Original Article

Comparison of the Incidences of Cuff-Related Trauma after Non-invasive Arterial Blood Pressure Measurement with and without Padding in Patients Undergoing Elective Surgery

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Objective: To compare the incidences of cuff-related trauma, including skin creasing and petechiae, occurring with and without padding in non-invasive arterial blood pressure measurement.

Materials and Methods: This prospective, non-randomized controlled study enrolled patients scheduled for elective surgery between May 2014 and August 2017. Automated, non-invasive, arterial blood pressure was measured in both arms of each patient, one taken with padding, and the other without. Twelve measurements were obtained on each arm, and at the same time, at 5-minute intervals. Demographic characteristics, underlying diseases, anesthetic technique, side of intravenous catheter, blood pressure during the study period, and data of cuff-related trauma were recorded.

Results: Of the 300 enrolled patients, 273 were finally analyzed. The incidences of cuff-related skin creasing occurring with and without padding were not different ($p = 0.134$), while the incidences of cuff-related petechiae were statistically lower with the padding technique ($p = 0.007$). The number of patients having severe skin creasing and mild petechiae was significantly reduced with padding ($p<0.05$). The female gender was an associated factor of cuff-related skin creasing; a body mass index of more than 25 kg/m^2 and the spinal anesthesia were associated factors of cuff-related petechiae.

Conclusion: The incidences of cuff-related petechiae and the severity of cuff-related skin creasing and petechiae were statistically reduced with the padding technique, compared to without padding. The female gender, a body mass index of more than 25 kg/m^2 and the spinal anesthesia were associated factors of cuff-related trauma.

Keywords: Non-invasive blood pressure, Cuff-related trauma, Complications

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Non-invasive arterial blood pressure measurement is a standard technique used in the anesthetic monitoring which is applied to all anesthetized patients[1-3]. Every patient receiving anesthesia has arterial blood pressure monitored and evaluated at least every five minutes to ensure the adequacy of the patient's circulatory function to the peripheral tissues during the anesthetics[1-3]. Arterial blood pressure measurements can be obtained in the clinical setting by two methods: direct and indirect. While the direct method involves using an intra-arterial catheter to obtain a direct measurement, the indirect method is less invasive and more practical, resulting in a popular use in a variety of clinical settings[1-4].

The indirect, or non-invasive, measurement can be performed using two different methods: a Doppler ultrasound probe or a stethoscope coupled to a manual pressure cuff with a sphygmomanometer or an oscillometric device such as Dinamap®. Automated oscillometers use an electronic pressure sensor and an algorithm to compute the values of the systolic and diastolic blood pressures from raw data by

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synchronizing with the cyclic expansions and contractions of the brachial artery[5]. In clinical practice, as automated oscillometers can be set to do repeated measurements, they are commonly used for anesthetized patients in operating theaters[1-3,6-8].

The inflatable cuff of an automated, noninvasive, oscillometric device is usually strapped around patient's upper arm to analyze the blood pressure. Several studies reported the incidences of complications arising after an operation due to the use of an oscillometric blood pressure monitor; these include acute dermal capillary rupture, phlebitis, skin necrosis, nerve injury, skin avulsion, deep vein thrombosis, Rumpel-Leede phenomenon and compartment syndrome[9-22]. Skin creasing and petechiae on the tissues under the cuff are also very common complications following noninvasive blood pressure measurements, especially after the device has been used for a long period[23-25]. In an attempt to protect the arm, padding can be applied to the upper arm under the cuff. The effectiveness of different paddings has been explored for many years[26].

To reduce the incidence of cuff-related trauma, our hospital has a policy that some material should be used as padding to cover the upper arm during non-invasive blood pressure monitoring in patients receiving anesthesia. However, the specific material used for this purpose has changed over time. Nowadays, the incidences of skin creasing and petechiae are reported periodically. The present study was designed to ascertain whether the use of a layer of Webril™ padding (Fiberweb Simpsonville Inc., Simpsonville, SC, USA) between the cuff and the skin could protect the skin from cuff-related trauma. The study aimed to examine the incidence of cuff-related trauma, including skin creasing and petechiae, and compare the incidences occurring with and without padding.

