

# Clinical trial comparing three types of cryotherapy in non-pregnant women

ENSAIO CLÍNICO COMPARANDO TRÊS MODALIDADES DE CRIOTERAPIA EM MULHERES NÃO GRÁVIDAS

ENSAYO CLÍNICO COMPARANDO TRES TIPOS DE CRIOTERAPIA EN MUJERES NO EMBARAZADAS

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## ABSTRACT

The objective of the present study was to compare three methods of cryotherapy in healthy non-pregnant women. This is a randomized controlled clinical trial that was conducted by 32 undergraduates of a private nursing college in the city of Sao Paulo, divided into three groups (iced water, soft ice, ice gel). The temperatures were verified (axillary, thigh, of the three ice packs) between zero and twenty minutes. The temperatures of the packs were the following: soft ice, from negative 9°C to 2°C; iced water, from 0°C to 8°C; and ice gel from negative 11°C to 2°C. There was a significant difference between the average thigh temperature values at 10 minutes ( $p=0.007$ ), 15 minutes ( $p=0.003$ ) and 20 minutes ( $p=0.005$ ). The gel was the most efficient cooling method. The three cryotherapy methods achieved the recommended temperature for analgesia and may be tested in women with perineal pain after childbirth.

## KEY WORDS

Cryotherapy.  
Ice.  
Women.  
Sensation.  
Skin temperature.

## RESUMO

O estudo teve como objetivo comparar três modalidades de crioterapia em mulheres saudáveis e não grávidas. Trata-se de um ensaio clínico randomizado, não controlado, com 32 alunas do curso de graduação de uma faculdade de enfermagem particular da cidade de São Paulo, divididas em três grupos (gelo água, gelo mole, gelo gel). Foram verificadas as temperaturas (axilar, coxa e das três bolsas de gelo) entre zero e vinte minutos. As temperaturas das bolsas foram: gelo mole de 9°C negativos a 2°C, gelo água de 0°C a 8°C e gelo gel de 11°C negativos a 2°C. Houve diferença significativa entre as médias das temperaturas da coxa com 10 minutos ( $p=0,007$ ), 15 minutos ( $p=0,003$ ) e 20 minutos ( $p=0,005$ ). O gel foi mais eficiente no resfriamento comparado aos outros dois métodos. As três modalidades de crioterapia atingem a temperatura recomendada para analgesia e podem ser aplicadas em puérperas com dor perineal após o parto normal.

## DESCRIPTORIOS

Crioterapia.  
Gelo.  
Mulheres.  
Sensação.  
Temperatura cutânea.

## RESUMEN

El estudio tuvo como objetivo comparar tres modalidades de crioterapia en mujeres saludables y no grávidas. Se trató de un ensayo clínico randomizado no controlado con 32 alumnas del curso de graduación de una facultad de enfermería particular de la ciudad de São Paulo (Brasil). Las alumnas fueron divididas en tres grupos (agua helada, hielo blando, gel helado). Fueron verificadas las temperaturas (axilar, del muslo y de las tres bolsas de hielo) entre cero y veinte minutos. Las temperaturas de las bolsas fueron: hielo blando, de -9°C a 2°C; agua helada, de 0°C a 8°C; gel helado, de -11°C a 2°C. Hubo diferencia significativa entre las medias de las temperaturas del muslo tomadas a los 10 minutos ( $p=0,007$ ), 15 minutos ( $p=0,003$ ) y 20 minutos ( $p=0,005$ ). El gel fue más eficiente en el enfriamiento comparado con los otros dos métodos. Las tres modalidades de crioterapia alcanzan la temperatura recomendada para la analgesia y pueden ser aplicadas en mujeres con dolor perineal posparto.

## DESCRIPTORIOS

Crioterapia.  
Hielo.  
Mujeres.  
Sensación.  
Temperatura cutánea.

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## INTRODUCTION

Cryotherapy is defined as the use of a substance applied to the body that removes body heat, decreasing tissue temperature. Methods include: cold compresses, using recipients, towels or a plastic bag with chopped ice; cold gel compresses; cold chemical compresses; immersion in ice and massage using ice, among others<sup>(1)</sup>.

