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### **REGIONAL ANESTHESIA**

# Ultrasound-guided quadratus lumborum block versus thoracic paravertebral block in gynecological cancer surgery: a prospective randomized trial

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# ABSTRACT

**Background & Objectives**: In the event that gynecologic cancer surgery (GC surgery) is going to be accompanied with extreme pain, many localized blocks will be provided. The quadratus lumborum block, often known as a QLB, is a fascial plane block that was developed relatively recently for the therapy of post-abdominal surgery discomfort. In the current study, a comparison is made between the effectiveness and safety of thoracic paravertebral block (TPVB) and quadratus lumborum block (QLB) in patients undergoing GC surgery.

**Methodology:** In this prospective comparative randomized trial, fifty patients with scheduled GC surgery were split evenly between two groups: QLB group (n = 25) to receive bilateral QLB type-2, or TPVB group (n = 25) to receive TPVB. The VAS scores were recorded at 1, 2, 4, 6, 12, and 24 h following surgery, and served as the key indicator of patient outcomes. Secondary outcomes were; the time to first request for the analgesic, the patient satisfaction, and the total morphine consumed as rescue analgesic in 24 h.

**Results:** At 2, 6, 12 and 24 h, the VAS scores of the QLB group were significantly lower than those of TPVB group. Only 12 (48%) of the QLB group patients required rescue morphine, compared to all patients in the TPVB group requiring it. QLB group showed more dermatomal distribution in comparison to the TPVB group. It took the TPVB group a much shorter time to demand their first painkiller (P = 0.001), and they also took significantly more total morphine (P = 0.001). An increased number of people in the QLB group reported satisfaction as a result of taking the analgesic.

**Conclusion:** Quadratus lumborum block is a promising technique for postoperative analgesia for patients undergoing gynecological cancer surgery. This block provides relatively prolonged duration of pain relief, compared to thoracic paravertebral block.

**Abbreviations**: FLACC - Face, Legs, Activity, Cry, Consolability scale; GC - gynecological cancer; QLB - quadratus lumborum block; QLB2 - Bilateral quadratus lumborum block; TPVB - thoracic paravertebral block; VAS - visual analogue scale

**Keywords**: Quadratus lumborum block; Thoracic paravertebral block; Gynecological cancer surgery; Postoperative pain management.

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### 1. INTRODUCTION

Pain experienced after gynecological surgery is a major source of patients' compromised quality of life.<sup>1</sup> It could be related to prolonged postoperative care, hospital stay, higher rates of complications, and increased readmission rates.<sup>2</sup> First-line therapy for postoperative pain relies traditionally on opioids.<sup>3</sup> In addition to drowsiness and respiratory depression, this may also cause nausea, vomiting, ileus, and abdominal pain from the opioids.<sup>4</sup> Avoiding opioid use with multimodal analgesia or regional blocks is currently the primary method to improve the patient's condition and functional recovery after surgery.<sup>5</sup>

Different regional nerve blocks have been introduced as components of multimodal analgesia. Thoracic paravertebral block (TPVB) is one of these procedures. Most of the investigations on TPVB focused on its use in breast and thoracic surgery.<sup>6,7</sup> Nevertheless, a systematic review involving 20 studies indicated that in adult patients following abdominal surgery, TPVB appeared to be a potent pain treatment modality.<sup>8</sup> Inguinal herniorrhaphy patients who had TPVB had much less postoperative pain and required fewer narcotics than those who received TAP block or ilioinguinal block.<sup>9</sup>

The quadratus lumborum block (QLB) is an innovative technique for the control of pain that is performed under ultrasound supervision following abdominal surgery. Local anesthetic (LA) injections are used in this approach to numb the thoracolumbar nerves.<sup>10</sup> These injections are placed close to the quadratus lumborum muscle. It is believed that the expansion of the lumbar afferent into the paravertebral area is responsible for the reduction in somatic and visceral pain that is linked with QLB.<sup>11</sup> It has been demonstrated that QLB is useful for postoperative pain after a wide variety of abdominal procedures,<sup>12-14</sup> including hysterectomy and cesarean section.

We conducted this trial to compare the analgesic efficacy and safety of ultrasound-guided quadratus lumborum blocks with ultrasound-guided thoracic paravertebral blocks in patients who were scheduled for surgery for gynecological cancer.

