

Title

Intraoperative pressure monitoring of the lower leg for preventing compression-related complications associated with the lithotomy position

Short title

Intraoperative pressure monitoring of lower leg

Authors

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Abstract

Background

Several serious complications are associated with the lithotomy position, including well-leg compartment syndrome and peroneal nerve paralysis. The aims of this study were to identify risk factors for the intraoperative elevation of lower leg pressure and to evaluate the effectiveness of monitoring external pressure during surgery for preventing these complications.

Methods

The study included 106 patients with a diagnosis of sigmoid colon or rectal cancer who underwent elective laparoscopic surgery between June 2019 and December 2020. We divided the posterolateral side of the lower leg into four parts (upper outside, upper inside, lower outside, lower inside) and recorded the peak pressure applied to each area at hourly intervals during surgery (called “regular points”) and when the operating position was changed (e.g., by head-tilt or leg elevation; called “points after a change in position”). When the pressure was observed to be higher than 50 mmHg, we adjusted the position of the leg and re-recorded the data. Data on postoperative leg-associated complications were also collected.

Results

The pressure was measured at a total of 1125 points (regular, n=620; after change of position, n=505). The external pressure on the upper outer side of the right leg (median, 36 mmHg) was higher than that on any other area of the lower leg. The pressure increase to more than 50 mmHg was observed not only during the change of position (27.5%) but also during regular points (22.4%). Bodyweight, strong leg elevation, and low head position were identified as factors associated with increased external pressure. There have been no compression-related complications in 534 cases at our institution since the introduction of intraoperative pressure monitoring.

Conclusions

Several risk factors associated with increased external pressure on the lower leg were identified. Intraoperative pressure monitoring might help reduction of pressure-related complications, needing further and larger prospective data collections.

Keywords:

Compartment syndrome, Peroneal nerve paralysis, Lithotomy position, Complications, Minimally invasive surgery.

Introduction

The lithotomy position is commonly used in gastrointestinal, urological, and gynecological surgery to access the pelvic and perineal organs [1]. However, several serious complications are associated with this position, including well-leg compartment syndrome (WLCS) and peroneal nerve paralysis.

WLCS is a condition in which the fascial compartment pressure in the lower leg exceeds the perfusion pressure, causing tissue ischemia and necrosis [2]. This is a potentially devastating complication that can result in permanent disability and even death. Although the overall incidence of WLCS in patients who undergo procedures while in the lithotomy position is estimated to be 1 in 3500[3], this figure is probably an underestimate of the true incidence, because many cases, especially those with less severe clinical features, might not be reported. Peroneal nerve paralysis is also a well-recognized compression-related complication following surgery in the lithotomy position. The most common site of compression is at the bony prominence of the fibular neck [4]. One study found that 1 in 3608 patients who underwent surgery in a lithotomy position developed neuropathy of the lower extremities postoperatively [5]. Several methods have been proposed to prevent compression-related complications, such as intermittent pneumatic compression[6], repositioning, infusion and blood pressure management, and appropriate observation of the lower legs[7, 8]. However, this complication, although infrequent, has not been completely prevented.

Although there are several known causes of these complications, including long operating time, young age, obesity, vascular disease, and inappropriate positioning, the excessive elevation of compartment pressure in the lower leg plays an important role [9]. Excessive external pressure on the lower leg leads to compartment syndrome or compression neuropathy, and there are some reports suggesting that external compression by the calf support increases the compartment pressure [10, 11]. However, external pressure on the lower leg usually cannot be monitored intraoperatively because both legs are draped.

Therefore, in this study, we sought to identify risk factors for the elevation of intraoperative external pressure on the lower leg and to determine the effectiveness of an external pressure monitoring system for preventing compression-related

complications.

Patients and Methods

Patients

We enrolled 106 patients who underwent elective laparoscopic surgery for sigmoid colon or rectal cancer between June 2019 and December 2020. The inclusion criteria were age over 20 years and provision of informed consent. Patients with limited lower limb mobility and those deemed unsuitable for participation in the study by the attending clinician were excluded. This study was approved by the institutional review board of Fukuoka University Hospital, Fukuoka, Japan, registered in the UMIN Clinical Trials Registry (U-19-06-002), and conducted in accordance with the Declaration of Helsinki. Written informed consent for enrollment in the study was obtained from all patients.

