Compression therapy in breast cancer-related lymphedema: A randomized, controlled comparative study of relation between volume and interface pressure changes

Robert J. Damstra, MD,^a and Hugo Partsch, MD,^b Drachten, The Netherlands; and Vienna, Austria

Objective: Short stretch bandages are very effective in the initial management of arm lymphedema. However, no studies to date have measured the pressure required to achieve specific amounts of volume reduction. The purpose of this study was to determine whether there is a difference between low and high-pressure bandaging in terms of therapeutically intended volume reduction of the compressed arm.

Methods: Experimental, randomized and comparative study with two study-groups consisting of high and low initial interface pressure bandages. Thirty-six hospitalized patients in Nij Smellinghe hospital suffering from moderate to severe unilateral breast cancer-related lymphedema not responsive to outpatient treatment were included. Bilateral arm volume was measured by inverse water volumetry before, after two hours and after 24 hours of bandaging. The amount of edema was calculated by subtracting the volume of the diseased arm from that of the contralateral side. Sub-bandage pressure was measured after bandage application and two hours later. Bandages were then re-applied and the pressure was measured again. Twenty-four hours later, the pressure measurement was repeated and bandages were removed for final volumetry. Patients were randomized into two groups: group A received low pressure bandages (20-30 mm Hg) and group B received high pressure bandages (44-58 mm Hg). The main outcome measures were reduction of arm volume and edema volume in the affected arm in both study groups. Secondary outcome parameters were changes in sub-bandage pressure and patient comfort.

Results: Median arm volume reduction after two and 24 hours was 104.5 mL (95% confidence interval [CI], 51.2-184.2) (-2.5%) (P < .0001) and 217 mL (95% CI, 143.9-280.2) (-5.2%) (P < .01) for group A and 56.5 mL (95% CI, -2.7-123.1) (n.s.) and 167.5 mL (95% CI, 105.2-316.1) (-4.2%) (P < .01) for group B, respectively. There was no statistically significant difference between the volume changes in group A and group B. After 24 hours, edema decreased by median percentage of 9.2% in group A and 4.8% in group B (n.s.). Bandages in group A were better tolerated. The sub-bandage pressure drop in the first two hours was between 41% and 48% in both treatment groups at both measuring sites. After 24 hours, the pressure drop was between 55% and 63%. No proximal swelling above the bandage was observed. *Conclusions:* Inelastic, multi-layer, multi-component compression bandages with lower pressure (20-30 mm Hg) are better tolerated and achieve the same amount of arm volume reduction as bandages applied with higher pressure (44-58 mm Hg) in the first 24 hours. (J Vasc Surg 2009;49:1256-63.)

Clinical Relevance: This study was conducted in the lymphedema department of the Nij Smellinghe hospital in Drachten, Netherlands from June 2007 to September 2008. The Medical Ethics Committee of the hospital approved the study and all patients signed informed consent.

The major manifestation of lymphedema (LE) is chronic swelling, which causes discomfort, loss of function, and morbidity due to lymphatic impairment. If left untreated, the condition will progress. After a proper investigation into the case of lymphedema and, in the case of LE following cancer treatment, exclusion of recurrent malignancy, a conservative treatment program should be conducted. Breast cancer related lymphedema (BCRL) is one of the most frequent causes

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of LE. The goals for treatment are to eliminate edema by reducing interstitial fluid production and to stimulate lymphatic propulsion by compression. In addition, lymph flow is stimulated by manual lymph drainage (MLD) and by exercises that improve the functional capacity. To minimize the risk of infection, maintenance of skin integrity and proper skin care are mandatory. The combination of these therapeutic modalities is called complex decongestive therapy (CDT). When the maximal therapeutic result is obtained, compression garments are then essential for the long-term management.¹

In the treatment of LE, various compression materials can be used. Based on an in vitro assessment, it has been customary to differentiate between "elastic" ("long stretch") and "inelastic" ("no-stretch" or "short stretch") compression bandages.² The elasticity is defined by the percentage of elongation of the material following application of a force of 10N/cm bandage width (Deutsches Institut für Normung [DIN] 61632). This elongation is between 0% and 10% for

From the Department of Dermatology, Phlebology and Lymphology, Nij Smellinghe Hospital^a and Private Practice.^b

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Reprint requests: R.J. Damstra, MD, Department of Dermatology and Phlebology and Lymphology, Nij Smellinghe Hospital, Compagnonsplein 1, 9202 NN Drachten, The Netherlands (e-mail: r.damstra@ nijsmellinghe.nl).

