Original Article

Prophylactic use of donut-shaped cushion to reduce sacral pressure injuries during open heart surgery

ABSTRACT

Background: Pressure injuries are likely to develop in the operating room due to the high temperature and humidity underneath the patients. This study was designed to reduce sacral pressure injuries using donut-shaped cushions on patients undergoing open heart surgery in a supine position for more than three hours.

Materials and Methods: Patients undergoing open heart surgery for more than three hours were randomly allocated. Depending on the allocation, either the donut-shaped cushion (donut group) or hydrophilic foam dressing (control group) was applied before draping. Patients were evaluated for the development of pressure injuries, National Pressure Ulcer Advisory Panel (NPUAP) stage, and injury size immediately after surgery, 48 hours, and seven days after surgery.

Results: Forty-five patients were enrolled in this study. Twenty-two were assigned to the donut group and 23 were assigned to the control group. Three patients developed pressure injuries of NPUAP stage I or higher. All injuries occurred in the control group, but there was no statistically significant difference ($P = 0.083$).

Conclusions: Patients who underwent cardiac surgery for more than three hours and used a donut-shaped cushion did not develop pressure injuries, although no statistical difference was noted. Specific preventative measures in the operating room may play a crucial role in preventing pressure injuries, and further research should be pursued.

Key words: Cardiac surgical procedure; donut-shaped cushion; postoperative complications; pressure injury

Introduction

Pressure injuries are characterized by necrosis of skin and deep subcutaneous tissues as a result of impaired capillary circulation due to continuous and repetitive pressure combined with friction and shear force to specific body parts. In bed-ridden patients, the primary cause of these injuries is pressure due to compression between a bony prominence and an external surface for a prolonged period.[1] Pressure injuries can lead to prolonged hospital stays, resulting in increased medical costs ($5,000–$40,000), additional surgery, and even death in severe cases.[2-4] By using support surfaces, regularly repositioning the patient, optimizing the patient's nutritional status, and moisturizing the sacral skin, pressure injuries can be avoided especially by those who are prone to develop these injuries, such as the elderly and those with physical impairments.[4-6] Avsar *et al*.[7] reported that frequent repositioning of patients in the intensive care

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unit (ICU) reduces the development of pressure injuries by 25%. However, repositioning is difficult for patients in the operating room (OR) under general anesthesia. An OR bed is in a different environment compared to those of standard beds or mattresses. A patient on an OR bed is exposed to a high-temperature environment due to warming devices such as warming blankets.[8] In addition, exposure to humidity and contact with blood, irrigations, and disinfectants increase the risk for injuries.[9] During cardiac surgery, patients are at risk for developing pressure injuries due to the prolonged period on the OR bed, inappropriate tissue perfusion, temperature fluctuations during surgery, and immobility in the early phase after surgery.[10] Despite the risk of developing pressure injuries in the OR, only a few studies on the prevention of postoperative pressure injuries after cardiac surgery have been performed. A self-adherent silicone border foam dressing was tested on patients in the ICU following cardiac surgery, but the results showed that there was no significant reduction in the number of pressure injuries.[11]

The donut-shaped cushion (width 35 cm, height 6, polystyrene beads filled cushion) is a cushion with a 10 cm diameter circular area open in the center [Figure 1]. Placement of the donut-shaped cushion on the sacral region during surgery limits contact of this area from the OR bed, and can reduce the risk for the development of pressure injury by decreasing pressure on this area, which is the most frequent site of postoperative pressure injury (39%) [Figure 2].[12] However, no study using a donut-shaped cushion during surgery has been performed.

Therefore, the authors designed a study to reduce sacral pressure injury using donut-shaped cushions on patients undergoing open heart surgery in a supine position for more than three hours.

Materials and Methods

This randomized, double-blind, prospective study was conducted from July 2018 to January 2019 after receiving approval from the Institutional Review Board of Ilsan Paik Hospital (IRB no. 017-06-008, Approval July 13, 2018), and was registered in the Clinical Research Information Service (Registration No. KCT0003138, Approval July 27, 2018). Written informed consent was obtained from all patients during the preoperative visit.