Study protocol

The patients were placed in a modified lithotomy position with stirrups (Levigator®, MIZUHO Corporation, Tokyo, Japan). All patients had intermittent compression devices on their lower leg. A pressure-distribution measurement system (SR softvision, Sumitomo Riko Company Limited, Japan) was used to evaluate the compression pressure on the posterolateral side of the lower leg in contact with the stirrup. We divided the posterior side of the lower leg into four areas (upper outside, upper inside, lower outside, and lower inside; Figure 1) and recorded the peak pressure at each site at hourly intervals during surgery (“regular points”) and when the operating position was changed (e.g., head-down tilt, leg elevation; collectively called “points after a change in position”).

We also recorded the degrees of head-down and right tilt and lower leg elevation at the time of recording each data point. Lower leg diameter and symptoms (sensorimotor impairment, induration, redness) were recorded before and after surgery. When the pressure was observed to be higher than 50 mmHg, we adjusted the position of the lower leg in the stirrup to reduce the pressure and re-recorded the data after adjustment.

A cutoff threshold of 50 mmHg was selected based on the study by Matsen et al. [12], which found that patients with maximum intracompartmental pressures of ≤ 45 mmHg did not require fasciotomy and had no residua of compartment syndrome while those with

maximum intracompartmental pressures of >55 mmHg showed significant loss of neuromuscular function attributable to compartment syndrome.

Study endpoints

The primary endpoint of the study was the incidence of compression-related complications (compartment syndrome or peroneal nerve paralysis). Secondary endpoints were risk factors for increased external pressure on the lower leg, frequency of lower leg pressure >50 mmHg, effectiveness of decompressing the lower leg when pressure exceeds 50 mmHg, incidence of lower limb neuropathy, and gross abnormality.

Statistical analysis

Given that this was a pilot feasibility study, no specific sample size calculation was performed. The study data were examined for statistical significance using analysis of variance. Multivariate analysis was performed using a logistic regression model. All statistical analyses were performed using JMP pro version 15.0 for Macintosh (SAS Institute Inc., Cary, NC, USA). A P-value <0.05 was considered statistically significant.

Results

Background Characteristics

The patient demographics are shown in Table 1. During surgery, all patients were placed in the Trendelenburg position with a right-down tilt. The 106 patients in the study included 12 in whom surgery was performed using a transanal approach that required strong leg elevation. Fifty-six patients were treated laparoscopically, 38 patients were treated by robotic-assisted surgery, and 12 were treated by a simultaneous laparoscopic and transanal/perineal endoscopic approach [13].

Pressures Recorded

Lower leg pressure was measured 4–40 times intraoperatively in each patient, and a total of 1125 data points (regular, n=620; change of position, n=505) was obtained. The pressures in each lower leg area are shown in Table 2. The highest external pressure among the 8 areas in both legs was recorded from the upper outer side of the right leg

(median, 36 mmHg). This might have been because most of the surgery was performed in the right-down tilt position, in which gravity would play an important role. Almost no external pressure was observed on the inferior half of the lower leg.

Factors associated with pressure on the upper areas of the lower leg

Patient-related factors associated with pressure on the lower leg are shown in Figure 2. We compared the relationship between external pressure and sex, body weight, BMI, and lower leg diameter. Male sex, high body weight, high BMI, and a large lower leg diameter were identified as potential contributors to the increased pressure on the upper areas of the lower leg.

Intraoperative factors associated with pressure on the upper areas of the lower leg are shown in Figure 3. The results were different for each of the four areas studied. We examined the relationship between the time from the start of surgery to the measurement point and leg pressure. We found a correlation between the pressure at the upper lateral side of the right leg and operative duration. As for the intraoperative position, in the moderate head-down position (10-20 degrees), the leg pressure showed an upward trend in all regions, but in the right lateral tilting and leg elevation position, the pressure changed differently depending on the areas of the lower legs.

Frequency of external pressure over 50 mmHg on the lower leg

The number and frequency of occasions when external pressure >50 mmHg in the lower leg was recorded are shown in Table 3. Regardless of the recording position, the frequency of a pressure >50 mmHg was 139 (22.4%) for all regular points (n=620) and 139 (27.5%) for all points after a change of position (n=505). External pressure >50 mmHg was recorded more often in the upper outside area of the right lower leg than in other areas.