# 2. METHODOLOGY

A total of fifty women, diagnosed with gynecological cancer were enrolled in this prospective, randomized trial between April 2021 and April 2022, at the Cairo University branch of the National Cancer Institute (NCI), which houses the surgical department. The protocol for the research was approved by the Institutional Review Board of the NCI (No. 201516033.3), and the study was registered with ClinicalTrials.gov (Identifier: NCT04827043).

Inclusion criteria were; BMI 20-40 kg/m<sup>2</sup>, ASA class II-III ladies scheduled for gynecological cancer surgery. Patients who were unwilling, or had a history of sensitivity to local anesthetics, psychological disorders, coagulopathy or therapeutic anticoagulant drugs, any local infection, as well as those on chronic pain therapy were excluded.

All patients were subjected to preoperative assessment including medical history, physical examination, and routine investigations. An intravenous (IV) cannula of 18 gauge was placed, and midazolam 0.02-0.05 mg/kg was administered IV. An antiemetic agent was given as premedication with continuous monitoring of the vital signs. A portable ultrasound machine (Sonosite Mturbo®; Inc., Bothell, WA, USA) with linear 6-13 MHz or curved 2-5 MHz transducer probes was used.

Using a computer-generated random number generator, participants were split into two groups of 25 each; e.g., QLB group and TPVB group.

### 2.1. Technique of QLB

The patient was positioned with the block side up. The ultrasonic probe was disinfected and coated with sterile covers. Under strict aseptic conditions, lidocaine 1% (2-5 mL) was injected in the skin and subcutaneous tissues. On the posterior portion of the QL, under ultrasound guidance, a 20-gauge echogenic needle (Pajunk, SonoPlex® Stim cannula, Geisingen, Germany; 100 mm) was advanced. It was possible to identify the QL muscle because it was attached to the lateral border of the transverse process of the L4 vertebral body. The psoas major muscle was found to be located anteriorly, the erector spinae muscle was found to be adherent



### Figure 1: CONSORT flow chart

to the tip of the transverse process.<sup>10</sup> This specific pattern was identified as a shamrock with three leaves. Among the fascial plane of the QL and the erector spinae muscle, the LA injection was given. A 0.3 mL/kg of bupivacaine 0.25% with 5  $\mu$ g/mL of epinephrine was injected into each side after negative aspiration and hydrodissection (3-5 mL of saline) was performed. Ultrasound was used to guide the spread of the injectate. Loss of sensation and dermatomal distribution were assessed.

### 2.2. Technique of TPVB

In the lateral position, TPVB was performed by a single injection at a single level.<sup>15</sup> A linear ultrasonographic probe was positioned transversely immediately lateral to the midline till identification of the rib and after palpation of the T10 spinal process. After locating and visualizing the intercostal gap, the probe is repositioned to its caudal position. The pleura, internal intercostal membrane, and superior costotransverse ligament were visible throughout the block.<sup>16</sup> A 100 mm 20-G echogenic needle (Pajunk, SonoPlex®, Germany) was placed around 2.5 cm from the midline. To access the transverse process, the needle was angled and advanced from the periphery to the midline, then it pierced the internal intercostal membrane. The pleura was always

visualized clearly, and ultrasound guidance was used to verify the insertion point. After careful aspiration, bupivacaine 0.25% with epinephrine 5  $\mu$ g/mL (0.3 mL/kg each side)<sup>17</sup> was injected slowly in small increments. Moreover, the pleura descended upon close examination. Before inducing anesthesia, the patients were observed for 30 min.

# 2.3. General anesthesia technique

After 3-5 min of preoxygenation with 100% O<sub>2</sub>, anesthesia was induced with fentanyl 1-2 µg/kg, propofol 2.5 mg/kg, and atracurium 0.5 mg/kg and endotracheal intubation achieved. Anesthesia was maintained with 1-1.5% isoflurane and atracurium besylate 0.1 mg/kg IV every 30 min. Fentanyl 1 µg/kg as an additional dose was given if the HR and MAP raised by 20% above the baseline value. After the completion of the surgical operation, inhalational anesthesia was discontinued. The effects of

muscular relaxation were reversed by neostigmine 0.04 to 0.08 mg/kg and atropine sulfate 0.02 mg/kg IV.