Materials and Methods

Study design and population

This prospective, non-randomized controlled study was approved by the Siriraj Institution Review Board (Si. 297/2013). Patients scheduled for elective surgery, with an estimated duration of 60 to 120 minutes between May 2014 and August 2017, at the Faculty of Medicine, Siriraj Hospital, Mahidol University (Bangkok, Thailand), were included. Patients aged over 18 years with an American Society of Anesthesiologists physical status classification of I-III were recruited. Patients having one or more of the following were excluded: a peripheral vascular disease; previous skin creasing or petechiae on the upper arm; a blood pressure difference between the two arms of more than 15 mmHg; and a blood clotting problem or a propensity to bleed easily. Moreover, patients taking anticoagulant drugs or were unable to understand the purpose of the study were not invited to join this research project. Patients who fulfilled the criteria received an explanation of its purpose and a description of the procedure and the outcomes measurement. Written informed consent was obtained from all participating patients.

In the operating theater, the patients were laid down with their arms supported, and they were allowed to rest for at least 5 minutes. The authors allocated one upper arm for padding while the other upper arm had no padding beneath the blood pressure cuffs with a computer web-based generator. The padding consisted of 6-inch-wide Webril™ (Fiberweb Simpsonville, Inc, Mansfield, The USA) padding, which was applied as a single-thickness layer. Automated, noninvasive, arterial blood pressure monitoring was undertaken for both arms using two oscillometric blood pressure monitors (Philips IntelliVue MP30, Philips, Amsterdam, Netherlands), using an inflatable cuff of appropriate width for each patient's arm. A total of 12 measurements were made for each side and at the same time, with 5-minute intervals between each measurement. After that, the blood pressure cuffs and padding were removed, and then the skin under the cuff on each arm was photographed using three pictures to cover the front, side and back of the upper arm. Patients having fewer than 12 measurements for any reason were excluded from the later analysis.

Data collection and outcomes measurement

All data were collected from patients' charts and recorded into a case record form by one of the authors. The following data were collected: demographic characteristics, gender, age, body mass index, underlying diseases, anesthetic technique, side of intravenous catheter, blood pressure during the study period, and any cuff-related complications with their severity.

Using the photographs taken after cuff release, the skin under the cuff was inspected and graded by a single assessor, who was blinded to whether padding had been used or not. Signs of cuff-related trauma in the forms of skin creasing and petechiae were graded separately. Grading was classified as none, mild (signs of cuff-related trauma less than half of the arm) or severe (signs of cuff-related trauma over half of

the arm).

The estimated independent factors of cuff-related trauma included gender; age; body mass index; underlying diseases, including hypertension, diabetes mellitus, dyslipidemia, asthma, thyroid disease, anemia and obesity; anesthetic technique (general anesthesia, spinal anesthesia and combined technique); and side of intravenous line. Data of those factors were collected for analysis to determine which, if any, are associated factors of cuff-related trauma.

Statistical analysis

The primary outcome was the incidence of cuff-related trauma. A sample size was calculated to detect a 20% difference in the incidences of cuff-related trauma occurring with and without padding. The sample size was based on data from a previous study[26]. Using nQuery Advisor version 7.0 (Statistical Solutions, Cork, Ireland), a test was performed to obtain a type I error of 0.05 and a power of 80%. The calculated sample size per group was 268 patients, which was increased to 300 patients to compensate for a dropout rate that was estimated to be less than 10%.

For statistical analysis, SPSS Statistics for Windows, version 18.0 (SPSS Inc., Chicago, IL, USA) was used. Categorical variables are presented as number and percentage, and continuous variables are presented as mean, standard deviation and range. Comparisons of the blood pressure of the two arms were analyzed using the paired t-test, while comparisons of the incidence and severity of cuff-related trauma were analyzed using the McNemar-Bowker test. All statistical tests were two-tailed, and a *p*-value of less than 0.05 was regarded as being statistically significant. Associated factors of cuff-related trauma were analyzed with the Chi-square or t-test, as appropriate.

Results

Of the 300 patients recruited for this study, 27 were excluded, leaving 273 for the final analysis. The study flow is in Figure 1, and the characteristics of the study population are at Table 1. The mean age was 47 years, with 77% of the subjects being female. The three most common underlying diseases were hypertension, diabetes mellitus and dyslipidemia. The most common anesthetic technique was general anesthesia (75.4%). The proportion of patients with an intravenous line in the padded arm was similar to that for patients with the intravenous line in the unpadded arm (44% vs. 56%, repectively).

The arterial blood pressure readings taken

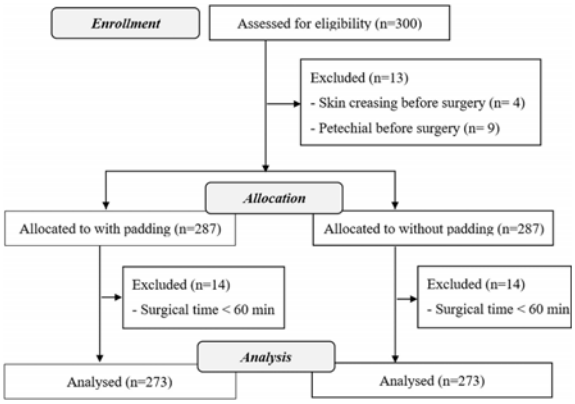

Figure 1. Study flow.