The physiological effect of cryotherapy is that it decreases the blood flow, reduces the metabolism and anesthetizes the application site<sup>(2)</sup>. It also acts on the circulation by causing vasoconstriction and decreasing the hematoma. These cold applications provoke discomfort during the first minutes, followed by paralysis and anesthesia, besides decreasing muscle spasms, edema and the metabolism<sup>(3)</sup>. Local circulation reduction decreases the edema, inflammation, hemorrhage and hematoma<sup>(4)</sup>.

Cold applications, below 10°C, are believed to relieve pain because they reduce the number of painful impulses from peripheral nerves to the brain and make them slower<sup>(5)</sup>.

These cold applications cannot revert the edema but, if used as soon as possible after an injury, its occurrence can be avoided<sup>(1)</sup>.

How cryotherapy acts in pain relief is not clear yet, but it is known that a 20-minute cold application can reduce the transmission of painful impulses by up to 29.4%, lasting about 30 minutes after its removal<sup>(6)</sup>. Other authors also recommend the use of ice bags for at least 20 minutes every two to three hours, because they believe that this simple treatment can offer excellent results to decrease discomfort and healing times<sup>(2)</sup>.

For cold applications to provide therapeutic benefits, skin temperature should go down to 13.8°C to decrease the local blood flow and 14.4°C for analgesic purposes<sup>(7)</sup>. When tissue cooling is very intense (-20°C to -70°C), tissue is destroyed. In ice applications in contact with the skin, however, in general, tissue cooling is superficial and reaches between 1°C and 10°C<sup>(1)</sup>.

A study that compared two cryotherapy modes applied in the eyebrow region found that the degree of cooling provoked by the cold compress strongly varied after the first minute, between 2°C and 17°C, with a median of 10°C. In the group with ice, temperature varied from 2°C to 10°C with a median of 7°C, after 4 and 5 minutes<sup>(8)</sup>.

Cold treatments for up to 30 minutes in healthy individuals do not seem to cause burns or other lesions<sup>(9)</sup>.

Treatment with ice in soft parts soon after an injury is efficient and should be maintained during the acute phase of the cure process, between 24 and 72 hours. At the start of the application, the pain threshold is raised and the edema reduced. Ice should be used for 30 minutes at most and with two-hour intervals between applications<sup>(10)</sup>.

The initial feeling of the skin in cold water is not comfortable but, as body temperature drops, a burning feeling occurs, followed by numbness and analgesia<sup>(4)</sup>. Cryotherapy provokes a cold feeling that lasts between one and three minutes, a burning feeling between two and seven minutes. Pain is interrupted between five and twelve minutes and profound vasodilation of the skin between twelve and fifteen minutes, without increasing the metabolism<sup>(3)</sup>.

The success of cryotherapy can be evaluated by muscle relaxation in the application area, followed by relief or decrease of pain and analgesics use<sup>(2)</sup>.

Contraindications for cryotherapy are Raynaud's disease or other vasospastic disorders, hypersensitivity to cold and cardiac disorders that affect the local circulation<sup>(1)</sup>. The Raynaud phenomenon is a vascular reaction to the cold application in which skin extremities can turn white, red or bluish, first affecting fingers and toes. Applying ice to anesthetized skin is also contraindicated<sup>(7)</sup>. Problems deriving from cryotherapy are rare, but care should be taken when applied to paralyzed or comatose, rheumatoid or hypertensive people<sup>(1)</sup>.

Research on the use of ice as a therapeutic form refers to orthopedic traumas and the postoperative period<sup>(8)</sup>. In women's health, perineal edema, hematoma and bruises are quite frequent morbidities after vaginal birth and nurse-midwives routinely and empirically use cryotherapy to treat these problems. Doubts still remain about the minimum time to reduce site temperature, permanence time of cooling after the application and how the region surrounding the application is affected<sup>(11)</sup>.

This research was conducted to compare three cryotherapy modes (ice bag, soft ice and gel bag) in healthy women who were not pregnant, to assess thigh temperature in each cooling mode and to describe the women's feelings when the ice was applied to their thigh in each cryotherapy modality. The goal was to check whether the cryotherapy modes under analysis reach the ideal temperature for analgesia, with a view to their use in puerperal women to relieve perineal pain in the postpartum period after normal birth.

## OBJECTIVE

To compare skin cooling by three superficial cold application methods in healthy and non-pregnant women.