The study enrolled 45 patients who were scheduled for open heart surgery under general anesthesia and were assessed as class III–IV according to the American Society of Anesthesiologists (ASA) physical status classification. The inclusion criteria were patients who underwent open heart surgery in a supine position for more than three hours and were admitted to the ICU after surgery.

Patients who already had pressure injuries in the sacral area before surgery, who died within 48 hours after surgery, and those whose surgery was terminated within three hours, were excluded.

Randomization was performed through a computer-based program (www.radomization.com) used in a non-stratified sequence in blocks of four. The generated allocations were sealed in opaque envelops and sequentially numbered by KJH. HMH. accessed sealed envelopes in turn to obtain the next allotment.

Before the patients entered the OR, viscoelastic polymer pads were placed on the OR bed. The cautery plate (Valleylab force FX, COVIDIEN, USA) was applied over the upper arm, and the monopolar mode was used during

Figure 1: Donut-shaped cushion (Outer circle 35 cm, height 6 cm, inner circle diameter 10 cm)

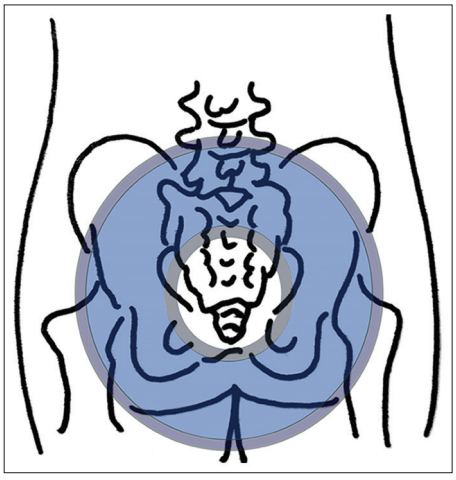

Figure 2: The frontal view of the donut-shaped cushion placement to the spinal column and pelvic region

surgery. Either a donut-shaped cushion (donut group) or a hydrophilic foam (control group) (20 cm × 20 cm × 0.5 cm, Korea Mundipharma, MEDIFOAM®) was then applied before draping, according to the results of random assignment, and removed after the surgery.

PBI, who did not know the groups to which the subjects belonged to, checked for the occurrence of pressure injuries, their sizes, and the National Pressure Ulcer Advisory Panel (NPUAP) stage, upon entry to the ICU immediately after the surgery, 48 hours, and 7 days after surgery. The stage, size, and skin color were recorded according to the 6-stage classification of the NPUAP for pressure injuries. Stage I involves non-blanchable erythema of intact skin. Stage II involves partial-thickness skin loss with exposed dermis. Stage III involves full-thickness skin loss. Stage IV involves full-thickness skin and tissue loss. The two other stages are unstageable pressure injury and deep tissue pressure injury.[1]

The preoperative data includes the patients' comorbidities, age, sex, body mass index (BMI), ASA physical status classification, serum albumin level, hemoglobin levels, glomerular filtration rate, European System for Cardiac Operative Risk Evaluation (EuroScore), lactate levels, and Braden scale.[13] The intraoperative data includes the type of surgery, duration of anesthesia, volume of blood loss, intraoperative urine output, volume of intraoperative fluid administration, transfusion, temperature, and cardiopulmonary bypass (CPB) time in cases where CPB was used. The postoperative data includes Braden scale, NPUAP stage, and size of pressure injury, if any.

We used a donut-shaped cushion preliminarily in eight patients, and the incidence of pressure injuries was 0%. As for the control group, the incidence of pressure injuries was 37.5% due to a chart review of eight patients who used a hydrophilic foam during a previous surgery of more than three hours.

When the type I error (alpha): 0.05 and type II error (beta): 0.2 were selected, total of 42 subjects (21 per group), were calculated. We planned to enroll a total of 45 subjects with a dropout rate of 5%.

All statistical analyses were performed using MedCalc software package, version 19.6.1 (MedCalc Software, Belgium) for Windows®. Incidence variables (gender, ASA physical status classification, operative type) were presented as the number of patients (percentage) and analyzed using the χ^2 test or Fisher's exact test. Continuous variables (age, weight, height, BMI, operation time, lactate, albumin) were reported as mean ± standard deviation or as median (interquartile range) and analyzed using an independent samples *t*-test after checking the normality with Shapiro-Wilk. Normally distributed continuous data were evaluated using an independent samples *t*-test, and non-normally distributed data were evaluated using the Mann-Whitney U test. *P* values of <0.05 were considered statistically significant.