As soon as the individual was fully awake, she was sent to the recovery room and given oxygen with humidification. The standard postoperative analgesic was 1 gm of paracetamol IV every 8 h. Rescue analgesia, e.g., morphine 1 mg bolus with 10 min lockout and 4-6 mg/h as an upper limit, was administered for the first 24 h, if the visual analogue scale (VAS) score  $\geq$  3. An independent, qualified anesthesiologist who was blinded to patient allocation and the type of the block, used VAS to assess each individual's pain, the morphine consumption, and the patient satisfaction. The patientrated level of pain using a VAS was a primary outcome. Patients' satisfaction, first request for analgesics and the amount of morphine consumed during the first 24 h following surgery were the secondary outcomes.

Adverse effects were recorded together with the heart rate, blood pressure, and breathing rate. Individual satisfaction level was calculated as the global satisfaction rated at four levels (very satisfied, satisfied, partially satisfied, and not satisfied) at the end of followup of 24 h after surgery.

### 2.4. Sample size estimation

As there was no previous similar study, we proposed that a 1-point difference is а statistically significant shift in VAS score during the postoperative period based on the previous studies. If the predicted standard deviation of the VAS ratings was also 1, then in order to have 90% power at a 0.05 two-tailed significance threshold, we would require a sample size of 23 participants per group. G\*Power 3.1.9.2 (Institut version für Experimentelle Psychologie, Heinrich Heine Universität, Düsseldorf, Germany) was utilized to determine the sample size. To account for potential drop-outs, 25 participants were randomly assigned to each group.

### 2.5. Statistical analysis

Statistical analysis was performed with IBM SPSS Statistics version 23.0, (IBM Corp. in Armonk, New York, USA). In order to determine whether or not the distribution was normal across all variables, the Kolmogorov-Smirnov test was carried out. Means, variances, and ranges, sometimes known as the mean, median, and range, were used to summarize the statistical data. In order to depict the qualitative data

accurately, we employed percentages and frequency counts. A chi-square test was carried out in order to investigate the degree of link between the qualitative variables. In order to compare the two groups of subjects based on quantitative information, either a t-test or a Mann-Whitney U-test was carried out. For the purpose of comparing repeated measurements, the Friedman test was utilized, and for a more in-depth examination of the data, the appropriate pairwise test was utilized. A P < 0.05 was used as the threshold for significant results.

### 3. RESULTS

Out of eighty-seven participants that were initially evaluated, 37 were found to be ineligible for one reason or another. Fifty records from participants were analyzed in the end (Figure 1). Table 1 shows that there was

statistically no significant variation between the two groups regarding initial characteristics.

Table 1: Baseline characteristics of the two studied groups				
	QLB Group (n = 25)	TPVB Group (n = 25)	P value	
Age (y)	57.9 ± 8.7	$60.4 \pm 8.0$	0.306	
ASA				
•	20 (80)	21 (84)	1.000	
•	5 (20)	4 (16)		
Weight (kg)	76.8 ± 10.0	71.6 ± 11.6	0.093	
Duration of surgery (min)	216 ± 27	213 ± 30	0.699	
Data are expressed as mean ± SD or n (%)				



Figure 2: Comparative intra- and postoperative changes in heart rates

Age, body weight, ASA physical status, and duration of surgery did not differ significantly (P > 0.05) across the groups.

There was no discernible difference in heart rate between the two groups (P = 0.913) and no statistically significant variation in heart rate (P = 0.191) as shown in Figure 2. Statistical analysis showed no significant differences in mean arterial pressure among the preoperative and postoperative periods in the QLB group (P = 0.382). On

the other hand, mean arterial pressure showed significant changes in the TPVB group (P < 0.001) (Figure 3). It is worth noting that all heart rate and blood pressure readings during the intraoperative and postoperative periods were within the clinically accepted ranges. The oxygen saturation was almost stable in the two groups up to 24 h postoperatively (Figure 4).