Factors associated with pressure exceeding 50 mmHg

The results of univariate and multivariate analysis of factors potentially associated with elevation of pressure 'at any site' (to >50 mmHg) are shown in Table 4. Multivariate analysis showed that high body weight, strong leg elevation (>60 degrees), and a head-

down position were independently associated with elevated pressure. On the other hand, univariate and multivariate analysis of factors potentially associated with elevation of pressure 'at right upper outside part' (supplemental table) shows that in addition to the previously mentioned ones, we found that large leg diameter and right lateral tilting of the table are significantly associated with elevation of external pressure.

Effect of repositioning of the lower leg

As mentioned above, elevated pressure (>50 mmHg) was observed for 278 (24.7%) of the 1125 data points; in 124 of these 278 cases (44.6%), the measurements were recorded after repositioning the lower legs in the stirrups. Repositioning of the lower leg was associated with a decrease in average pressure from 60.8 mmHg to 41.2 mmHg. At 97 of the 124 points (78.2%), the pressure decreased to <50 mmHg.

Postoperative complications

Postoperative complications are shown in Table 5. There were no major compression-related complications (Clavien-Dindo grade II or higher). Furthermore, in the 5 years before the introduction of intraoperative pressure monitoring, the frequency of postoperative compression-related complications in the lower leg, including cases that did not require surgical intervention, was 0.2% (7/3368), among patients who had undergone surgery in the lithotomy position at our institution. Since the introduction of this monitoring system in 2017, no compression-related complications requiring surgical treatment have occurred in the 534 patients who have undergone minimally invasive colorectal surgery, including the 106 cases described in this report.

Discussion

In this study, we monitored the pressure on the lower leg during minimally invasive surgery for left-sided colon cancer and made several important observations. First, external pressure could become elevated in any area of the lower leg at any time during surgery but was most frequently observed on the right upper side of the lower leg. Second, repositioning of the lower leg in the stirrup was effective for decompression.

Third, several risk factors for elevated pressure were identified. Fourth, the use of a pressure monitoring system could be effective for preventing pressure-related complications, but additional large-scale prospective data collection is needed.

One of the important causes of compression-associated complications in the lithotomy position, such as WLCS or peroneal nerve paralysis, is prolonged and excessive pressure against the posterolateral side of the lower leg, which can cause damage to the muscle compartment or the nerve itself [11, 14]. This excessive pressure is considered to be caused by an imbalance of pressure distribution, perhaps as a result of a shift in leg position in the stirrup during surgery.

Intraoperatively, the appearance of the lower leg in the leg support device cannot be observed directly because the leg is covered by a surgical drape. Several methods for intraoperative monitoring of the pressure in the muscle compartment of the lower leg have been reported, including a needle manometer, a slit catheter, and an 18-gauge needle [10], but all these methods are invasive and not practical. However, the monitoring system used in this study is non-invasive and provides an easy-to-use method for evaluating an excessive load on a specific area on the lower leg.

We found that the external pressure on the lower leg exceeded the threshold (50 mmHg) at 24.7% of all points measured, and this increase may not have been noticed without the use of the pressure monitoring system. Furthermore, an elevation in pressure was observed regardless of whether there had been a change in position, meaning that there is a risk of increased pressure at any time during surgery. When the pressure exceeded the threshold, repositioning of the lower leg decreased the pressure at all points (78% below the threshold). This real-time adjustment of the position of the lower leg in the stirrup would be effective for the prevention of compression-related complications.

Although we set the threshold for decompression at 50 mmHg in this study, the cut-off value for an increased risk of compression-related complications remains debatable. A previous study found that the capillary blood pressure in human skin was 32 mmHg with microinjection [15]. Another study recommended that the external pressure loading to the skin surface should be kept at <32 mmHg or as low as possible [16]. However, the relationship between external pressure and compartment pressure has not been clearly

elucidated. The currently accepted value for a diagnosis of compartment syndrome is within 30 mmHg of the diastolic blood pressure minus the intracompartmental pressure [17]. Another study in patients with a compartment pressure of >55 mmHg who had significant loss of neuromuscular function attributable to compartment syndrome proposed an absolute value of 45 mmHg [12].