## METHOD

This is a non-controlled randomized clinical trial. Participants were 32 women, divided in three groups – *Ice Bag*, an ice bag prepared with 240ml of water, *Soft Ice Bag*, a

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mixture with two thirds of water and one third of 70% alcohol, and *Ice Gel Bag*, a (commercialized) ice bag<sup>(a)</sup>.

Participants were randomly divided in the three abovementioned groups, following a computer-generated randomization table, applied when they were included in the research.

Inclusion criteria were: being over 18 years of age, not being pregnant, not presenting any previous signs of hypersensitivity to cold, nor pathological antecedents that contraindicated the use of cryotherapy. The exclusion criterion was being allergic to cold.

The study was developed at the laboratory of a private Nursing College in the South of São Paulo. Students who complied with the inclusion criteria were contacted before, after or during class intervals, when they received information about the study goal and how they would participate. Next, they signed the free and informed consent term and the randomization table was applied to define which study group they would be part of. After identifying the group, one of the researchers applied the cryotherapy mode on the middle third of the internal side of the right thigh. Each student received one single cryotherapy modality and remained in horizontal dorsal decubitus position on a bed, with her head on a pillow. Two researchers collected the data during the morning periods on working days in October 2007.

Initially, the student's body temperature was verified with a digital Techline® armpit thermometer, model TS-101, placed in the armpit region, previously dried with paper towels. Next, the bag of one of the three cryotherapy modes was applied for 20 minutes.

The ice and soft ice bags were made using plastic bags of 8cm wide and 16cm long, using a 240ml of water and water (160ml) mixed with 70% alcohol (80ml), respectively. These two bags were closed at the end with elastic. All three bags were previously placed in the freezer at a temperature of -10°C, where they were kept for more than three hours and removed in the form of ice.

The bags were wrapped in thin, diaper-like cotton tissue, 20cm wide and 20cm long, thus avoiding direct contact with the skin.

During the bag application time, environmental temperature was also verified with an Incoterm® environment

thermometer, model-TA 60.02. Thigh temperature was measured with a digital Minipa® dual-channel thermometer, model MT 405 and a surface thermocouple MTK01, placed on the internal side of the median line of the right thigh and fixed using Micropore®. The thermocouple remained on the site no local during the 20 minutes the bag was being applied. Bag temperature was assessed with a digital Minipa® thermometer, model MT 405, using an immersion thermocouple MTK13 that remained inside the bag during the entire application time.

To control the bag application time, a digital watch with a chronometer was used, brand Timex® model WR50m. Temperatures of the bags and internal side of the thigh were controlled at: zero (T0), five (T5), ten (T10), fifteen (T15) and twenty minutes (T20).

The data collection instrument was a two-part form, the first of which contained identification data and the second temperature control and the feelings the students mentioned.

Approval from the Ethics Committee at Hospital Israelita Albert Einstein (No 659/07) was obtained before data collection started.

The analysis of quantitative variables involved the observation of minimum and maximum values and calculation of means, standard deviations and medians. Kruskal-Wallis' non-parametric test was used and significance was set at 5%. The three skin cooling methods were compared using the one-factor variance analysis test (ANOVA). For qualitative variables, absolute and relative frequencies were calculated.

## RESULTS

In total, 180 students were registered at the private college under analysis, 15 of whom were excluded because they were male; 95 were in training and not present at the institution; 38 students refused to participate because they thought that using the ice bag would be uncomfortable and the remaining 32 students accepted to participate in the research. In this group of 32 participants, 11 were submitted to the soft ice bag, 11 to the ice water bag and 10 to the gel bag.

Means, standard deviations, medians, minimum and maximum ages, armpit, thigh and environmental temperatures are shown in Table 1.