Table 1. Patients' demographics

	Number (n = 273)
Gender	
Male	64 (23)
Female	209 (77)
Age (year)	47±13
Body mass index (kg/m^2)	24.0±4.7
Underlying diseases	
Hypertension	56 (45.9)
Diabetes mellitus	25 (20.5)
Dyslipidemia	19 (15.6)
Asthma	8 (6.5)
Thyroid disease	6 (4.9)
Anemia	4 (3.3)
Obesity	4 (3.3)
Anesthetic techniques	
General anesthesia	206 (75.4)
Spinal anesthesia	48 (17.6)
Combined technique	19 (7.0)
Intravenous line	
Without padding	153 (56)
With padding	120 (44)

The data are presented as mean ± standard deviation or n (%)

with and without padding were not different at all-time points during the study period (p>0.05; Figure 2). The baseline blood pressures in both groups were approximately 130/80 mmHg; they decreased about 30% during the first twenty minutes and subsequently maintained a steady level until the completion of the study period.

The incidence of skin creasing was 91.9% on the arm with padding, which was comparable to the

corresponding figure of 93.8% on the unpadded arm, (p = 0.134). The number of patients having cuff-related skin creasing and the severity of that creasing are shown with statistical significance in Figure 3. The proportion of patients having severe skin creasing with the padding technique was lower than that for the without-padding group (24.5% vs. 43.6%), with an absolute risk reduction [ARR] of 19.1% (95% CI 11.0 to 26.6). The number of patients who needed to be padded to prevent severe skin creasing (number needed to treat [NNT]) was 5. The number of patients showing mild skin creasing was slightly more when padding was applied (67.4% vs. 50.2%). Only 3 patients did not have any cuff-related skin creasing on either arm, while 270 patients (98.9%) had some degree of skin creasing after the study period had finished. Skin creasing occurred at the same severity between with and without padding in 126 patients (46.2%). By comparison, 102 patients (37.4%) showed less skin creasing after applying the padding, whereas 45 (16.5%) had more skin creasing on the padded arms.

In contrast to the results for skin creasing, the incidence of petechiae was statistically lower for the padded side than the unpadded side (12.8% vs. 26.7%, p = 0.007), with an ARR of 13.9% (95% CI 7.8 to 19.5). The number of patients having cuff-related petechiae and the degrees of severity are shown with statistical significance at Figure 4. The incidence of patients having mild petechiae fell from 23.1% for cuffs without padding to 11.0% with padding; the ARR of mild petechiae due to padding was 12.1% (95% CI 5.8 to 18.3), and the number of patients who needed to be padded to prevent mild petechiae, NNT was 8. However, the incidences of patients with severe petechiae were not different between the two techniques (1.8% without padding vs. 3.7% with). Petechiae was not evident on both arms in the case of 181 patients (66.3%), this may be caused from blood pressure levels of patients in this study which were not high and resulted in less pressure effect under the blood pressure cuff. Of the 92 patients with petechiae after the study period, 62 (67.4%) showed less severity on the padded side, 22 (23.9%) showed more severe petechiae on the padded side, and 8 (8.7%) had the same level of petechiae severity for both sides. Additionally, this study did not reveal any serious cuff-related complications arising from the blood pressure measurements in either group, for example, dermal capillary rupture, skin necrosis, nerve injury or compartment syndrome.

The associated factors of cuff-related trauma, including skin creasing and petechiae, are at Table 2.

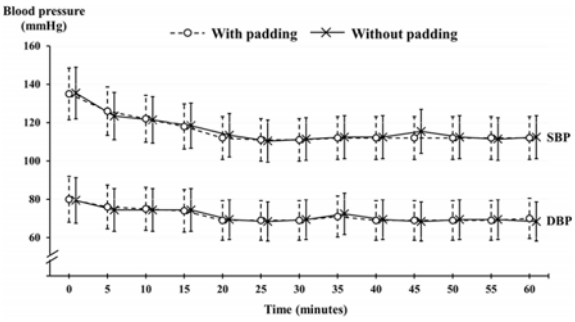

Figure 2. Comparison of arterial blood pressures with and without padding.
SBP = systolic blood pressure; DBP = diastolic blood pressure.