In this series, male sex, high body weight, high BMI, and a large lower leg diameter were risk factors for increased pressure. The muscle volume of the lower leg is also considered to be a risk factor for compartment syndrome [8]. In general, compared with females, males have a greater amount of muscle in the lower legs and a larger lower leg diameter and therefore are more affected by external pressure.

A low head position during surgery was associated with increased external pressure, possibly because the position of the lower leg was displaced in the stirrup and the pressure was transferred from the heel to the calf [18]. Right lateral tilting of the operative table was found to be a risk factor for increased pressure on the upper lateral area of the right leg (supplemental table) and the upper inner area of the left leg, although no significant difference was found for the four sites as a whole. It is assumed that the right rotation of the operating table causes a change in the weight-bearing area of the lower leg in the stirrup. Regarding elevation of the lower leg, we found that strong lower leg elevation (>60 degrees) was associated with increased pressure in the lower leg. Moreover, there has been a report suggesting that elevation of a patient's leg from the supine position results in a 2-mmHg decrease in mean arterial pressure within the calf for each 2.5-cm vertical increment in height above the heart [3]. In addition to the increased external pressure, a head-down tilt, in particular, may impair tissue perfusion further, thereby putting the patient at even greater risk of WLCS.

Another finding in this study was that there was no pressure on the inferior area of the lower leg, which possibly reflects structural problems with the Levitator stirrups used. A wide distribution of pressure is theoretically ideal for the prevention of compression-related complications. A device that disperses pressure would be beneficial for preventing these complications. Increasing the contact area with the lower leg and dispersing the pressure is a subject for future investigation.

This study has several limitations. First, although there have been no compression-

related complications in the 534 patients who have undergone the surgery in the lithotomy position since the introduction of monitoring, the number of patients is too small to confirm the efficacy of intraoperative pressure monitoring system on lithotomy position. This monitoring might be useful for preventing these complications, but this needs to be confirmed in a larger study with more cases. Second, as discussed earlier, based on the results of previous reports, we set the threshold to 50 mmHg. However, it is unclear whether or not this value is appropriate. Moreover, in this study, the pressure on the surface of the lower leg was measured rather than that of the muscle compartment. It is also necessary to investigate the relationship between external pressure and compartment pressure. Third, in this study, we only focused on the peak pressure on the lower leg and did not take consider the effect of other factors known to be associated with compression-related complications. Despite these potential limitations, the results of this study make a significant contribution toward elucidating the mechanism underlying the development of compression-related complications in the lower leg during surgery performed in the lithotomy position.

Conclusions

Several risk factors associated with focal intraoperative elevation of external pressure on the lower leg were identified in this study. Intraoperative pressure monitoring system might help prevent compression-related complications but needs further and larger prospective data collections.

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Disclosures

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Nagano, Akira Komono, Naoya Aisu, Gumpei Yoshimatsu, Yoichiro Yoshida, Suguru Hasegawa have no conflicts of interest to disclose.

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Table 1. Patient background characteristics

Factors	n=106
Age (years)	65.0 (51.0–73) ^a
Sex (M / F)	71 / 35
Height (cm)	165.6 (155.0–169.0) ^a
Weight (kg)	63.0 (52.5–75.3) ^a
Body mass index	23.3 (20.3–27.0) ^a
Tumor location (Sigmoid colon / Rectum)	44 / 62
Operative procedure	
Lap / Robotic / Transanal or transperineal	56 / 38 / 12
Operative duration (min)	385 (269–467)

Lap; laparoscopic. ^a; Median (interquartile range).

Table 2. External pressure on each area of the lower leg (n=1125 points)

	Right (mmHg)	Left (mmHg)
Upper outside	36 (26–46)	32 (23–41)
Upper inside	27 (20–37)	29 (21–39)
Lower outside	0 (0–0)	0 (0–0)
Lower inside	0 (0–0)	0 (0–0)

Median (interquartile range)

Table 3. Frequency of pressure in any area of the lower leg exceeding 50 mmHg

	Regular (620 points)	Change in position (505 points)
Right upper outside, n (%)	87 (14.0)	92 (18.2)
Right upper inside, n (%)	38 (6.1)	32 (6.3)
Left upper outside, n (%)	47 (7.6)	41 (8.1)
Left upper inside, n (%)	35 (5.6)	40 (7.9)
Any part of the leg, n (%)	139 (22.4)	139 (27.5)