"no-stretch" bandages, between 10% and 100% for short stretch bandages, and > 100% for long stretch bandages.

By applying several layers over each other, the multilayer bandage system as a whole attains the characteristics of an inelastic system, even when the single components are elastic.²

Initial management of upper limb lymphedema with inelastic multi-layer bandaging (IMLB) is usually part of CDT. However, up to this point, the deciding parameter of the interface pressure, which is the dosage of compression therapy, has been measured only in patients with chronic venous insufficiency.²

Only recently we reported the sub-bandage pressure measurements for leg LE.³ Studies to measure the pressure in arm LE have rarely been performed before: thus, the compression pressure required to obtain the highest volume reduction per unit of time is unknown. In a pilot study, we found interface pressure values between 30-40 mm Hg exist after routine bandaging.

In this study, we aimed to compare the effect of lowversus high interface pressure for arm volume reduction in BCRL after two and 24 hours. Our working hypothesis was that high pressure would be more effective than low pressure in terms of volume reduction, since this has been demonstrated in leg LE.

METHODS

Study design and population. This study was conducted in the lymphedema department of the Nij Smellinghe hospital in Drachten, Netherlands from June 2007 to September 2008. The Medical Ethics Committee of the hospital approved the study and all patients signed informed consent.

The study population consisted of 36 female patients with unilateral breast cancer-related lymphedema (BCRL) who were randomized by using sealed envelopes into two groups of 18 patients each. Group A received bandages with low interface pressure (20-30 mm Hg) and group B received bandages exerting high interface pressure (44-58 mm Hg). All patients had lymphedema and were hospitalized because outpatient treatment was not successful in terms of removing pitting edema and improving the mobility and condition of the patient. The primary outcome parameters were the reduction of arm volume and reduction of edema volume in the affected arm. The difference in arm volume between the affected and the normal sides defined the amount of arm edema. The secondary outcome parameters evaluated were changes in sub-bandage pressure, patient comfort, side effects such as proximal swelling, and safety.

Inclusion and exclusion criteria. All patients were female (more than 18 years of age) and had to be at least 12 months post-treatment for breast cancer without signs of recurrence. Only patients with moderate (volume difference 20%-40%) to severe edema (difference > 40%) were included. Clinical severity was staged according to ISL guidelines⁴ to stage 2 LE, with a real pitting component. Patients with allergies to any of the used materials, severe



Fig 1. Kikuhime device placed at the dorsal wrist region and below the elbow.

systemic diseases, acute superficial or deep vein thrombosis, or arterial occlusive disease or documented thrombophilia were excluded.

Bandaging materials and techniques. All patients were treated with the same bandages by specially trained staff. Certified multilayer short stretch compression bandages (Rosidal Lymphset, Arm, Lohmann & Rauscher, Rengsdorf, Germany) were used, consisting of a foam layer and two short stretch cotton wool bandages. After applying pressure-measuring probes, the arm was carefully bandaged at either the high or low-pressure range. The bandages started at the base of the hand and covered the arm up to the shoulder. The hand and fingers were bandaged as well.

The bandages were removed after two hours in order to measure the short-term volume reduction and new bandages were applied for the next 24 hours within the same pressure range. All patients were encouraged to be active and no other therapeutic interventions were performed. Special attention was paid to the eventual signs of proximal swelling above the bandages at the shoulder. The first 18 patients were assessed for tolerability and comfort of the bandages using a visual analogue score (VAS).