**Table 1** - Mean, standard deviation (sd), median, minimum and maximum age, armpit, thigh and environmental temperature - São Paulo - 2007

Variable	N	Mean	sd	Median	Minimum	Maximum	p
Age	32	22.1	4.9	21.0	18.0	40.0	0.253
T armpit	32	36.4	0.8	36.4	35.1	37.2	0.170
T thigh	32	28.9	2.7	29.5	17.0	32.0	0.524
T environ.	32	21.9	1.2	22.0	21.0	24.0	0.082

<sup>(a)</sup> Therapeutic compress measuring 8cm width by 16cm length and 1.5cm thickness, containing 220g of thermal mass based on non-toxic acrylic thickener – thermal gel. [www.babycarebrasil.com](http://www.babycarebrasil.com)

Participants' ages ranged from 18 to 40 years, with a mean age of  $22.1 \pm 4.9$  years. No statistically significant difference was found in the three groups regarding the following variables: age, armpit temperature, initial thigh temperature and environmental temperature.

Data on bag temperature at 0, 5, 10, 15 and 20 minutes of application are displayed in Table 2.

**Table 2** - Mean, standard deviation, median, minimum and maximum bag temperature according to application time - São Paulo - 2007

Group/Time	Bag temperature (°C)					
	N	Mean	sd	Median	Minimum	Maximum
<b>T 0 min</b>						
Soft ice	11	-2.5	3.4	-2.0	-9.0	2.0
Ice gel	10	-5.3	3.7	-6.5	-11.0	1.0
Ice water	11	4.3	2.6	4.0	0.0	8.0
<b>T 5 min</b>						
Soft ice	11	-3.5	2.8	-4.0	-9.0	0.0
Ice gel	10	-6.4	2.1	-7.0	-9.0	-1.0
Ice water	11	2.7	2.1	2.0	0.0	6.0
<b>T 10 min</b>						
Soft ice	11	-3.3	2.1	-3.0	-8.0	-1.0
Ice gel	10	-6.6	1.7	-7.0	-9.0	-3.0
Ice water	11	2.2	1.8	2.0	0.0	5.0
<b>T 15 min</b>						
Soft ice	11	-2.3	2.2	-1.0	-7.0	0.0
Ice gel	10	-5.5	2.8	-7.0	-9.0	1.0
Ice water	11	2.3	1.8	2.0	0.0	6.0
<b>T 20 min</b>						
Soft ice	11	-1.6	1.9	-1.0	-6.0	0.0
Ice gel	10	-4.4	3.4	-5.0	-7.0	3.0
Ice water	11	2.4	1.8	3.0	0.0	6.0

The initial temperature of the soft ice bag varied between  $-9^{\circ}\text{C}$  and  $2^{\circ}\text{C}$ , against  $0^{\circ}\text{C}$  to  $8^{\circ}\text{C}$  for the ice water bag and  $-11^{\circ}\text{C}$  to  $2^{\circ}\text{C}$  for the ice gel bag, demonstrating that the ice gel bag reached the lowest temperature.

Table 3 shows data on the decrease in thigh temperatures after 0, 5, 10, 15 and 20 minutes of bag application.

**Table 3** - Mean, standard deviation, median, minimum and maximum thigh temperature according to application time - São Paulo - 2007

Group/Time	Thigh temperature (°C)						p
	N	Mean	sd	Median	Minimum	Maximum	
<b>T 0 min</b>							
Soft ice	11	28.4	3.9	30.0	17.0	32.0	0.253
Ice gel	10	29.7	1.4	29.5	28.0	32.0	
Ice water	11	28.8	1.8	29.0	24.0	31.0	
<b>T 5 min</b>							
Soft ice	11	13.2	4.6	12.0	5.0	23.0	0.067
Ice gel	10	9.4	2.5	10.0	6.0	12.0	
Ice water	11	13.8	5.5	13.0	8.0	26.0	
<b>T 10 min</b>							
Soft ice	11	10.5	4.3	10.0	2.0	20.0	0.007
Ice gel	10	5.4	1.9	5.5	3.0	9.0	
Ice water	11	9.0	3.7	8.0	4.0	18.0	
<b>T 15 min</b>							
Soft ice	11	8.9	3.6	9.0	1.0	16.0	0.003
Ice gel	10	3.8	1.9	3.5	1.0	7.0	
Ice water	11	7.8	3.5	7.0	3.0	15.0	
<b>T 20 min</b>							
Soft ice	11	8.0	3.2	8.0	1.0	14.0	0.005
Ice gel	10	3.5	1.7	3.0	1.0	6.0	
Ice water	11	6.5	2.9	3.0	6.0	13.0	

The ice gel bag showed the lowest mean thigh temperature at all intervals, except at baseline. The comparison of the three cooling methods using the variance analysis test (ANOVA) showed a significant difference in mean thigh temperatures at T10 ( $p=0.007$ ), T15 ( $p=0.003$ ) and T20 ( $p=0.005$ ). The ice gel bag was more efficient for superficial skin cooling when compared with the other two methods. Behavior of the ice water and soft ice bags was similar.