Table 4. Univariate and multivariate analysis of factors associated with elevation of external pressure (any part ≥ 50 mmHg)

		Univariate			Multivariate		
Variables	n	>50mmHg	%	P-value	Odds ratio	95% CI	P-value
Gender				<0.0001			0.1012
Male	767	230	30.0%		reference		
Female	358	48	13.4%		0.689	0.44-1.07	
Weight (kg)				<0.0001			<0.0001
-49	280	16	5.7%		reference		
50-69	499	103	20.6%		4.11	2.0-8.47	0.0001
70-	346	159	46.0%		13.2	5.67-31.0	<0.0001
BMI (kg/m ²)				<0.0001			
-24.9	705	108	15.3%				
25-29.9	359	135	37.6%				
30-	61	35	57.4%				
Leg diameter (cm)				<0.0001			0.197
-32.9	430	41	9.5%		reference		
33-34.9	320	82	25.6%		1.49	0.89-2.5	0.133
35-	375	155	41.3%		1.67	0.94-2.89	0.081
Operative duration (hrs)				0.0009			0.7975
-3	418	99	23.7%		reference		
3-6	465	113	24.3%		1.15	0.76-1.75	0.512
6-	242	66	27.3%		1.12	0.74-1.69	0.59
Low head position (degree)				<0.0001			0.0004
-9.9	469	84	17.9%		reference		
10-19.9	433	144	33.3%		2.13	1.46-3.12	<0.0001
20-	223	50	22.4%		1.58	0.98-2.54	0.0581
Right down tilt (degree)				0.0025			0.0692
0	568	116	20.4%		reference		
0.1-7.5	279	77	27.6%		1.26	0.85-1.89	0.2504
7.6-	278	85	30.6%		1.59	1.07-2.36	0.0207
Lower leg elevation (degree)				<0.0001			<0.0001
-9.9	954	229	24.0%		reference		
10-59.9	145	32	22.1%		0.93	0.58-1.5	0.767
60-	26	17	65.4%		10.9	4.11-28.7	<0.0001

CI; confidence interval.

supplemental table

Table 4. Univariate and multivariate analysis of factors associated with elevation of external pressure (right upper part) \geq 50mmHg)

		Univariate			Multivariate		
Variables	n	>50mmHg	%	P-value	Odds ratio	95% CI	P-value
Gender				<0.0001			0.9692
Male	767	157	20.5%		reference		
Female	358	22	6.1%		0.99	0.55-1.78	
Weight (kg)				<0.0001			<0.0001
-49	280	9	3.2%		reference		
50-69	499	53	10.6%		1.6	0.53-4.79	0.4
70-	346	117	33.8%		5.21	1.55-17.6	0.0076
BMI (kg/m ²)				<0.0001			
-24.9	705	60	8.5%				
25-29.9	359	97	27.0%				
30-	61	22	36.1%				
Leg diameter (cm)				<0.0001			0.0018
-32.9	430	15	3.5%		reference		
33-34.9	320	51	15.9%		3.29	1.42-7.60	0.0053
35-	375	113	30.1%		4.25	1.77-10.2	0.0012
Operative duration (hrs)				0.026			0.326
-3	418	53	12.7%		reference		
3-6	465	76	16.3%		1.35	0.89-2.06	0.158
6-	242	50	20.7%		1.31	0.80-2.16	0.2769
Low head position (degree)				<0.0001			0.004
-9.9	469	50	10.7%		reference		
10-19.9	433	94	21.7%		2.12	1.34-3.35	0.0013
20-	223	35	15.7%		1.98	1.12-3.50	0.0195
Right down tilt (degree)				0.0037			0.0379
0	568	70	12.3%		reference		
0.1-7.5	279	56	20.1%		1.75	1.09-2.81	0.0197
7.6-	278	53	19.1%		1.64	1.02-2.64	0.0409
Lower leg elevation (degree)				<0.0001			<0.0001
-9.9	954	145	15.2%		reference		
10-59.9	145	17	11.7%		0.634	0.351-1.14	0.1303
60-	26	17	65.4%		21.7	7.71-60.8	<0.0001

Table 5. Postoperative complications (n=106)

Complication	n (%)
Pain	4 (3.7)
Numbness	2 (1.9)
Flare	2 (1.9)
Heat sensation	0
Induration	0
Restrictions in movement	0
Motor disturbance	0
Sensory disturbance	1 (0.9)

Figure legends

Figure 1. Intraoperative monitoring of pressure on the lower leg.