Figure 3: Comparative intra- and postoperative changes of mean arterial pressure





Table 2: Comparative VAS score among QLB and TPB group (Mean $\pm$ SD)				
VAS time	QLB group	TPVB group	P value	
1 h	$1.60 \pm 0.96$	1.76 ± 0.83	0.570	
2 h	2.52 ± 0.59	2.08 ± 0.49	0.008	
4 h	2.68 ± 0.48	2.76 ± 0.44	0.533	
6 h	$2.52 \pm 0.51$	2.96 ± 0.61	0.009	
12 h	2.64 ± 0.57	3.56 ± 0.65	< 0.001	
24 h	2.92 ± 0.70	4.40 ± 0.65	< 0.001	

Table 3: Morphine needs among QLB and TPVB			
	QLB group	TPVB group	P value
Need morphine	12 (48.0%)	25 (100.0%)	< 0.001
Total morphine (mg/24 h)	2.56 ± 3.14	9.96 ± 2.39	< 0.001
Time to first morphine request (h)	16.67 ± 4.23	12.88 ± 1.88	0.001
Data are expressed as mean $\pm$ SD, or n (%); P < 0.05 considered significant			

Table 4: Comparison amongst QLB versus TPVB group as regarding dermatomal distribution				
		QLB group	TPVB group	P value
Dermatomal Distribution 1	T6	5 (20.0)	0 (0.0)	< 0.001
	T7	9 (36.0)	1 (4.0)	
	Т8	8 (32.0)	11 (44.0)	
	Т9	3 (12.0)	13 (52.0)	
Dermatomal Distribution 2	T11	0 (0.0)	6 (24.0)	< 0.001
	T12	3 (12.0)	12 (48.0)	
	L1	13 (52.0)	7 (28.0)	
	L2	9 (36.0)	0 (0.0)	
Data presented as n (%); $P < 0.05$ considered significant				

Table 5: Comparative patient satisfaction in the groups				
Patient Satisfaction	QLB group	TPVB group	P value	
Very satisfied	15 (60.0)	7 (28.0)		
Satisfied	10 (40.0)	15 (60.0)	0.031	
Partially satisfied	0 (0.0)	3 (12.0)		
Data presented as n (%); $P < 0.05$ considered significant				

VAS scores were comparable between QLB and TPVB groups up to 12 h postoperative, then there were significantly higher levels of VAS scores in TPVB group in comparison to QLB group. specially at 12 and 24 h (P < 0.001).

The time to first request for rescue analgesics was shorter in the TPVB compared to QLB group;  $12.88 \pm 1.88$  h vs.  $16.67 \pm 4.23$  h (P = 0.001) respectively (Table 3).

Total morphine consumption was significantly more in the TPVB compared to QLB group;  $9.96 \pm 2.39$  vs. 2.56  $\pm 3.14$  mg/24 h respectively (Table 3).

The dermatomal distribution of sensory block was measured during the first 40 min after performing the block. Table 4 shows the dermatomal distribution of sensory blocks in number of patients for both QLB and TPVB. More patients of QLB group experienced a loss of cold and pinprick feeling amongst dermatomal levels T7 and L2, while more patients in TPVB group experienced a loss of sensation among dermatomal levels T8 and T12.

Regarding patient satisfaction, all patients in QLB group were satisfied or very satisfied. TPVB group showed global satisfaction level, but 3 cases were partially satisfied in this group (Table 5).

No complications regarding LAST, hematoma formation, infection, pneumothorax, vascular injury or pleural injury, were reported. Two patients developed hypotension in the TPVB group, which was managed by

intermittent doses of ephedrine 3 mg IV and intravenous fluids.

# 4. DISCUSSION

Gynecologic cancers are often treated with major abdominal surgery that is commonly associated with postoperative pain in more than 60% of patients as well as significant psychological distress.<sup>18</sup> However, postoperative pain management after gynecological surgery is often inadequate.<sup>19</sup> Restricted ambulation, thrombosis, wound dehiscence, chronic pain, and extended recovery times are all consequences of ineffective postoperative pain management.20 Incorporating a multimodal pharmacologic strategy into the enhanced recovery after surgery (ERAS) route is a current area of focus.<sup>1</sup> Essential components of ERAS interventions include neuraxial (e.g., epidural, spinal) blocks, peripheral nerve blocks, and wound infiltration regional analgesic approaches.<sup>21,22</sup> Due to the challenges hypotension, excessive of ambulation, fluid administration, and problems of neuraxial technique, thoracic epidural analgesia, which was formerly considered the gold standard, has fallen out of favor in the recent past.23

There are multiple studies on various types of cancers that explore the role of regional block in cancer recurrence. Most regional techniques in these studies were epidural or PVB. Study done by Exadaktylos and his colleagues including 129 participants showed that the reduction in breast cancer recurrence was approximately four-fold if the patients received PVB during surgery and postoperatively.<sup>24</sup> In a study by Biki and his colleagues, 225 patients with prostatic cancer were followed for about 3-13 years, explained that prostatic carcinoma recurrence decreased up to 57% after they had an epidural procedure as reported.<sup>25</sup>

This study demonstrated that patients undergoing surgery for gynecological cancer found QLB to be a potent and efficient analgesic method under general anesthesia. Compared with TPVB, QLB group reported much less severe pain up to 24 h after surgery with more dermatomal distribution than TPVB. After surgery, cases required less rescue morphine analgesia, had prolonged analgesia duration and decreased total morphine consumption because of QLB. All patients showed hemodynamic stability under both techniques.

