Thieme

Induction of Labor Using Castor Oil Cocktail – an Analysis of Real-world Data

Geburtseinleitung mithilfe eines Rizinusöl-Wehencocktails: eine Real-World-Datenanalyse

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ABSTRACT

Introduction
Induction of labor is indicated when benefits of delivery outweigh benefits of prolonged pregnancy, which is not always welcomed by women. Castor oil is accepted as an "old household remedy" for labor induction but is not yet part of the official guidelines. Nevertheless, it is often used, mostly even before the women are admitted to the hospital. Data on its actual benefits and safety are missing. Upon accepting the real-world practice of applying castor oil cocktail for labor induction we added castor oil as one option of labor induction in our clinical routine for multiparous women at term, with a history of at least one vaginal delivery. Here we aimed to generate data on the effectivity and safety of castor oil in labor induction by analyzing the real-world data generated in our cohort.

Methods
In our retrospective analysis we included data of a cohort of 148 multiparous women induced by castor oil cocktail and of 286 matched controls receiving established methods according to the current guidelines for labor induction. The castor oil cocktail was prepared following a standardized recipe with quality-tested castor oil. Statistical analysis was performed with SPSS 27.0.

Results
Perinatal outcome data including the rate of vaginal deliveries did not differ between groups, except significantly more neonates were admitted to the neonatal intensive care unit in the group receiving established methods for induction of labor ($p = 0.01$). In 39 women (26 %), administration of castor oil cocktail alone failed to induce labor. The time from initiation of labor induction until delivery was significantly shorter in the castor oil cocktail group ($p = 0.04$).

Conclusion
Our study demonstrates the safety and effectivity of a castor oil cocktail induction in multiparous women at term in a hospital-based setting using quality-controlled castor oil in a standardized recipe.

ZUSAMMENFASSUNG

Einleitung
Eine Geburtseinleitung ist dann indiziert, wenn die Vorteile einer Entbindung die Vorteile einer fortgesetzten Schwangerschaft, die von Frauen nicht immer erwünscht wird, überwiegen. Rizinusöl gilt als „altes Hausmittel“ für die Geburtseinleitung, wurde aber bisher nicht in die offiziellen Leitlinien aufgenommen. Es wird aber dennoch öfters eingesetzt, meistens sogar, bevor Frauen ins Krankenhaus kommen. Es fehlt aber an Daten zu den tatsächlichen Vorteilen und der Sicherheit von Rizinusöl bei der Geburtseinleitung. Da wir den Einsatz eines rizinusölbasierten Cocktails zur Weheneinleitung in der Praxis akzeptieren, haben wir Rizinusöl als eine weitere Option zur Geburtseinleitung am errechneten Geburtstermin bei Multipara-Frauen, die schon mindestens einmal vaginal entbunden hatten, in unsere klinische Praxis aufgenommen. Ziel dieser Studie war es, Daten zur Effektivität und Sicherheit von Rizinusöl bei der Weheneinleitung zu sammeln, indem wir die Real-World-Daten, die für unsere Kohorte erzeugt wurden, analysierten.

Methoden
Unsere retrospektive Analyse untersucht die Daten einer Kohorte von 148 Multipara-Frauen, die einen Rizinusöl-Wehencocktail zur Geburtseinleitung erhielten, sowie von 286 vergleichbaren Kontrollpatientinnen, bei denen die Geburtseinleitung mit etablierten Methoden gemäß den aktuellen Leitlinien zur Geburtseinleitung durchgeführt wurde. Der Wehencocktail mit Rizinusöl wurde gemäß einer standardisierten Rezeptur mit qualitätsgeprüftem Rizinusöl zubereitet. Die statistische Analyse wurde mit SPSS 27.0 durchgeführt.

Ergebnisse
Es gab keine Unterschiede in den perinatalen Daten einschließlich der Rate vaginaler Entbindungen zwischen den Gruppen, mit einer Ausnahme: Es wurden signifikant mehr Neugeborene aus der Gruppe, die mit etablierten Geburtseinleitungsmethoden behandelt wurde, auf die neonatologische Intensivstation verlegt (p = 0,01). Bei 39 Frauen (26 %) schlug der Versuch, die Geburt durch die Verabreichung eines Wehencocktails mit Rizinusöl einzuleiten, fehl. Die Zeit von Beginn der Geburtseinleitung bis zur Entbindung war signifikant kürzer in der Gruppe, die den Rizinusöl-Wehencocktail erhielt (p = 0,04).