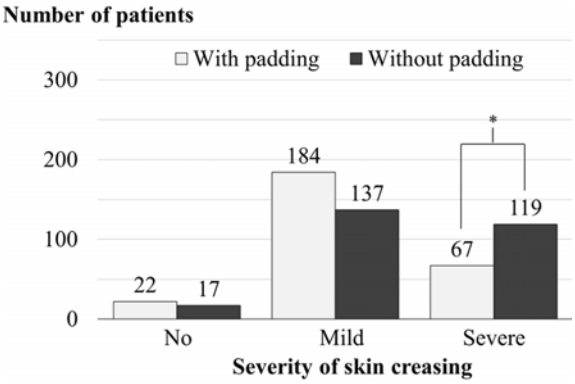

Figure 3. Comparison of the number of patients reporting skin creasing. The data are analyzed for the with-padding and the without-padding techniques with the McNemar-Bowker test. *p-value <0.05 indicates statistical significance.

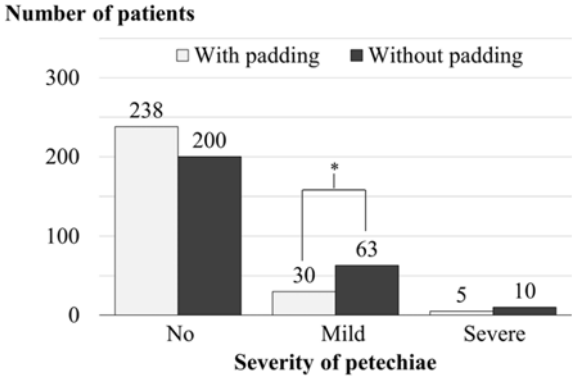

Figure 4. Comparison of number of patients reporting petechiae. The data are analyzed for the with-padding and the without-padding techniques with the McNemar-Bowker test. *p-value <0.05 indicates statistical significance.

Table 2. Associated factors of cuff-related skin creasing and petechiae

	Skin creasing (n = 273)			Petechiae (n = 273)		
	Yes (n = 251)	No (n = 22)	*p*-value	Yes (n = 35)	No (n = 238)	*p*-value
Gender: female	198 (78.9)	11 (50)	0.002	29 (82.9)	180 (75.6)	0.346
Age (year)	47.6±13.2	44.9±15.3	0.355	44.1±10.1	47.9±13.7	0.052
Body mass index ≥25 kg/m^2	93 (37.1)	8 (36.4)	0.949	20 (57.1)	81 (34.0)	0.008
Underlying disease						
Hypertension	53 (21.1)	3 (13.6)	0.583	10 (28.6)	46 (19.3)	0.206
Diabetes mellitus	25 (10.0)	0 (0)	0.239	4 (11.4)	21 (8.8)	0.541
Dyslipidemia	18 (7.2)	1 (4.5)	1.000	2 (5.7)	17 (7.1)	1.000
Asthma	8 (3.2)	0 (0)	1.000	2 (5.7)	6 (2.5)	0.273
Thyroid disease	6 (2.4)	0 (0)	1.000	2 (5.7)	4 (1.7)	0.172
Anemia	4 (1.6)	0 (0)	1.000	1 (2.9)	3 (1.3)	0.424
Obesity	4 (1.6)	0 (0)	1.000	0 (0)	4 (1.7)	1.000
Anesthetic technique						
General anesthesia	189 (75.3)	17 (77.3)	0.361	32 (91.4)	174 (73.1)	0.041
Spinal anesthesia	43 (17.1)	5 (22.7)		1 (2.9)	47 (19.7)	
Combined technique	19 (7.6)	0 (0)		2 (5.7)	17 (7.1)	
Intravenous line						
Padded side	112 (44.6)	8 (36.4)	0.454	11 (31.4)	109 (45.8)	0.110

The data are presented as mean ± standard deviation or n (%). Data were analyzed with the Chi-square or t-test, as appropriate

There was a relationship between female gender and cuff-related skin creasing (odds ratio 3.7, 95% CI 1.5 to 9.1), while there was relationship between a body mass index of more than 25 kg/m^2 and cuff-related petechiae (odds ratio 2.6, 95% CI 1.3 to 5.3). The anesthetic technique was another associated factor of cuff-related petechiae; spinal anesthesia was a risk reduction factor with an odds ratio of 0.17 (95% CI 0.02 to 0.87) compared with general anesthesia; while the combined general and regional technique had an odds ratio of 0.64 (95% CI 0.14 to 2.90) compared with general anesthesia alone.