No significant differences in mean temperatures were found at T0 (0.253) and T5 ( $p=0.067$ ).

Data related to the feelings the women mentioned and how they were mentioned at 5, 10, 15 and 20 minutes of application are shown in Table 4.

**Table 4** - Feelings mentioned by students according to bag application time - São Paulo - 2008

Group/Time	Feeling (N)				
	Cold	Stitch	Burning	Numbness	Anesthetized
<b>T 5 min</b>					
Soft ice	5	2	2	3	-
Ice gel	2	2	4	2	-
Ice water	7	3	2	-	-
<b>T 10 min</b>					
Soft ice	5	1	3	1	-
Ice gel	3	2	4	-	1
Ice water	6	2	2	1	-
<b>T 15 min</b>					
Soft ice	1	2	2	7	-
Ice gel	5	1	0	1	3
Ice water	5	2	2	1	1
<b>T 20 min</b>					
Soft ice	-	-	-	2	9
Ice gel	-	-	1	-	8
Ice water	2	-	-	2	7

The feeling the women most mentioned at five minutes was cold for the soft ice and ice water bags and burning for the gel. After ten minutes, the students still related cold with regard to the soft ice and ice water application, and the burning feeling continued for the ice gel bag. At fifteen minutes, the main report for the soft ice was numbness, against cold for the ice water and ice gel applications. It should be highlighted that, in this phase, three participants in the ice gel group mentioned anesthesia sensation, with the lowest mean skin temperature. Anesthesia was the feeling that stood out after twenty minutes of cold bag application in the three groups.

## DISCUSSION

Few studies were found in women's health that compared cold treatments. In orthopedics, on the other hand, cryotherapy is a very frequent and more investigated practice.

A research that compared three cold application modes, wet ice, dry ice and cryogenic compress in the arm region, on the right triceps, found initial skin temperatures between 29.5°C and 30.0°C. After 15 minutes of application, skin temperature had dropped to 12°C in case of wet ice, 9.9°C for dry ice and 7.3°C for the cryogenic compress, with a

statistically significant difference between wet ice, dry ice and compress. No statistically significant difference was found between dry ice and cryogenic compress<sup>(11)</sup>.

Another recent study involving healthy volunteers assessed four cryotherapy methods, crushed ice, gel bag, pea-shaped ice and immersion in ice and water, during 20 minutes of application on the right ankle. It was observed that crushed ice and immersion in ice and water showed a significantly larger difference in the reduction of superficial skin temperature ( $19.56 \pm 3.78^\circ\text{C}$  and  $16.99 \pm 2.76^\circ\text{C}$ , respectively) when compared with the gel bag ( $13.19 \pm 5.07^\circ\text{C}$ ) and pea-shaped ice ( $14.59 \pm 4.22^\circ\text{C}$ )<sup>(12)</sup>.

A research that analyzed healthy persons' tolerance to cold treatment in the eyebrow region compared cold compresses and ice bags. Findings showed initial body temperatures around 33°C in the two groups, with medians of 23°C for the compress and 26°C for the ice bag after one minute of application<sup>(8)</sup>. Cold applications can arouse different responses in various body regions due to the presence of muscles and fat tissue on the application site.

An American study of 32 healthy participants compared repeated immersion ankle baths at three temperatures (1°C, 10°C and 15°C). At 1°C, greater pain was mentioned in case of immersion when comparison with 10°C and 15°C. Hence,

health professionals should pay attention to the temperature used for cryotherapy<sup>(13)</sup>.

In this research, it was observed that, in the three groups, at 5 minutes and up to 20 minutes, mean superficial thigh temperatures ranged between 3.5°C and 8°C, below the 14°C needed to provoke the analgesia effect<sup>(7)</sup>.