Results

Forty-five patients were enrolled in this study. Twenty-two were assigned to the donut group, while 23 were assigned to the control group [Figure 3]. There were no dropouts. The patients' demographic data did not show intergroup differences [Table 1].

The proportion of preoperatively bed-ridden patients was not different between both groups (control group $n = 2$, 8.7% vs. donut group $n = 4$, 18%, $P = 0.35$), but the duration of postoperative ICU stay was longer in the control group (4 days, 3.0–7.8 days) than in the donut group (2 days, 2.0–3.0 days) ($P = 0.002$). The hospitalization duration until the operation was not significantly different (control group 4 days, 3.0–5.8 days vs. donut group 6.5 days, 3.0–9.0 days, $P = 0.129$) [Table 1].

Pressure injury of NPUAP stage I or higher developed in three patients (13%), and all were in the control group, but there was no significant difference ($P = 0.083$). Data of the three patients are summarized in Table 2. Two patients developed pressure injuries immediately after surgery, were Stage I, and measured 5 cm × 5 cm and 10 cm × 10 cm, respectively. One patient developed a pressure injury on the 7th postoperative day, was Stage II, and measured 2 cm × 5 cm. All three patients underwent valve surgeries with CPB, and the areas involved were the sacral regions.

The comparative analysis results between the patients with and without pressure injuries showed that among the factors which were known to be associated with pressure injuries, preoperative albumin (without pressure injury 4.01 ± 0.53 g/dL vs. with pressure injury 2.91 ± 0.66 g/dL, $P = 0.001$), and preoperative hemoglobin (without pressure injury 12.53 ± 2.37 g/dL vs. with pressure injury 9.37 ± 0.32 g/dL, $P < 0.001$) were significantly different. However, postoperative albumin, postoperative hemoglobin, and preoperative and postoperative lactate were not different. The difference between preoperative and postoperative albumin (without pressure injury 0.92 ± 0.51 g/dL vs. with pressure injury 0.37 ± 0.04 g/dL, $P = 0.07$) was not significant. The difference between preoperative and postoperative

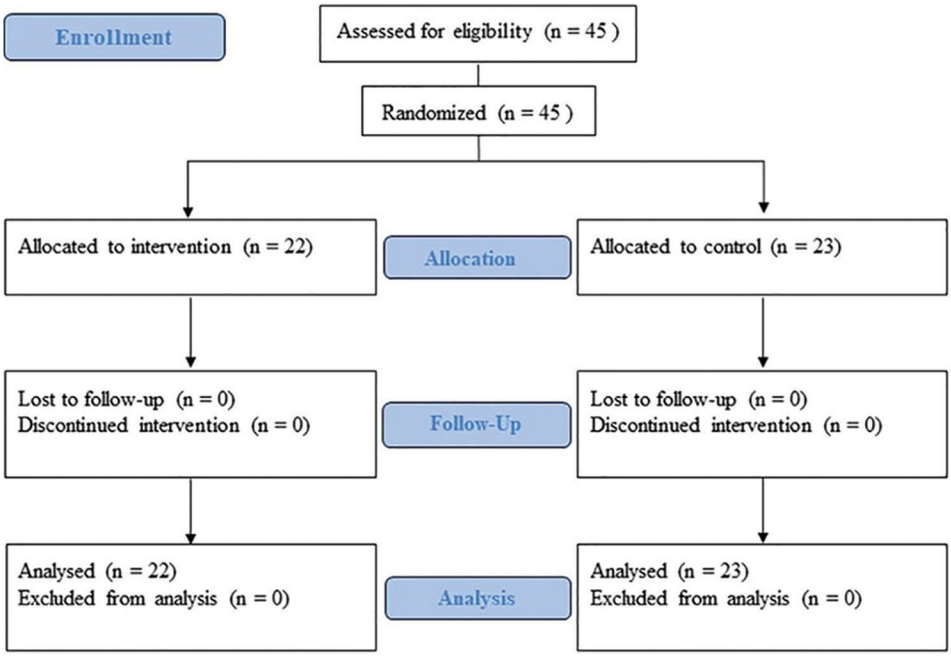

Figure 3: CONSORT flow chart for the study patients

hemoglobin (without pressure injury 2.47 ± 1.53 g/dL vs. with pressure injury 0.63 ± 0.51 g/dL, $P = 0.05$) was significant.

