcomes. In addition, cost-benefit analyses and evaluations of patient satisfaction with this approach should be undertaken.

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Conflict of interest

All authors participating in this study reported no conflicts of interest.

Authors' contribution

Rally Edema made substantial contributions to the study's conception and design, data acquisition, analysis and interpretation, and drafted the manuscript. Patrick Okonta contributed to the conception and design, supervised the research, and critically revised the manuscript for important intellectual content. Ayotunde Adeyinka contributed to study design, data acquisition, and manuscript revision. Amos Ekoh contributed to data acquisition, analysis, and interpretation. Lloyd Jagu contributed to data interpretation, literature review, and critical revision of the manuscript. All authors approved the final version of the manuscript and agree to be accountable for all aspects of the work.

Data availability

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request, subject to appropriate ethical and institutional approvals

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