Schlussfolgerung
Unsere Studie zeigt die Sicherheit und Effektivität eines mit qualitätsgeprüftem Rizinusöl nach einer standardisierten Rezeptur hergestellten Rizinusöl-Wehencocktails zur Geburtseinleitung bei Multipara-Frauen am Termin im Krankenhaus.

Introduction

Induction of labor (IOL) is indicated when the benefits of delivery outweigh the benefits of prolonged pregnancy [1, 2, 3, 4, 5] or the risk of an adverse outcome increases with further prolongation of pregnancy, like in cases of diabetic pregnancies, macrosomia, or placental insufficiency [6]. As shown by Grobman et al., elective IOL at 39 weeks of gestation in low-risk women does not increase the risk of perinatal adverse events but significantly reduces the number of caesarean sections (CS) compared with expectant management [7]. However, women often still perceive induction of labor as an interference with the natural course of labor and evaluate it negatively on an emotional level.

The hormone inducing labor is prostaglandin. Thus, current induction methods are mainly based on drug administration containing prostaglandins or mechanical devices triggering the release of endogenous prostaglandins [2]. Labor induction using prostaglandins has shown to be effective and safe in numerous studies [8, 9, 10, 11, 12, 13, 14, 15] and thus administration of prostaglandins is recommended to induce labor in most international guidelines [16]. Depending on the route of administration or the type of synthetic prostaglandin used, the safety profile of mechanical induction has been shown to be more favorable but may not be as effective as using prostaglandins for IOL [13].

Castor oil, extracted from the *Ricinus communis* plant, was the first reported medical procedure to induce labor in the first half of the last century and was already used by the ancient Egyptians [17, 18]. Castor oil exerts its effects through ricinoleic acid, a hydroxylated fatty acid. Research on mice has shown that ricinoleic acid specifically activates the EP3 prostanoid receptor [19, 20]. It has been shown to not only have a laxative effect but is also effective on the uterus to induce labor [2]. In the 1960 s, oxytocin replaced castor oil in obstetric care primarily to mitigate gastrointestinal side effects [18]. Misoprostol, developed in 1973 for treating gastric ulcers, entered the market in the mid-1980 s and was described as mimicking natural labor [17, 21]. Misoprostol is now the most commonly used drug in the setting of labor induction at term and has been increasingly criticized recently by the public.

Both as a result of the public debate and independently of it, castor oil is increasingly explicitly requested by women as an alternative to prostaglandins, as it is accepted as an “old household remedy”. Consequently, castor oil cocktail is often applied in outpatient settings at home, ahead of hospital admission for labor induction. It has been shown that depending on the quantity and quality of castor oil used to induce labor, effectiveness and severity of side effects do vary [22], leaving it to be a risky practice, especially without monitoring of fetal and maternal well-being.

To diminish the occurrence of unmonitored outpatient inductions utilizing castor oil and to accommodate women's preferences, we began offering castor oil as one of the options for labor induction in our routine clinical practice, using a standardized recipe containing solely quality-tested castor oil. Based on findings from a prior perspective, randomized, double-blind, placebo-controlled clinical trial conducted by Gilada et al. [23], which demonstrated the ineffectiveness of castor oil in primiparous women, we restricted its administration to multiparous women.

The objective of this study was to assess the safety and effectiveness of castor oil for labor induction specifically in multiparous women analysing the real-world data collected in our cohort.

Material and Methods

In a retrospective analysis, we compared a cohort of pregnant women receiving a castor oil cocktail for IOL with a cohort of pregnant women induced by guideline recommended methods. Subjects in the control group were identified by 1:2 matching by parity, age of the mother, and year of treatment. We included data of singleton pregnancies after completed 37 weeks of gestation indicated for IOL at our tertiary care obstetric unit between 2014 and 2021. We excluded cases with a history of caesarean section and primiparous women.

In our institution induction by castor oil cocktail is offered to multiparous women asking for alternative methods of labor induction since 2010. It was implicated into our institutional guidelines and consent forms in 2012. Women receiving castor oil cocktail for labor induction all consented and signed for application of this method.