Discussion

The authors observed three postoperative sacral pressure injuries in the study population, and all three cases occurred in the control group that was using the hydrophilic foam. However, the incidence rate was not statistically different.

Several studies have been performed to evaluate the risk factors for the development surgery-related pressure injury. According to a recent systematic review, the risk factors most associated with the development of postoperative pressure injury include age, BMI, underlying disease such as heart failure and diabetes, preoperative Braden scale, duration of surgery, the length of postoperative ICU stay, and hospitalization duration until the operation.[14] In this study, there were no differences between both groups in these risk factors except on the length of postoperative ICU stay. Seven patients in the control group (vs. none in donut group) remained in the ICU for more than seven days. The main reasons were unstable vital signs (hypotension necessitating inotropic support in three patients, cardiac arrest in one patient, and atrial fibrillation in one patient), and delayed ventilator weaning (two patients). A total of three patients developed pressure injuries in this study: two patients immediately after surgery (one discharged from ICU before seven days) and one patient on the 7th ICU day. The patient who developed pressure injury on the 7th ICU day was most likely due to the prolonged ICU stay. However, this is not the case for the two patients who developed pressure injuries immediately after surgery.

Kim *et al*.[15] reported that low preoperative albumin and high preoperative lactate were significant factors associated with the development of a postoperative pressure injury. In our study, the preoperative albumin in patients who developed pressure injuries were lower than those in patients who did not develop pressure injuries. However, there was no difference in the levels of lactate. There was also no difference of change between preoperative and postoperative albumin. The preoperative albumin level reflected poor nutrition before surgery, so the preoperative albumin itself might affect the incidence of pressure injuries more than change between preoperative and postoperative albumin.

Several trials have investigated methods to prevent the development of postoperative pressure injury. In the study of Santamaria *et al*.,[16] the authors applied a multi-layered soft silicone foam dressing to the sacrum and heel of trauma and critically ill patients in the emergency room and observed for any development of pressure injuries during the patient's stay in the ICU. There was a statistically significant reduction in the development of pressure injuries in the group to which silicone foam dressing was applied compared to that of the control group.[16] In the OR, using a five-layer silicone sacral foam dressing for elective vascular surgical cases resulted in a significant decrease in OR-related sacral pressure injuries.[17] The 2019 National Pressure Injury Advisory Panel (NPIAP, old

Table 1: Demographic data

	Control group (*n*=23)	Donut group (*n*=22)	*P*
Age (years)	66.7±13.6	64.2±13.0	0.094
Sex (M/F), *n*	13/10	16/6	0.262
Weight (kg)	63.7±13.8	63.6±12.0	0.401
Height (cm)	161.5±9.0	165.4±8.5	0.984
BMI (kg/m^2)	24.3±4.4	23.1±3.1	0.377
ASA class, *n* (%)*			
III	21 (91)	21 (95)	0.581
IV	2 (9)	1 (5)	
Diabetes Mellitus, *n* (%)	12 (51.1)	11 (48.9)	0.885
Euro SCORE	2.8±2.1	2.3±2.1	0.514
Operation type			0.559
Off-Pump CABG, *n* (%)	9 (39)	12 (54)	
On-pump CABG, *n* (%)	1 (4)	1 (5)	
Valve op, *n* (%)	11 (48)	9 (41)	
Re-op, *n* (%)	0 (0)	1 (5) †	
Aneurysm resection, *n* (%)	2 (0.05)	0 (0)	
CPB, *n* (%)	14 (61)	11 (50)	0.468
CPB time (min)	142.5 (130, 190)	165 (151, 189)	0.146
Operation time (min)	375 (351, 410)	405 (350, 430)	0.585
Blood loss (ml)	1,000 (800, 2000)	1,000 (500, 1500)	0.810
Transfusion (ml)	550 (300, 788)	550 (300, 700)	0.973
Preoperative Hb (g/dl)	11.7±1.9	13.0±2.7	0.821
Postoperative Hb (g/dl)	10.4±1.3	10.4±1.4	0.402
Preoperative albumin (g/dl)	3.8±0.6	4.1±0.6	0.986
Postoperative albumin (g/dl)	3.1±0.5	3.2±0.5	0.507
Preoperative lactate (mmol/dl)	1.5±1.3	0.9±0.4	0.061
Postoperative lactate (mmol/dl)	2.0±1.2	1.7±1.1	0.358
Preoperative GFR (ml/min/1.17 m^2)	70.3±31.4	73.0±33.4	0.883
Preoperative Braden scale	19.9±3.5	19.9±4.3	0.997
Postoperative Braden scale	8.5±2.9	8.9±3.8	0.705
Preoperatively bedridden, *n* (%)	3 (13)	4 (18)	0.638
Hospitalization until surgery, day	4 (3.0, 5.8)	6.5 (3.0, 9.0)	0.129
Postoperative ICU stay, day	4 (3.0, 7.8)	2 (2.0, 3.0)	0.002