The goal of cryotherapy is to reduce the temperature of the application site to between 10 and 15°C, but no evidence has been found in literature about the duration and frequency of application. There is little evidence on the effect of subcutaneous fat quantities on superficial skin cooling, although this data should be taken into account<sup>(14)</sup>. The last systematic Cochrane Library review, based on seven clinical trials, concluded that there is little evidence to support the efficacy of ice treatment for perineal pain reduction after delivery<sup>(15)</sup>.

In the present research, the use of ice gel showed lower mean temperatures than other cooling forms after 10, 15 and 20 minutes of application. This finding may suggest the possibility of reducing usage time for the gel bag. After 15 minutes of use, the gel reached a mean temperature of 3.8°C, much below the 7.2°C for ice water and 8.9°C for soft ice. Acceptance levels of this practice were very high, as only one student ceased to participate, who requested that the ice gel bag were removed because she felt very cold and uncomfortable.

A randomized and controlled research<sup>(16)</sup> that compared two ice treatment forms for acute ankle twists found that patients subject to an experimental treatment (ten minutes of application, followed by ten minutes rest and again ten minutes of ice) experienced significantly less pain to perform activities than patients subject to standard treatment (20 minutes of continued application every two hours).

A randomized and controlled clinical trial, involving 70 patients in the postoperative period of shoulder surgery, assessed the use of ice and found that patients in the cryotherapy group experienced less pain, greater satisfaction and comfort and managed to sleep longer. These volunteers reported application temperatures between 7.2°C and 13°C as comfortable. The authors highlighted that pain reduction occurs when skin temperature is brought down to between 10 and 15°C<sup>(17)</sup>.

Cryotherapy can cause different levels of discomfort, depending on the temperature that is used. During the first three minutes, cold therapy provokes a cold feeling; followed by burning (2 to 7 minutes), pain interruption (12 to 15 minutes) and profound vasodilation of the skin without increasing the metabolism<sup>(3)</sup>. Thus, treatment can be uncomfortable for new users but, after repeated application, discomfort tends to decrease<sup>(13)</sup>. Hence, temperatures of at

least 0 °C are recommended for sitz baths with ice to relieve perineal pain after vaginal birth<sup>(4)</sup>.

Among healthy individuals who used cold compresses, the abovementioned research on cryotherapy in the eyebrow region found 29.8% of burning, 10.8% anesthesia, 8.1% pain in the eyebrow and 48.6% no symptoms. On the other hand, in the ice bag group, 90.6% did not mention any symptoms and 9.4% complained of a burning feeling during the first minute<sup>(8)</sup>. Although it is simple, safe and low-cost, in cryotherapy, professionals need to stimulate patients to face the initial feelings of cold, burning and numbness before analgesia is achieved<sup>(4)</sup>.

The feelings women in this research most mentioned in the first five minutes were: cold (14/32), stitch (7/32) and burning (8/32), most frequently mentioned in the ice gel group, which can be explained by the fact that average temperature was 9°C, against 13°C in the other two groups. One possible justification for the relative variation between the feelings the students mentioned could be differences among participants in terms of subcutaneous fat tissue quantities in the application region, a variable that was not controlled in this research. Skinnier women may have perceived symptoms faster than obese women. After 10 minutes, the gel group mentioned burning as the main feeling, while the cold feeling prevailed in the other two groups. At 15 minutes, the cold feeling was still mentioned (11/32), while numbness stood out in the soft ice group (7 cases – 63.6%). At the end of the 20-minute period, the feeling of anesthesia was observed in the three groups (24/32).

Patients should be advised about the possible feelings cryotherapy can cause as, in one research, people who did not receive this information reported greater pain provoked by the cold than those who received previous information about what they might feel during the cold application<sup>(18)</sup>.

## CONCLUSION

The application of the ice water, gel and soft ice bags reached temperatures below 14°C in the thigh region, which according to some authors cause analgesia and anesthesia on the application site.

Mean superficial skin temperatures when using the ice gel bag at 10, 15 and 20 minutes were significantly lower than that of ice water and soft ice bags. The feelings the women mentioned were: cold, stitch, burning, numbness and anesthetized.

Thus, it is concluded that the ice gel bag provoked greater skin cooling, and that these cryotherapy modes (ice water, soft ice and ice gel) can be tested in puerperal women. The application time of 20 minutes could be reduced though, mainly if the option is to apply ice gel.

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