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Original Article

Fresh Frozen Plasma Versus Solvent Detergent Plasma for Cardiopulmonary Bypass Priming in Neonates and Infants Undergoing Cardiac Surgery: A Retrospective Cohort Study

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Objective: Compared with fresh frozen plasma (FFP), Omniplasma has been attributed to an increased coagulation potential and an increased fibrinolytic potential. This study aimed to compare Omniplasma and FFP used for cardiopulmonary bypass (CPB) priming regarding the incidence of postoperative thrombotic or hemorrhagic complications and outcomes in pediatric patients undergoing cardiac surgery.

Design: A retrospective observational cohort study

Setting: This single-center study was performed at the University Medical Center Groningen.

Participant: All pediatric patients up to 10 kg undergoing cardiac surgery with CPB.

Interventions: Procedures in which FFP was used for CPB priming were compared with those in which Omniplasma was used.

Measurements and Main Results: The primary outcome parameter was a composite endpoint consisting of the following: (1) pediatric intensive care unit (PICU) mortality, (2) thromboembolic complications, and (3) hemorrhagic complications during PICU stay. The authors included 143 procedures in the analyses, 90 (63%) in the FFP group and 53 (37%) in the Omniplasma group. The occurrence of the combined primary endpoint (FFP 20% *v* Omniplasma 11%, p = 0.18) and its components did not differ between the used CPB priming agent). Omniplasma for CPB priming was associated with decreased unfractionated heparin administration per kg bodyweight (585 IU *v* 510 IU, p = 0.03), higher preoperative and postoperative activated clotting times (ACT) discrepancy (90% *v* 94%, p = 0.03), a lower postoperative ACT value (125 *v* 118 seconds, p = 0.01), and less red blood cell transfusion per kilogram bodyweight (78 *v* 55 mL, p = 0.02). However, none of the variables differed statistically significantly in the multivariate logistic regression analyses.

Conclusions: The authors did not find an association between the plasma used for CPB priming and thromboembolic and hemorrhagic complications and death in neonates and infants undergoing cardiac surgery. Omniplasma seems to be safe to use in this population.

Key Words: cardiopulmonary bypass; fresh frozen plasma; solvent detergent plasma

ADMINISTRATION OF fresh frozen plasma (FFP) (Sanquin Blood Services, Nijmegen, the Netherlands) is used routinely in pediatric cardiac surgery, foremost for priming of the heart-lung machine.[1] Every FFP unit is obtained from a single

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donor, resulting in a high variability regarding the concentration of coagulation factors among units.[2,3] Moreover, FFP administration risks include the transmission of lipid-enveloped viruses, transfusion-related acute lung injury, allergic reactions, and transmission of prions, parasites, and bacteria.[4-7]

To overcome these potential life-threatening drawbacks, solvent–detergent-treated plasma (SD-treated plasma, Omniplasma) was developed and introduced in 2013.[1] Omniplasma is made from a pool of 600- to-1,200 apheresis plasma donations obtained from Dutch nonremunerated donors out of the same pool from which FFP is obtained.[8] Therefore, using Omniplasma instead of FFP may have a beneficial effect concerning a more homogeneous profile of coagulation factor concentration. It also is marketed as OctoplasLG, Octaplas, and Octaplasma in other countries.[9] However, Omniplasma has been attributed to an increased coagulation potential, presumingly caused by contact activation during the production process, and an increased fibrinolytic potential due to reduced concentrations of factor V, free protein S, and α2-antiplasmin compared to FFP.[10] Whether there is a detectable clinical difference in the coagulation effects of Omniplasma compared to FFP usage remains unclear, especially in the pediatric cardiac surgery population. Omniplasma and FFP are used for priming cardiopulmonary bypass (CPB) circuits during pediatric surgery, but there are insufficient data on perioperative coagulation patterns and postoperative thrombotic complications or outcomes.

This study aimed to compare Omniplasma and FFP used for CPB priming regarding the incidence of postoperative thrombotic or hemorrhagic complications and outcomes in pediatric patients undergoing cardiac surgery.