Values are presented as the mean±SD, median (IQR) or numbers (%). M, Male; F, Female; BMI, Body Mass Index; ASA, American Society of Anesthesiologists; EuroSCORE, European System for Cardiac Operative Risk Evaluation; CABG, Coronary artery bypass grafting; op, operation; Re-op, Re-operation; CPB, Cardiopulmonary bypass; Hb, Hemoglobin; GFR, glomerular filtration rate; ICU, intensive care unit. * There were no ASA class I or II patients. † This was a case of redo AVR due to infective endocarditis on POD 21 after Aortic valve replacement (AVR). The patient was assigned to the donut-shaped cushion group in both surgeries. No pressure injury was observed before re-do operation

Table 2: Characteristics of patients with pressure injury

Pt.	Sex /Age	BMI (kg/m^2)	Op	CPB Time (min)	Op Time (min)	Pre/Post lactate (mmol/dl)	Pre/Post Albumin (g/dl)	Pre/Post Hb (g/dl)	Post op NPUAP Stage/Size (W x H cm)		
									Postop 0 hour	Postop 48 hours	Postop 7 day
1	F/76	20.25	MVR, AVR	191	460	1.4/1.4	3.06/2.66	9.6/10.8	I/ 5 x 5	I/ 5 x 5	I/ 5 x 5
2	M/81	18.22	MVR	125	365	5.2/2.4	3.49/3.12	9.5/9.3	I/ 10 x 10	I/ 10 x 10	I/ 10 x 10
3	M/45	23.06	MVR, AVR	427	665	0.7/2.3	2.19/2.52	9/9.5	none	none	II/ 2 x 5

Pt., Patients; BMI, Body mass index; Op, Operation; CPB, cardiopulmonary bypass; min, minutes; Pre, Preoperative; Post, Postoperative; Hb, Hemoglobin; NPUAP stage, The National Pressure injury Advisory Panel; W, width; H, height; F, female; M, male; MVR, Mitral valve replacement; AVR, Aortic valve replacement

NPUAP) guideline recommends using a pressure redistribution support surface on the operating table, such as a viscoelastic polymer pad, in patients undergoing surgery and are at risk of developing pressure injuries (Strength of evidence B1).[1] Meanwhile, a soft silicone multi-layered foam dressing is recommended in patients at risk of developing pressure injuries, but evidence for surgical patients is insufficient.[1]

There are concerns that using a donut-shaped cushion can increase the risk of developing pressure injuries by compressing the blood flow from the periphery to the center. The guideline issued by the NPIAP in 2019 recommends against using a ring or donut-shaped positioning device to prevent pressure injuries, as it may cause tissue damage due to high pressure on the edges of the device. However, this is a

guideline for seated individuals.[1] This guideline's referenced article is not mainly about donut-shaped cushions and is not an experimental paper on central ischemia or a randomized control trial.[18] If the area to which the donut-shaped cushion is applied to is a flat and homogeneous tissue, the assumption that central ischemia can occur inside the cushion ring may be reasonable. However, the sacral area, where pressure injuries frequently develop, and the thigh area, where the donut-shaped cushion mainly applies pressure, are different tissues. In fact, in an experimental article measuring blood flow according to pressure, there is a report that the thigh could withstand pressures of 80 mmHg or more without being damaged, whereas the sacral area was damaged at a pressure of 14 mmHg.[19] According to the law of physics, when the pressure in one area decreases (in this case, sacral area), the other area's pressure (in this case, thigh area) inevitably increases for patients of the same weight. However, since the cushion-covered area is wider than the sacral area, the pressure per unit area can be further reduced. Also, if the sacral area pressure can be distributed to less vulnerable areas, the risk for developing pressure injuries may be reduced.