The castor oil cocktail was prepared according to our standardized recipe (▶ **Fig. 1**) using quality-tested castor oil from the university hospital's pharmacy. If onset of labor has not occurred within 12 hours after consumption of the cocktail, IOL was continued using guideline standard methods, like mechanical IOL with a double balloon catheter, misoprostol or dinoprostone. Oral misoprostol was given at an initial dose of 50 µg, followed by subsequent doses of 100 µg administered every 4 h for a maximum of 48 h. 10 mg dinoprostone was inserted vaginally releasing 0.3 mg of dinoprostone per hour, for a maximum application time of 48 hours. The vaginally placed double balloon catheter remained for 12 hours, followed by prostaglandins if onset of labor was not established. Monitoring during IOL was performed according to the German guidelines irrespective of the method applied.

As primary endpoints we analyzed the rate of vaginal deliveries and perinatal outcome data. Secondary outcome parameters described are the frequency of cases in which labor was not induced by the castor oil cocktail after 12 hours and the duration from initiation of induction to delivery.

Data collection

Clinical data were collected from the electronic patient records. Clinical information collected included maternal age, gravidity, parity, body mass index (BMI), gestational age at delivery, reasons for and methods of IOL. BMI was calculated from maternal height and pre-pregnancy weight. Gestational age was calculated using the last menstrual period or crown-rump-length retrieved from earliest available ultrasound.

▶ **Fig. 1** Castor oil cocktail recipe.

Perinatal outcome included mode of delivery, application of epidural analgesia, non-reassuring fetal status, frequency of fetal scalp blood testing, time interval from induction to delivery, umbilical cord arterial pH, Apgar score, and postnatal admission to neonatal intensive care unit (NICU). The induction to delivery interval was calculated from the time the woman was admitted to the labor ward for IOL to the time of delivery. For further analysis, the cases were grouped as follows: delivery on the day of admission, delivery within two days of admission and delivery later than two days after admission. Data handling and analysis was in adherence with the Declaration of Helsinki. Ethical approval for this study was given by the ethical committee of our institution (2022–2679-Daten).

Statistical evaluation

Statistical analysis was performed with SPSS 27.0 (IBM Corp., released 2020. IBM SPSS Statistics for Windows, Version 27.0. Armonk, NY: IBM Corp.). Chi^2 test or Fisher exact test were used to compare categorical data. Most of the continuous data were not normally distributed; therefore, our data are presented using median and interquartile range. Nonparametric tests were used to compare continuous data between groups. A p value < 0.05 was considered to indicate statistical significance (2-tailed).

Results

During the study period from 2014 to 2021, 1140 multiparous women meeting the inclusion criteria underwent IOL at our university hospital. 148 (13 %) requested and received a castor oil cocktail for IOL. Therefore, the matched control group, which was induced using established methods, consisted of 296 women who met the relevant criteria.

▶**Table 1** Maternal and pregnancy characteristics.

Variable	Castor oil cocktail	Established methods	p value
Total, n	148	296	
Median age in years, median (IQR)	34 (30–36)	33 (30–36)	0.86
BMI before pregnancy in kg/m², median (IQR)	22.7 (20.8–25.7)	25.1 (22.1–29.6)	**< 0.01**
Gestational age in days, median (IQR)	286 (281–289)	281 (274–287)	**< 0.01**
Gestational age in weeks, median (IQR)	40 (40–41)	40 (39–40)	**< 0.01**
Gravidity, median (IQR)	2 (2–3)	3 (2–3)	0.71
Parity, median (IQR)	1 (1–2)	1 (1–2)	0.99
Indications for induction of labor			
Post-date pregnancy	84 (57)	94 (32)	**< 0.01**
PROM	6 (4)	54 (18)	**< 0.01**
Placental insufficiency	24 (16)	50 (17)	0.89
Estimated fetal weight exceeding 4 kg	5 (3)	25 (8)	0.46
Insulin dependent diabetes mellitus	7 (5)	14 (5)	0.99
Request of the mother	4 (3)	18 (6)	0.16
Hypertensive diseases in pregnancy	7 (5)	13 (4)	0.99
Others	8 (5)	21 (7)	0.55
Unknown	3 (2)	7 (2)	0.99