Methods

The study authors conducted a retrospective observational single-center cohort study. Institutional approval was given for this study, and the local Medical Ethics review board waived the need for informed consent. This study was performed with data from the operating room and a closed-format mixed pediatric intensive care unit (PICU) in a Dutch tertiary referral hospital. The design and conduct of this study followed the Strengthening the Reporting of Observational Studies in Epidemiology checklist for observational cohort studies.[11] The primary outcome parameter of this study was a composite endpoint consisting of (1) PICU mortality, (2) thromboembolic complications, and (3) hemorrhagic complications. Secondary endpoints were the individual parameters of the combined primary endpoint and all other variables that may be affected by the used priming agent; for instance, markers of coagulation and transfusion of blood products. The authors included all consecutive pediatric patients weighing up to 10 kg and undergoing elective and emergency cardiac surgery with CPB between January 2019 and October 2021.

They extracted patient characteristics and perioperative data. Patient characteristics included age, Pediatric Risk of Mortality II score at PICU admission, surgical intervention, body weight, length, CPB, and aortic cross-clamp time. The administered fibrinogen, protamine, prothrombin complex concentrate (Cofact; Prothya Biosolutions B.V.), antithrombin, unfractionated heparin (UFH), tranexamic acid, and blood products were recorded. Preoperative and postoperative values for activated clotting time (ACT), activated partial thromboplastin time, prothrombin time, international normalized ratio, fibrinogen levels, and hematocrit were collected, as well as intraoperative rotational thromboelastometry values. CPB data included the type of CPB circuit, priming constituents, heparin dosage, blood products, and coagulation agents administered during CPB. The authors collected data from the first 24 hours after PICU admission, including the amount of transfused blood and blood products and chest drain output. They also included the duration of mechanical ventilation, length of PICU admission, and survival to discharge from the PICU. Thromboembolic and hemorrhagic complications were identified by a review of the medical records. The authors included all thromboembolic complications diagnosed clinically by ultrasound or other radiologic examination, including stroke during the length of stay in the PICU. Hemorrhagic complications were defined as complications for which an intervention was necessary, as well as cerebral hemorrhage within 3 days of the primary intervention.

Institutional Guidelines

The appropriate CPB oxygenator was chosen based on the calculated blood flow (body surface area x cardiac index of 2.8 for patients <1 year or <10 kg). The authors' standard CPB circuit for the studied population consisted of the Baby RX05 oxygenator (Terumo Cardiovascular Systems) and the Sorin roller pump. The circuit was, per protocol, primed with 225 mL of packed red blood cells (RBC) + mannitol + Ringer's lactate, 45 mL of albumin 20%, 45 mL of plasma (FFP or Omniplasma), and 1,000 IU of UFH. RBC, sodium hydrogen carbonate 8.4%, and potassium chloride 7.45% were added and dosed based on patient characteristics to a total priming volume of 315 mL. The plasma product for CPB priming was chosen based on the availability and preferences of the individual care teams. Anticoagulation before CPB was achieved with an initial dose of 300 IU/kg of UFH. Once an ACT of >400 seconds was confirmed, CPB was initiated. Adequate anticoagulation was monitored during CPB by ACT measurement, with a target of >400 seconds every 20-to-30 minutes. After weaning from CPB, heparin was antagonized with 1 IU of protamine sulfate per 1 IU of heparin of the initial dose. The transfusion of blood and blood products after CPB was based on the clinical judgment of the individual care team in accordance with institutional guidelines.[12] The transfusion trigger for RBC transfusion was a targeted hematocrit of 28%, with a lower limit of 25% during CPB and >28% after CPB. Platelets were transfused when below 75×10^9/L or in case of thrombocytopathy. Indication for transfusion of plasma, fibrinogen, and concentrated clotting factors was made based on thromboelastometry and/or laboratory research. After the surgery, patients were transferred to the PICU.

Table 1
Baseline Characteristics and Outcomes of the Plasma Product Used for CPB Priming