Measurement of sub-bandage pressure. An air-filled pressure transducer (Kikuhime; TT Medi Trade, Sorø, Denmark) with the large probe $(12 \times 10.5 \text{ cm diameter})$ was used to measure sub-bandage pressure. The accuracy and variability of this method has been described previously.⁵ Pressure was measured when the arm was extended to 160° on a table at two locations: the dorsal side of the lower arm and the lateral side of the arm distal from the elbow (Fig 1) Pressure measurements were performed after bandage application, at two hours before and after bandage renewal, and at twenty-four hours. For pressure measurements, the strength of the bandage application was guided by pressure measurement during bandaging, thereby avoiding higher pressures at the proximal measuring point compared with the distal. If the pressure was not in the required range, the arm was rebandaged. Pressure group A ranged from 21 to 30 mm Hg

	T = 0	T = 2 hours	New bandage	T = 24 hours
Group A				
Distal	27 (26-39)	16.5 (14-19)	28 (25.529)	10 (7.5-12)
Proximal	26 (25-27.5)	15 (13.5-17)	27.5 (24.5-29)	10 (8-12.5)
Group B				
Distal	50.5 (46-52.5)	28.5 (28.5-40)	51 (50-54)	21.5 (10-25.5)
Proximal	49 (47-52.5)	28.5 (24-33)	51 (4854)	20 (17-24)

Table I. Sub-bandage pressures (mm Hg) (x+SD) measured at the distal and proximal sites in both treatment groups

Significant differences ($P \le .001$) were observed between 0 and 2 hours, and between "new bandage" and 24 hours.

and group B was bandaged within a range of 45 to 55 mm Hg. Table I shows the initial mean pressure values measured at the distal and proximal arm.

Inverse water volumetry. Inverse water volumetry (IWV) is a derivative of classic water displacement volumetry and measures a shortage of water instead of an overflow (Fig 2). This validated method measures the volume of the whole arm including the hand. IWV was performed on both arms at zero, two, and twenty-four hours after application of compression bandages. The contralateral arm was used as the control. Edema in the lymphedematous arm was assessed by subtracting the volume of the healthy contralateral arm from the volume of the diseased arm. During the volumetry, the staff was unaware of patients' treatment group.

Statistical analysis. The medians and interquartile ranges are given. Repeated analysis of variance (ANOVA) and Tukey's multiple comparisons were used to compare the initial values of pressure and volume versus the several subsequent values.

Comparisons between the two treatment groups were performed using the non-parametric Mann-Whitney-test. The variation coefficient was given as the percent proportion of the statistical deviation from the mean in repeated measurements. A comparison of pressure and volume loss was made using the non-parametric correlation Spearman coefficient (Graph Pad, San Diego, Calif). P < .05 was accepted as significant. The power of our study with a sample size of n = 18 for both groups was 7.1% with a standard deviation (sd) of (sd = 137) for a 10% volume reduction and 18.6% (sd = 137) for a 25% volume reduction.

To achieve a power of 80% with 95% reliability, the sample size in the case of 10% volume reduction is n = 741 and for 20% reduction is n = 119. However, from a practical point of view and regarding our research aim, these numbers are not realistic. This factor may be a statistical limitation of our study.

RESULTS

The basic characteristics of the patients included in the study are summarized in Table II.

Reduction of total arm volume. When compared with the initial stage, the arm volume in group A showed a significant median difference of arm volume after two hours of 104.5 mL (95% confidence interval [CI], 51.2-184.2)



Fig 2. The inverse water volumetry (IWV) device in use.

(-2.5%) (P < .001) and of 217 mL (95% CI, 143.9-280.2) (-5.2%) (P < .01) after 24 hours (P < .001). In group B, the corresponding values were 56.5 mL (95% CI, -2.7-123.1) (n.s.) and 167.5 mL (95% CI, 105.2-316.1) (-4.2%) (P < .01). (Fig 3). There was no significant difference in the total volume changes between the two groups after two and twenty-four hours. In both groups, four patients showed a slight volume increase that was more pronounced in group B, thus explaining the wide range of confidence intervals.

Reduction of arm edema. Arm edema was calculated by subtracting the volume of the normal arm from that of the lymphedema arm. Compared with the baseline, group A showed a significant reduction of edema with median values from 1347 mL (interquartile range [IQR], 953.5-2129) to 1366 mL (IQR, 963.5-1941) after two hours (P< .05) and to 1222 mL (IQR, 832-1846) after twenty-four hours (P < .001). The corresponding values in group B were 1167 mL (IQR, 821.5-1845) before treatment, 1194 mL (IQR, 755-1811) after 2 hours and 1111 mL (IQR, 661-1552) after 24 hours (Fig 4). Only the edema reduction after 24 hours was significant (P < .001).