Data are n (%) or median and interquartile range (IQR) unless otherwise specified
BMI = Body Mass Index; PROM = Premature Rupture Of Membranes
$p < 0.05$ is significant and bold

Baseline characteristics

▶ **Table 1** shows maternal and pregnancy characteristics. Median age, gravidity, and parity did not differ between groups. Gestational age at delivery was higher in the castor oil group (median 286 days vs. 281 days; $p < 0.01$), BMI was significantly lower in the castor oil group (median 22.7, min. 16, max. 40 vs. median 25.1, min. 16, max. 55; $p < 0.01$). Predominantly, IOL was initiated due to late or post term pregnancy, premature rupture of membranes (PROM), placental insufficiency, estimated fetal weight exceeding 4 kg, diabetes mellitus (DM), request of the mother or hypertensive diseases in pregnancy. The most common cause of IOL was post-date pregnancy, which was significantly more common in the castor oil group (57 % vs. 32 %; $p < 0.01$), followed by PROM, which was significantly more common in the group of women receiving established methods for IOL (18 % vs. 4 %; $p < 0.01$).

▶**Table 2** Perinatal outcome.

Variable	Castor oil cocktail	Established methods	p value
Mode of delivery			**0.35**
Vaginal	137 (93)	262 (89)	
Operative Vaginal Delivery	5 (3)	12 (4)	
Caesarean section	6 (4)	22 (7)	
Amniotomy	8 (5)	24 (8)	0.33
Epidural analgesia	11 (7)	29 (10)	0.39
Non-reassuring fetal status	32 (22)	64 (22)	0.99
Fetal scalp blood testing, n (%)	7 (5)	12 (4)	0.80
Induction to delivery interval, n (%)			**0.04**
< 1 day	68 (46)	99 (34)	**0.01**
1–2 days	64 (44)	160 (55)	**0.04**
> 2 days	14 (10)	32 (11)	0.74
Arterial pH, median (IQR)	7.23 (7.18–7.29)	7.22 (7.17–7.28)	0.35
1-min APGAR, median (IQR)	9 (8–9)	9 (8–9)	0.17
5-min APGAR, median (IQR)	10 (9–10)	9 (9–10)	0.24
10-min APGAR, median (IQR)	10 (10)	10 (9–10)	0.28
NICU admission	3 (2)	24 (8)	**0.01**

Data are n (%) or median and interquartile range (IQR) unless otherwise specified.
$p < 0.05$ is significant and bold