This prospective comparative randomized double blinded study suggested that QLB2 (bilateral QLB) reduced VAS scores compared to TPVB. The main finding was the superiority of QLB2 in reducing pain score specially at 12 and 24 h postoperatively. The two blocks appear to be comparable from 0 h up to 12 h postoperatively. These findings are consistent with those of a study by Lee and coworkers that indicated patients who had radical cystectomy experienced no more pain relief from a single injection of QLB than they would have from 24 h of continuous PVB.<sup>26</sup>

In our trial, we employed 0.25% bupivacaine 0.3 mL/kg for both the QLB2 and TPVB, while Lee and colleagues used a greater dosage of local anesthetic (0.5%), along with dexmedetomidine as an adjuvant and hydromorphone as a postoperative patient-controlled analgesia (PCA).<sup>26</sup>

Lin et al. published a meta-analysis of 14 studies involving 1001 patients found that QLB2 was more effective than a control group at reducing pain scores and postoperative morphine consumption in patients who had abdominal surgeries. This was performed during patients' abdominal operations.<sup>27</sup> Subgroup analyses of patients who underwent spinal anesthesia, however showed that QLB2's analgesic benefit wore off after 24 h. When compared to the control group, they experienced much less discomfort at 6, 12, and 24 h.<sup>27</sup>

Taman et al., discovered that in pediatric patients after laparoscopic abdominal surgery, a QLB can result in a lower Face, Legs, Activity, Cry, Consolability scale (FLACC) score and more effective postoperative pain relief than an erector spinae plane block (ESPB). In the study by Taman et al., patients received bupivacaine 0.25% (0.5 mL/kg) injected bilaterally into QLB2 and also into the transverse process of the thoracic spine (T8) for ESPB. The FLACC score for the QLB group was significantly lower than that of the ESPB group at 6, 8, 12 and 20 h postoperatively.<sup>28</sup>

In patients after major gynecological surgery, Melnikov et al. found that the TPVB significantly reduces VAS scores both at rest and during movement. He also claimed that the TPVB was more effective than the TAP block at relieving pain. <sup>17</sup> The results of the current investigation are consistent with these hypotheses. Abdelrahman et al., also found that after open kidney procedures, the VAS score was significantly lower in the TPVB group within the first 24 h postoperatively compared to the TAP block. In addition, the TPVB group consumed less morphine overall.<sup>29</sup>

However, Sabry et al. concluded that when it comes to analgesic efficacy, opioid intake, and length of hospital stay following radical cystectomy, there is no difference amongst continuous QLB and TPVB. They arrived at this conclusion after contrasting the two approaches. Whatever the case may be, our study used a single dose of 0.3 mL/kg bupivacaine 0.25% with epinephrine 5  $\mu$ g/mL per side, while they used a continuous infusion of 0.3 mL/kg bupivacaine as a bolus then 0.1 mL/kg/h infusion on both sides. Also, we did bilateral single shot TPVB at T10 while they performed bilateral continuous TPVB. We administered morphine in intermittent doses for postoperative pain relief if VAS  $\geq$  3 while they injected nalbuphine 0.1 mg/kg when VAS  $\geq$  4).<sup>30</sup>

In contrast to our study, Priya et al. demonstrated that there was no difference in pain scores at rest and movement (NRS). In their study, the patients received bilateral QLB2 with injection of bupivacaine 0.25% 0.3 mL/kg/side in LSCS with spinal anesthesia. This study is different from our result in being in healthy patients, while our patients are gynecological cancer patients. They used fentanyl for postoperative pain but we used morphine as analgesic.<sup>31</sup>

As regarding total morphine consumption and the first time of morphine request, the QLB2 group showed a longer duration of analgesic action ranging from (16-24 h) postoperative in comparison to TPVB. The time to need morphine bolus dose was significantly shorter in TPVB. Also, the total morphine consumption was significantly lower in QLB than TPVB during postoperative 24 h.<sup>32</sup>