The median differences concerning total edema reduction after 24 hours were 230.5 mL (95% CI, 135.5-283.9) in group A and 146 mL (95% CI, 101.2-313.5) in group B (n.s.).

Sub-bandage pressure in lymphedema patients. Table I shows all sub-bandage pressure values measured in 36 lymphedema arms. Pressure values measured at the distal and proximal positions of the lower arm were similar, both

Table II. Basic characteristics of study groups

	$\begin{array}{c} Group \ A\\ (n=18) \ LPB \end{array}$	Group B (n = 18) HBP
Mean age in years (SD)	60.5 (45-84 years)	61.2 (50-73 years)
Side of the arm (left/right)	9/9	9/9
Time of LE onset after operation (months)	11.3 (3-50)	11.4 (3-30)
Partial mastectomy with axillary clearance (%)	7/18 (38.8)	6/18 (33.3)
Total mastectomy with axillary clearance (%)	11/18 (61.1)	12/18 (66.6)
Received radiotherapy (%)	100	100
Absolute volume healthy arm (min-max; mL), $t = 0$	2841 (2246-4326)	3040 (2029-4546)
Absolute volume affected arm (min-max; mL), $t = 0$	4390 (2986-6592)	4393 (2243-5822)
Volume difference between both arms (%) at $t = 0$	154	144

There was no significant difference of any single parameter between group A and group B.



Fig 3. Volume reduction of lymphedematous arm. Group A (left) showed a significant volume decrease after two and 24 hours; group B (**right**) only after 24 hours. Differences compared with baseline: ***P < .001, **P < .01.

for the initial bandages and for new bandages applied after two hours. The sub-bandage pressure drop in group A at the distal measuring point was 48% for the first two hours and 63% after twenty-four hours respectively. The corresponding values in group B were 44% and 55%.

There was no significant correlation between the changes in arm volume and sub-bandage pressure (Fig 5).

Quality of life and discomfort. At the beginning and the end of the study (after 24 hours), the 18 participants (nine group A, nine group B) filled out a questionnaire containing a visual analogue score (VAS). The group with the high-pressure bandage indicated more complaints of pain and discomfort, especially for the first two hours. The low-pressure bandage was better tolerated during the whole study. Close attention was paid to the proximal region of the shoulder above the bandage in order to monitor local swelling due to fluid movement by the bandage. This phenomenon was not observed, and no patient showed additional local pitting above the bandaged region.

DISCUSSION

Modern conservative treatment of lymphedema is based on CDT consisting of compression, MLD, physical exercise, and skin care. The exact contribution of each of these separate procedures to the overall effect is unclear. There is a wide range of inter-individual performance of techniques, exercise methods, and compression bandaging systems, which makes a scientific assessment of CDT difficult. Only a few randomized controlled studies are available concerning the effect of CDT.

In a recent systematic review, Moseley et al⁶ found just four studies that investigated the effect of compression by bandaging or garment alone in BCRL. Two controlled studies showed that compression therapy with and without additional MLD was equally effective for BCRL.^{7,8} Badger et al⁹ compared the effect of 18 days of short stretch bandaging followed by compression hosiery with that of compression hosiery alone in leg and arm LE. They showed



Fig 4. Edema reduction in the treated arm. Group A (left) shows a significant decrease after two and 24 hours; group B (right) only after 24 hours. Differences compared with baseline: ***P < .001, *P < .05.

Correlation Change of Pressure/Change of Volume First 2 h, all bandages 2 h-24 h , all bandages



Fig 5. There is no correlation between change in arm volume and sub-bandage pressure in the first two hours, and a poor correlation between two and 24 hours.

that initial compression therapy with subsequent use of hosiery was twice as effective as hosiery alone.

Some studies have been performed concerning measuring the under-garment pressure.^{10,11} A major limitation of these studies is the discrepancy between the under-garment pressure claimed by the manufacturer and the actual interface pressure due to the large variety of types of garments and inter-individual variation in measuring garments.

In 1999, Williams and Williams¹² measured the pressure on the arm with various garments in nine patients during the maintenance phase. The pressure measured ranged from 7 to 64 mm Hg, depending on the types of garments. They concluded that the selection of compression garments as part of LE treatment is a complex endeavor and that "off-the-shelf" hosiery is not suitable. They found no relationship between the manufacturerindicated compression class and the actual pressure in patients.