Discussion

The present study demonstrated that although the padding technique could reduce the incidence of cuff-related petechiae by approximately 14%, it could not reduce the incidence of cuff-related skin creasing after noninvasive arterial blood pressure measurement, compared with the use of the non-padding technique, on patients undergoing elective surgery. We used a band of single-thickness, non-adhesive cotton wool as padding for the upper arm before applying a blood pressure cuff, whereas a previous study published in 2001 by Archer et al used a double-thickness layer of the same material[26]. They reported a 30% reduction in the overall incidence of cuff-related trauma (skin creasing and petechiae) by employing the padding technique[26].

The severity of cuff-related trauma, including skin creasing and petechiae, were also significantly reduced when padding was present between the cuff and the skin. The number of patients having severe cuff-related skin creasing fell by 20% and the number having mild cuff-related petechiae dropped by 10%. The present study showed a similar result to the one by Archer; they found there was a marked decrease in the number of patients having severe cuff-related trauma (skin creasing and petechiae) by using the padding technique (2.6% vs. 56.3%)[26].

The higher reductions in both the incidence and severity of cuff-related trauma reported in the Archer study may be an effect of the use of a double-thickness layer of padding, i.e., twice as thick as that used in our study. The increased thickness of the padding might allow more pressure under the cuff to be absorbed than the single-thickness layer we used. Another reason may be the difference in the duration of the study period and the number of blood pressure measurements. In Archer's study, they made three blood

pressure measurements at 2-minute intervals (a total of 6 minutes), whereas we made twelve blood pressure measurements at 5-minute intervals (a total of 60 minutes)[26]. The higher number of measurements in our study (12 vs. 3) coupled with the longer duration for the study period (60 vs. 6 minutes) might result in the higher incidences and severity of cuff-related skin creasing and petechiae in the present study.

However, our results did demonstrate an increased incidence of 17% in mild cuff-related skin creasing using the padding technique, which was similar to the 23% obtained in the Archer study[26]. This confirmed that the padding was associated with a significant reduction in the intensity of cuff-related skin creasing and petechiae, but it increased the incidence of mild cuff-related skin creasing. Therefore, a thin layer of padding of less than 2 millimeters is recommended for patients undergoing repetitive blood pressure measurement[26,27]. Compared to previous studies, no incidence of serious complications was reported at the end of the study period[10-26].

Multiple factors, including gender, age, body mass index, underlying diseases, anesthetic techniques and side of intravenous line, were recorded and analyzed as associated factors with cuff-related trauma. Female gender was the only associated factor which showed an increased risk (3.7 times) of cuff-related skin creasing. This may be because women tend to have more subcutaneous fat than men; the fat may result in higher pressure under the blood pressure cuff, causing female patients to have more skin creasing[28]. This reason may also explain why patients who had a body mass index of more than 25 kg/m^2 had a 2.6 times higher risk of cuff-related petechiae.

Limitation

The present study had some limitations. Firstly, some patients might have a difference in the sizes of their left and right arms, while only one size of blood pressure cuff was used for both arms of each patient. This might have caused a difference in the pressure of the inflated cuff and hence the arterial blood pressure reading. However, there was no statistically significant difference in the systolic and diastolic arterial blood pressures between both arms, as shown at Figure 2. In addition, this study identified only three associated factor for cuff-related trauma after noninvasive arterial blood pressure measurement. This may be because the sample size was calculated to detect a difference in the incidences of cuff-related trauma occurring with and without padding, not to determine the associated factors. If the sample size is increased in a future study, additional associated factors might be detected.

Conclusion

The use of single-thickness Webril^{TM} padding significantly reduced the incidence of cuff-related petechiae after non-invasive arterial blood pressure measurement in patients undergoing elective surgery. This technique also significantly decreased the severity of skin creasing and petechiae. Female gender is an associated factor of cuff-related skin creasing; a body mass index more than 25 kg/m^2 and the spinal anesthesia were associated factors of cuff-related petechiae.

What is already known on this topic?

There are numerous incident reports about the complications of oscillometric blood pressure monitors, which are commonly used for anesthetized patients in operating theaters. Many strategies have been used to reduce the incidence of cuff-related trauma.

What this study adds?

The present study compared the incidences of cuff-related trauma, including skin creasing and petechiae, occurring with and without single-thickness padding. The severity of cuff-related trauma and the associated factors of cuff-related trauma have been demonstrated.

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Trial registration

Clinical Trials.gov registration as NCT 02614 976.

Potential conflicts of interest

The authors declare no conflict of interest.

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