- a) Placement of the pressure-distribution measurement system to evaluate the compression pressure on the posterolateral side of the lower leg in contact with the stirrup. UO: upper outside; UI: upper inside, LO: lower outside; LI: lower inside.
- b) The peak pressure of each area is indicated. This shows the case of a right foot.

Figure 2. Patient factors associated with external pressure on the lower leg.

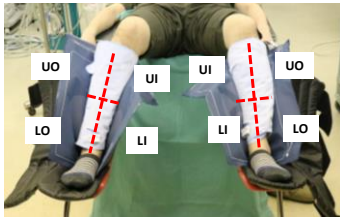
- a) Gender (M: male, F: female), b) body weight (low: 35–49.9 kg, middle: 50–69.9 kg, high: 70– kg), c) BMI (low: 15–24.9 kg/m², middle: 25–29.9 kg/ m², high: 30– kg/ m²), d) leg diameter (thin: <32.9 cm, normal: 33–34.9 cm, fat: 35– cm).

Figure 3. Intraoperative position-related factors associated with external pressure on the upper areas of the lower leg.

- a) operative duration (0–3 h, 3–6 h, 6– h), b) low head position degree (0–10, 10–20, 20–), c) right down tilt degree (0 , 1–7.5 , 7.6–), d) lower leg elevation degree (0–10, 10–50, 50–)

Figure 1

a)



UO : upper outside
UI : upper inside
LO : lower outside
LI : lower inside

b)

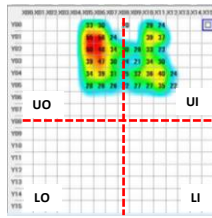
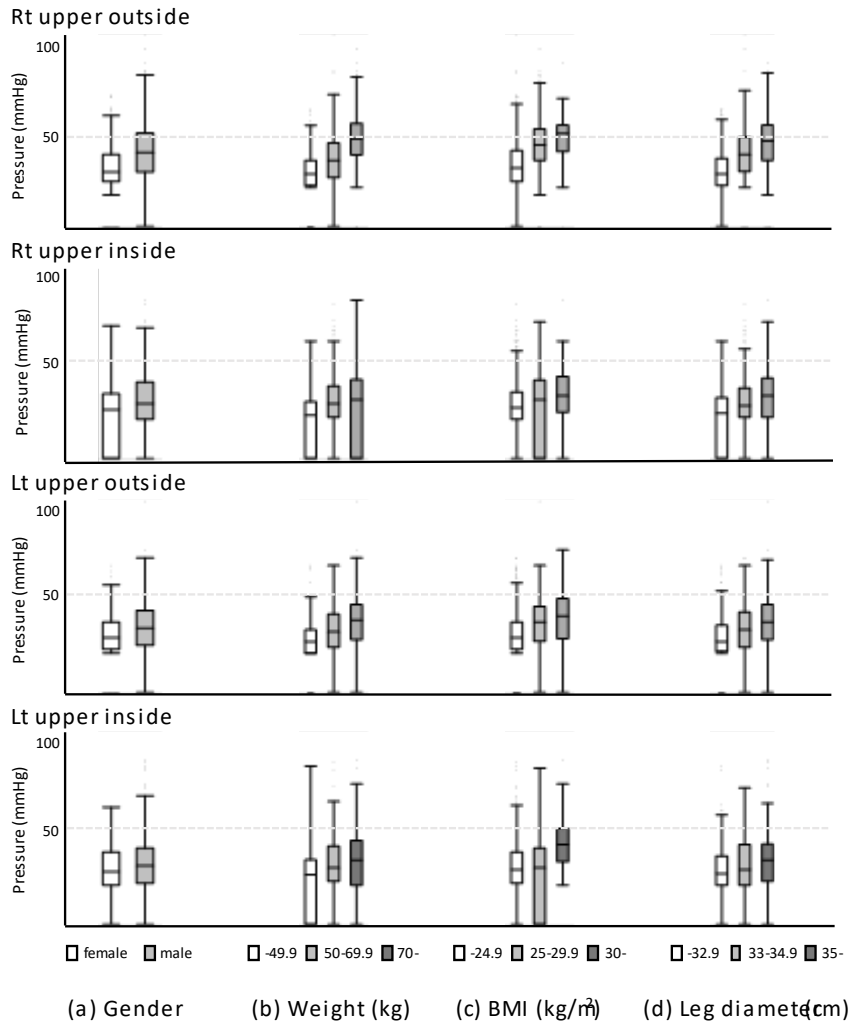