Until now, no studies have been published that measure the interface pressure under inelastic bandages in BCRL.

In our protocol, we focused on compression by measuring the short-term effect of IMLB in relation to volume reduction depending on the interface pressure.

IMLB is the preferred method and is usually applied by trained staff following existing guidelines.¹³

Water displacement devices are the gold standard for volumetry of the extremities.¹⁴⁻¹⁷ The classic water displacement method measures the overflow of water. Due to many disadvantages of this overflow technique, inverse water volumetry (IVW) was developed for measuring the shortage of water. This volumetric method has been validated and shown to be reliable and highly reproducible with high intra-class correlation coefficients.¹⁸

The pressure measuring device, Kikuhime, contains probes of two sizes; one with a size of 10×12.5 cm, the other one with a diameter of 3 cm. We chose the large probe, mainly because some preclinical studies showed a lower degree of spontaneous pressure loss (only 8 mm Hg in 55 hours).¹⁹ The accuracy of pressure readings obtained immediately after application of the compression has been shown to be high, and the variation coefficient with repeated measurements was reported to be between 2.1% and 7.1%.²⁰ By using the large probe, the influence of the circumference differences at both sites is diminished. Due to the influence of the local radius at both measure points, a pressure gradient could be expected, according to Laplace's law. However, we measured the proximal and distal sub-bandage pressure within the range needed during bandaging. Therefore a pressure gradient was not present.

The outcome of our study is surprising because it disagrees with previous studies of edema reduction in the lower extremities. While it had been shown that compression reduces venous stasis-induced swelling in a dose-dependent manner in the legs,^{21,22} the situation appears to be quite different in arm LE where lower pressure is obviously at least as effective as high pressure. This is true not only for the first two hours after bandage application, but also after 24 hours.

The observed volume reduction can largely be explained by a decrease in swelling, as a shift of fluid to the upper part of the shoulder was not observed.

Regarding the different effects of compression pressure on the legs as compared to the arms, it is important to note that the hydrostatic pressure that must be overcome by external compression is much higher in legs than in arms. In standing position, the venous pressure in the distal leg equals the weight of the blood column between the heart and the measuring point, which is about 80-100 mm Hg. The high intravenous pressure in the upright body position will always increase the lymphatic load by promoting increased fluid extravasation. High external pressure is necessary in order to counteract this extravasation. The venous pressure in the arm is much lower than that of the leg due to the lower weight of the blood column between heart and hand. Thus, less external compression will be needed to reduce extravasation from the venules into the tissue and to promote re-absorption of tissue fluid. Especially in the first two hours after starting compression, low-pressure bandages seem to be sufficient to remove large amounts of volume (Fig 5). The arm-volume reduction by bandaging is probably not only due to a pressure-dependent shift of Starling's equilibrium but also to a stimulation of lymphatic drainage.

Secondly, lympho-dynamics should also be considered besides the veno-dynamic aspect. In healthy arms, the distance from the arm to the thoracic duct is short and the intra-lymphatic pressure varies with the intra-thoracic pressure. The lymphatic drainage is stimulated with relatively low or even negative intra-lymphatic pressures. In BCRL, the lymphatic drainage is deficient because of the damage of major lymph collectors and lymph-nodes by surgery and/or radiation leading to lymphatic congestion.²³

In general, two main effects of compression on the lymphatics have to be considered. The first of these is that an increase of the tissue pressure leads to a stretch of the anchoring filaments attached to the initial lymphatics, which causes an opening of the initial lymph capillaries. Another is the enhancement of the spontaneous contractions of the lymph-collectors that normally occurs under the influence of rhythmic pressure changes.²⁴ Inelastic compression material exerting a relatively low resting pressure and high massaging pressure peaks during movement and may promote the autonomous lymphatic contractions.¹⁹ The required pressure to achieve optimal edema reduction depends obviously on the underlying pathology in different body regions and is therefore difficult to assess.