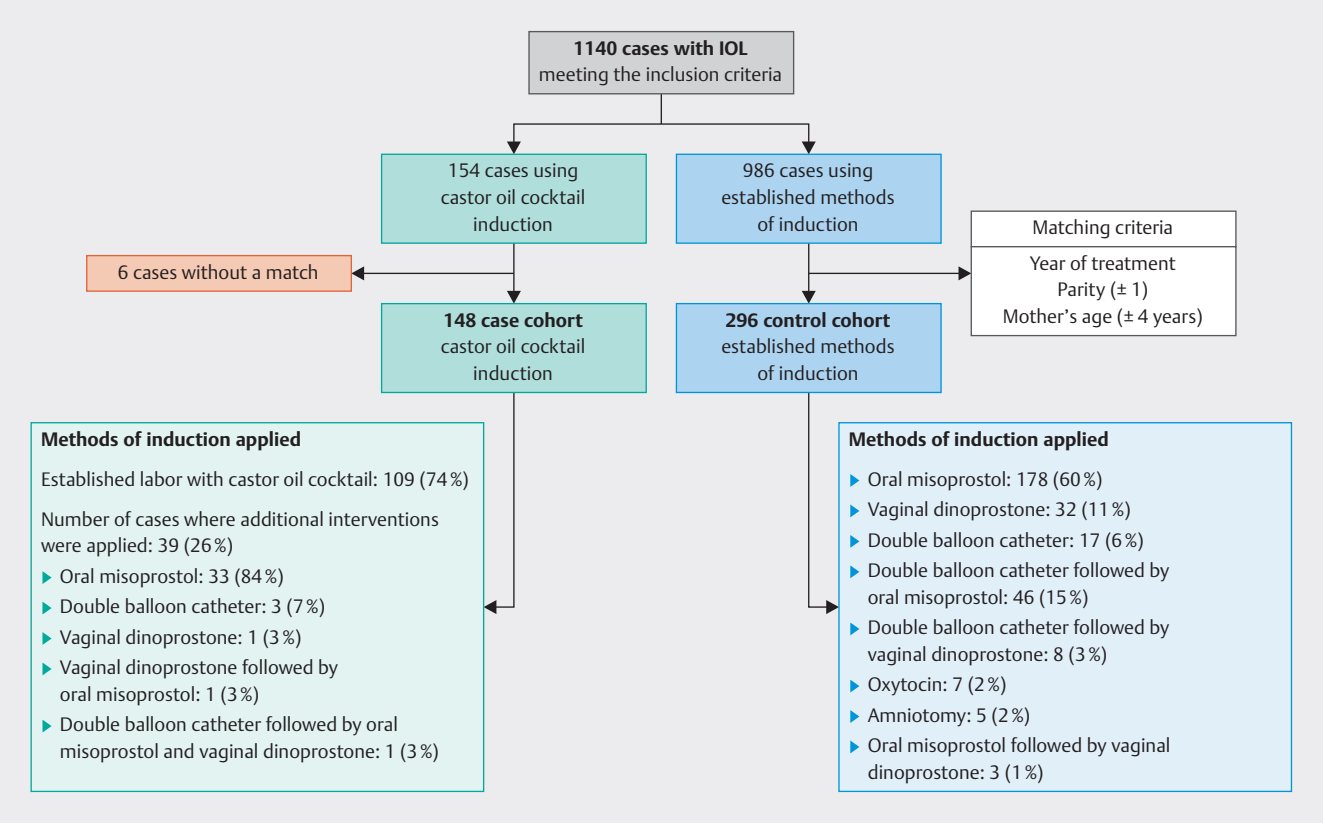
Results of labor induction

Onset of labor was established in 109 (74 %) women receiving solely a castor oil cocktail. In contrast, the castor oil cocktail did not induce labor in 39 women (26 %) after 12 hours. Therefore, IOL was continued with oral misoprostol in 33 cases, three with a double balloon catheter and one with vaginal dinoprostone. The remaining methods of IOL are displayed in ▶ **Fig. 2**.

In the control group 178 (60 %) women received misoprostol for IOL, in 71 (24 %) a double balloon catheter was placed, 32 (11 %) women received dinoprostone, seven (2 %) women oxytocin, and five (2 %) women were induced by amniotomy. Of the group being induced by double balloon catheter, this method failed to establish labor in 54 (76 %) women. IOL was continued with either misoprostol in 46 women or dinoprostone in eight women (▶ **Fig. 2**).

Perinatal outcome data

Perinatal outcome data are summarized in ▶ **Table 2**. The rate of vaginal deliveries in both groups (93 % vs. 89 %) is comparable. Overall, a good perinatal outcome was observed. The induction to delivery interval was significantly shorter in women receiving a



▶ **Fig. 2** Applied methods of labor induction in the study cohort.

castor oil cocktail for IOL in comparison to the control group (p = 0.04). The number of cases assigned to the group delivering in "less than one day" was significantly higher in the castor oil cocktail group than in the control group (46 % vs. 34 %; p = 0.01). Control cases were more often assigned to the subgroup "one to two days" (p = 0.04). There was no difference in the proportion of cases assigned to the group "more than two days" (p = 0.74).

There were significantly more neonates admitted to the NICU in the control group (8 % vs. 2 %; p = 0.01) (▶ **Table 2**). Indications for NICU admission are depicted in ▶ **Table 3**. The most common reason was respiratory distress in both groups.

▶ **Table 3** Comparison of indications for NICU admission.

Variable	Castor oil cocktail (n = 3)	Established methods (n = 24)	p value
Indication for admission			0.05
Respiratory Distress	2 (67)	14 (58)	
Hypoglycemia	0	3 (13)	
Neonatal infection	1 (33)	0	
Congenital malformation	0	4 (16)	
Others	0	3 (13)	

Data are n (%) or median and interquartile range (IQR) unless otherwise specified.
p < 0.05 is significant and bold

Discussion

The objective of this study was to evaluate the everyday practice of IOL by using the consumption of castor oil cocktails as a frequently requested alternative to conventional methods, aiming to generate real-world data on the safety and effectiveness of castor oil.