Figure 2. Patient's factors associated with external pressure on the lower leg

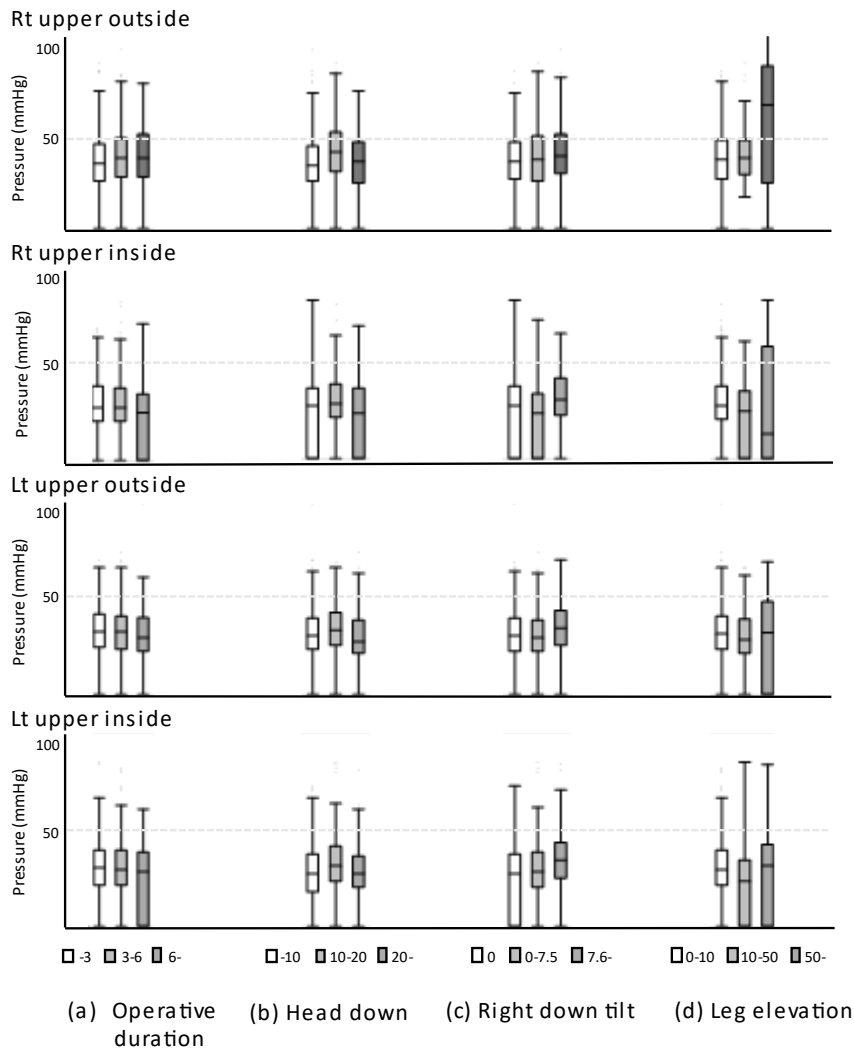


Body weight was classified as <49.9 , 50-69.9, 70- . (kg)

BMI was classified as <24.9 , 25-29.9, 30- . (kg/m^2)

Leg diameter was classified as <32.9 , 33-34.9, 35- . (cm)

Figure 3. Intraoperative position-related factors associated with external pressure on the upper areas of the lower leg.



Operative duration was classified as 0, 3-6, 6- . (h)
 Head down degree was classified as 0-10, 10-20, 20- .
 Right down tilt degree was classified as 0, 1-7.5, 7.6- .
 Leg elevation degree was classified as 0, 10-50, 50- .