Another concern when using a donut-shaped cushion is its height (6 cm). There is concern that it causes back pain because it increases lumbar lordosis in the patient. However, when the patient's weight presses on the donut-shaped cushion, its height will be reduced to less than 6 cm. Furthermore, a chest roll 15 to 20 cm is applied below the scapula to facilitate surgical access during cardiac surgery in our hospital, which causes hyperextension of the spine; a donut-shaped cushion may reduce this. In this study, no patients complained of back pain.

Our study has several limitations. Our sample size was small, although we calculated the sample size according to our pilot study. A difference in pressure injury incidence between the pilot study and this study might have been the cause. In the pilot study, the incidence of pressure injury with NPUAP Stage I or higher in the donut group was 0%, whereas the control group was 37.5%. However, in this study, the incidence rate was still 0% in the donut group, whereas the control group was 13%. The incidence rate was also lower than previously published reports for patients who underwent cardiac surgery, which was as high as 29.5%. The authors considered the following possibilities for the difference in incidence between the pilot study and this study. First, in the pilot study, the average operation time was 490 min (378.75–525.0 min), which was significantly longer than the average operation time of 375 min (350.0–426.25 min) ($P = 0.018$) in this study. Second, the preoperative albumin level was significantly lower in the pilot study (3.04 ± 0.60 g/dL) than that of the present study (3.94 ± 0.60 g/dL) ($P < 0.001$). Third, the preoperative lactate level was significantly higher in the pilot study (2.13 ± 1.36 mmol/dL) compared to this study (1.26 ± 1.03 mmol/dL) ($P = 0.004$). These factors, which can affect the development of postoperative pressure injuries, might have influenced the difference in incidence between the pilot study and this study. In the authors' analysis, the control event rate was 0.13 (3/23) and the experimental event rate was 0 (0/22). Assuming an alpha of 0.05 and beta of 0.10, the estimated population size to tell the difference of the effect would be 148; assuming an alpha of 0.05 and beta 0.20, it would be 112.

In addition, using a hydrophilic foam dressing as a control might have reduced the incidence of pressure injuries. According to a study by Brindle *et al*.,[11] applying a silicone border foam dressing reduced the incidence of pressure injuries in cardiac surgery patients from 11% to 2%. However, not performing this practice in the control group was thought to be unethical since applying a hydrophilic foam dressing to patients undergoing open heart surgery to prevent the development of pressure injuries is routine in this hospital.

Another limitation is of the three patients who developed pressure injuries, one patient's operation time was the longest of all enrolled patients (665 min) as it was a double valve surgery. However, the five longest operation times (which correspond to the first quartile) in the donut group and control group (in minutes) were 595, 488, 465, 460, 450, and 665, 555, 485, 460, 430, respectively. These values were not statistically different (465 min vs. 485 min, $P = 0.83$).

Nevertheless, our study is one of a few conducted to prevent the development of pressure injuries in the OR. Although there was no statistically significant difference, the donut group's incidence of pressure injuries was 0%. If the pressure injuries developed within 72 hours after surgery, it is due to injury during surgery and not during the ICU stay.[20] Unlike other previous studies, we investigated the prevention of pressure injuries starting from the OR. Regarding pressure injuries, prevention is the most important because once pressure injuries develop, it causes pain, decreases the quality of life, and increases the duration of hospital stay, cost, and mortality.[21,22]

In conclusion, patients who underwent cardiac surgery for more than three hours and used a donut-shaped cushion did not develop pressure injuries, although no statistical difference was noted. Hence, specific operating room

measures may play a crucial role in preventing pressure injuries, and further research is guaranteed.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest

There are no conflicts of interest.

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