We could convincingly demonstrate the safety and effectiveness of castor oil cocktail for IOL in a cohort of 148 multiparous women who received a castor oil cocktail compared to 296 multiparous women induced by conventional methods. In both groups there was a high rate of vaginal deliveries with a corresponding low rate of caesarean section (4 % vs. 6 %) which did not differ between groups (▶ **Table 2**). The German perinatal statistics of 2022 report a caesarean section rate of 4 % for the Robson-category 3 including term deliveries in multiparous women, which corresponds to our data. Neonates in the castor oil group were at significantly lower risk to be admitted to NICU (2 % vs. 8 %; p = 0.01). However, this is most likely explained by the higher, although not statistically significant, amount of uncomplicated pregnancies in the castor oil cocktail group (▶ **Table 2**). The overall percentage of neonates requiring NICU admission in our hospital is 7 %, consis-

tent with the Cochrane review on IOL methods, where oral misoprostol induction resulted in an 8% admission rate [13]. Finally, the induction-to-delivery interval was significantly shorter following castor oil cocktail initiation for IOL.

While several studies demonstrate the effectiveness and safety of castor oil cocktails [22, 24, 25, 26, 27, 28, 29, 30], a retrospective cohort study by Boel et al. found no difference in labor duration, perinatal outcomes, or adverse events between women receiving castor oil and those managed expectantly [31]. Gilada et al. conducted a prospective, randomized, double-blind, placebo-controlled clinical trial demonstrating the safety and efficacy of castor oil for IOL in multiparous post-date women, with similar perinatal outcomes and adverse effects between groups. However, this effect was not observed in primiparous women [23]. Furthermore, Knaus et al. demonstrated a significant interaction between castor oil and parity, with a higher rate of cesarean sections in primiparous women receiving castor oil cocktail [32]. Consequently, castor oil cocktail is exclusively offered to multiparous women in our hospital.

Despite limited studies on the safety and efficacy of castor oil and although current guidelines do explicitly not recommend its use, it is widely administered by midwives to stimulate labor. A national survey of members of the American College of Nurse-Midwives revealed that 93% reported using castor oil to stimulate labor [22]. The refusal to employ castor oil cocktails in clinical settings often leads to unsupervised consumption at home, where non-standardized recipes prevail and the quality of castor oil preparations remains untested by certified methods. Our data confirm the safety and effectiveness of IOL applying castor oil cocktail in a cohort of multiparous pregnant women induced at term using a standard recipe with quality tested castor oil in a clinical setting of a tertiary care hospital.

The main limitations of this study include its retrospective, single-center design and the general reliability of electronic patient records. However, a notable strength is the relatively large cohort of multiparous women. Including high-risk cases resulted in a heterogeneous study cohort, further strengthening our study. As a result of the matching criteria applied, the study cohort differed in BMI and gestational age at birth. However, since mean BMI was in both groups below the threshold for obesity and the difference in gestational age of birth was not of clinical relevance we did not consider this as a confounder. Additionally, all women received a castor oil cocktail prepared according to a standardized recipe containing quality-tested castor oil, ensuring consistent administration of the pharmacologically active substance. Compared to other studies, we used a lower volume of castor oil (20 ml vs. 60 ml) [23, 24]. Due to the retrospective nature of the study, the induction-to-delivery interval was calculated as the difference between admission and delivery dates, rather than in hours, which is another limitation of our study. However, our data show that the use of castor oil for labor induction does not lead to a prolongation of IOL. While the lack of documentation of adverse effects or patient satisfaction may be considered a further limitation, the authors can report from their clinical experience that side effects appeared no more frequent in castor oil-induced women, consistent with the meta-analysis by Moradi et al. [24].

Conclusions

Our study findings present compelling evidence supporting the safety and efficacy of employing a castor oil cocktail for labor induction in multiparous women at term within a tertiary care setting. A critical prerequisite for utilizing such a cocktail is the adoption of a standardized preparation comprising exclusively quality-tested castor oil. Nonetheless, additional research is imperative before considering the incorporation of this method into current guidelines. Our data not only establish a solid foundation for future clinical trials but also underscore the necessity of strict adherence to a precisely defined protocol, as evidenced by the consistently safe outcomes observed.

Conflict of Interest

The authors declare that they have no conflict of interest.

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