Stanton et al²⁵ studied the patho-physiologic changes in 24 BCRL patients by scintigraphic research. They suggest that active contractile lymphatic collectors have to work against a central resistance caused by the axillary lymphatic impairment. This leads to pump failure, diffuse filling of the fine dermal network with a rerouting of fluid demonstrated scintigraphically by dermal backflow and clinically by swelling. Modi et al²³ performed lymphatic congestion lymphoscintigraphy in healthy and BCRL patients and demonstrated a lymphatic pump failure in BCRL. In healthy persons, a mean compression of 39 mm Hg (range, 10-60 mm Hg) is required to allow lymph flow from the wrist to the axilla. This pressure range fits nicely into experiments, which showed that a bandage pressure of 40-70 mm Hg prevents lymph-flow from the wrist to the axilla.²⁶ In BCRL, the lymphatic contractile force is reduced to 24 mm Hg (range, 0-60 mm Hg).²⁴ These figures might explain the idea that high compression pressure could block the remaining lymphatics.

In leg lymphedema, a resting pressure of around 45 mm Hg is recommended as the standard intensive therapy for initial management.¹ Pressure values higher than 60 mm Hg are not beneficial concerning intra-lymphatic pressure and flow.²⁴ However, a considerable loss of subbandage pressure starting immediately after application of IMLB has to be taken in consideration. These bandages do not contain elastic fibers that would keep the pressure sustained due to their raining force. Therefore the volume reduction of the extremity and partly with the fatigue of the material^{2,3} seem to be the main reasons for the pressure loss.

However, some patients in our present series showed no volume reduction but a clear drop in the interface pressure, explaining the poor correlation between the volume and pressure changes over time. In these cases, the local indentation of the pressure transducer into the skin and by softening of the compressed tissue, could explain the reduction of pressure but not the arm volume. In addition, the type and amount of padding under the bandage plays an obviously important role and should be considered in future studies. 27

A practical argument favoring higher pressure comes into play when high-pressure bandages are left in place for several days, which may cause some initial discomfort. Due to the high amount of pressure loss, especially during the first hours after application, the sub-bandage pressure will soon come to a range comparable to the values achieved in our group A immediately after application. A bandage on the arm applied with high pressure would thus offer the advantage of staying in place for a longer time period, but after the initial pressure loss, it would likely achieve a comparable effect to low pressure bandages changed every day.

The present data have distinct practical implications:

- 1. In the initial treatment phase of arm lymphedema bandaging, the bandage is applied on a daily basis. Lowpressure (20-30 mm Hg) short stretch bandages are equally effective as bandages applied with much higher pressures (50-60 mm Hg), but with less discomfort for the patient.
- 2. If the bandages are to be left in place for several days, it may be advisable to use higher initial pressures, even when there is some initial discomfort, which will usually subside after some hours. Despite the high degree of pressure loss and initially reduced effectiveness, the longer time interval before the bandage has to be changed may be a practical advantage.
- 3. Our data show an exponential arm volume decrease, with the largest amount of reduction in the first two hours. According to our experience and in accord with recent literature, the phase of dramatic volume reduction is terminated after two to three days.²⁸

Future studies should investigate the stage at which time bandages can be replaced by compression stockings, while taking into account the practical problem of proper fit. A second area of interest would be to measure volume reduction in patients with LE when using bandages applied with different strengths and padding in order to find the most effective pressure range.

CONCLUSIONS

Inelastic, multi-layer, multi-component compression bandages allow immediate reduction of volume in lymphedema arms. With daily bandage renewal, within the statistical limitations of our study, low sub-bandage pressures between 20-30 mm Hg are effective and better tolerated than highpressure bandages by the patient. The difference in effect of high sub-pressure and low sub-bandage pressure, if it exists, is too small to make a preference for high-pressure bandages. The therapeutically intended volume reduction together with the type and amount of padding beneath the bandage is the main reason for the initial fast drop of sub-bandage pressure in high pressure bandaging and explains the need for frequent bandage change at the beginning of lymphedema therapy. This study was conducted in the lymphedema department of the Nij Smellinghe hospital in Drachten, Netherlands from June 2007 to September 2008. The Medical Ethics Committee of the hospital approved the study and all patients signed informed consent.

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AUTHOR CONTRIBUTIONS

Conception and design: RD/HP Analysis and interpretation: RD/HP Data collection: RD Writing the article: RD Critical revision of the article: HP Final approval of the article: RD, HP Statistical analysis: HP Obtained funding: RD Overall responsibility: RD

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