In addition, a meta-analysis of 7 trials involving 346 pediatric patients was conducted by Zhao et al. The rate of postoperative rescue analgesia was shown to decrease significantly within the first 24 h of the study. While the other 3 studies used different methods, 4 compared QLB2 to caudal or TAP blocks.<sup>33</sup>

In line with our findings, Yousef et al., found that QLB2 improved postoperative analgesia in cases undergoing complete abdominal hysterectomy while reducing their need for opioids.<sup>14</sup> A study by Taman et al., too, found that in pediatric cases following laparoscopic abdominal surgery, QLB gives higher analgesic efficacy and reduced opioid intake compared to ESPB.<sup>28</sup>

Against our result, the study by Yuan et al. compared between QLB and TPVB in laparoscopic renal surgery and reported that cumulative morphine consumption and long-term VAS scores showed the efficacy and safety of QLB as an alternative to TPVB in abdominal surgery. Their study may be attributed to the difference in the technique; QLB with two different volumes of ropivacaine 0.5%, 0.3 mL/kg and 0.6 mL/kg per side, while we performed QLB2 and in plane TPVB. Also, their study involved laparoscopic renal patients who might have less pain scores than gynecological cancer surgery.<sup>34</sup>

The dermatomal distribution of our study showed a significant difference between the QLB and TPVB group. The QLB showed a wider dermatomal distribution ranged from T7 to L2 approximately, while in TPVB, the distribution only included 3-5 dermatomes.

Our findings are consistent with those found in the research conducted by Wang et al., who compared QLB

and TPVB in cases who had undergone laparoscopic partial nephrectomy. They found that both QLB2 and TPVB had sensory block ranges that covered the nerve distribution area responsible for the pain conduction of laparoscopic partial nephrectomy. This helps to explain why QLB2 produced a non-inferior pain relief effect when compared with TPVB. However, QLB2 produced a wider sensory block range than TPVB did.<sup>31,32</sup> The results ares inconsistent with Abd Ellatif and Abdelnaby, who reported that QLB appears to have the same dermatomal distribution as ESPB in patients with open nephrectomy.<sup>35</sup>

In our study, the hemodynamic values (MAP and HR) were comparable among the two studied groups intraoperative and in the first 12 h postoperative.

In our study, QLB showed that all cases were generally quite satisfied. Despite the fact that TPVB demonstrates overall satisfaction with service, there are 3 cases that were only partially satisfied.

In terms of adverse effects and complications, no cases were recorded of local anesthetic toxicity, hematoma or infection, lower limb weakness, desaturation, or respiratory depression. There were only two patients in the TPVB group who had hypotension. Both of these patients required ephedrine 9 mg and intravenous fluids; however, the hypotension was only a temporary condition.

## **5. LIMITATIONS**

A larger sample size at different gynecological cancer centers is required to confirm and validate the results. Another limitation; we did not differentiate between the types of gynecological procedures and the type of incision, midline incision, Pfannenstiel incision, or others.

## 6.CONCLUSION

The era of ultrasound-guided nerve blocks has facilitated the appearance of many novel effective nerve block procedures. Of these new techniques is the quadratus lumborum block, which is considered as an indirect thoracic paravertebral block. Quadratus lumborum block and thoracic paravertebral block appear to be safe and effective in gynecological cancer surgery. As regards gynecological cancer surgery. There is a significant amount of research that needs to be done in order to demonstrate the efficacy, safety, and feasibility of various quadratus lumborum block techniques, as well as the efficacy of different types of local anesthetics and additional agents.

### 7. Availability of Data

Numerical data generated in this study is available on request with the corresponding author.

### 8. Conflict of interests

The authors disclose zero conflict of interest with this article's publication.

#### 9. Ethics Review and Approval

The ethics committee at The National Cancer Institute (NCI), Cairo University, gave their stamp of approval to this prospective randomized study. The National Cancer Institute's IRB has given its blessing to the study's design (No. 201516033.3).

### **10. Registration for Clinical Trials**

ClinicalTrials.gov has a record of the study. ID: NCT04827043

### **11. Authors Contribution**

EM, FH: conduction of the study work

KA, EA: manuscript editing

TT: literature search

MH: statistical analysis and review

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