	All n = 143	FFP n = 90 (63%)	Omniplasma n = 53 (37%)	p Value
Baseline characteristics				
Female sex, n (%)	70 (49)	42 (47)	28 (53)	0.48
Weight, median (IQR), g	5,430 (3,750-6,858)	42,88 (3,518-6,113)	6,360 (5,385-7,855)	0.00
Length, median (IQR), cm	60 (52-66)	54 (50-63)	65 (59-72)	0.00
BMI, median (IQR), kg/cm^2	14.60 (13.48-15.77)	14.35 (13.24-15.80)	14.88 (13.98-15.84)	0.06
PRISM II, median (IQR)	9 (5-14)	10.5 (6-14)	7 (4-10.5)	0.03
Age, median (IQR), d	124 (14-203)	44 (8-148)	189 (134-313)	0.00
Intervention, n (%)				
VSD and/or ASD	47 (33)	26 (29)	21 (40)	0.04
ASO	29 (20)	24 (27)	5 (9)	
Other	68 (48)	40 (44)	27 (51)	
Combined endpoint, n (%)	24 (17)	18 (20)	6 (11)	0.18
PICU mortality, procedures	13 (9)	10 (11)	3 (6)	0.37
PICU mortality, cases	8 (6)	7 (8)	1 (2)	
Hemorrhagic	15 (11)	12 (13)	3 (6)	0.15
Thromboembolic	6 (4)	4 (4)	2 (4)	1.00
PICU				
Mechanical ventilator, d	5 (2-12)	5 (2-12)	5 (2-11)	0.62
Chest-drain production, mL/24 h	91 (57-140)	78 (52-126)	107 (73-161)	0.05
Chest-drain production, mL/24 h/kg	16 (11-26)	17 (11-28)	14 (11-24)	0.47
Anesthesiology				
FFP, mL/kg	0 (0-25)	19 (0-32)	0 (0-0)	0.00
Omniplasma, mL/kg	0 (0-13)	0 (0-0)	17 (7-29)	0.00
RBC, mL/kg	28 (10-49)	35 (11-53)	22 (10-40)	0.08
Platelets, mL/kg	0 (0-0)	0 (0-0)	0 (0-0)	0.11
TXA, mg	45 (0-115)	40 (0-100)	60 (0-150)	0.33
Heparin, IU	3,000 (2,250-4,000)	2,500 (2,000-3,500)	3,500 (2,500-4,250)	0.01
Heparin, IU/kg	557 (465-696)	585 (493-736)	510 (455-665)	0.03
Protamine, IU	3,000 (2,200-3,500)	2,500 (2,000-3,500)	3,000 (2,500-4,000)	0.00
Protamine, IU/kg	508 (427-685)	532 (445-696)	487 (423-658)	0.22
Fibrinogen, mg/kg	19 (0-56)	30 (0-60)	0 (0-52)	0.18
CPB				
Perfusion time, min	107 (75-150)	113 (82-155)	94 (66-135)	0.04
Cross-clamp time, min	61 (37-93)	71.5 (46-96)	52 (32-83.5)	0.08
Lowest temperature,˚C	31 (29-32)	31 (28-32)	31 (31-33)	0.05
Priming blood, mL/kg	16 (11-28)	20 (13-30)	15 (8-20)	0.00
Priming FFP, mL/kg	7 (0-12)	11 (7-13)	0 (0-0)	0.00
Priming Omniplasma, mL/kg	0 (0-6)	0 (0-0)	7 (6-8)	0.00
Priming heparin, IU/kg	186 (145-267)	232 (163-283)	155 (127-190)	0.00
Blood during ECC, mL/kg	15 (10-25)	18 (12-30)	12 (7-20)	0.01
ECC blood, mL/kg	35 (25-49)	40 (28-53)	29 (23-40)	0.01
Total				
Heparin, IU	6,500 (4,500-9,000)	6,000 (4,500-8,000)	7,000 (4,750-9,500)	0.10
Heparin, IU/kg	1,223 (959-1,579)	1,331 (1,004-1,627)	1,139 (849-1,396)	0.01
Blood, mL/kg	70 (40-119)	78 (44-124)	55 (36-86)	0.02
FFP, mL/kg	20 (0-47)	41 (21-65)	0 (0-0)	0.00
Omniplasma, mL/kg	0 (0-27)	0 (0-0)	35 (22-46)	0.00
ACT, s				
Baseline	109 (102-124)	110 (103-126)	109 (100-122)	0.43
Postoperative	121 (110-138)	125 (114.25-147)	118 (107-125)	0.01
Δ/s × 100	93 (82-100)	90 (78-99)	94 (89-101)	0.03
Hb, mmol/L				
Baseline	7.65 (7.10-9.20)	7.80 (7.20-9.45)	7.50 (6.83-8.83)	0.17
Postoperative	6.80 (6.00-7.40)	6.90 (6.18-7.50)	6.55 (5.93-7.30)	0.28
HcT, %				
Baseline	0.38 (0.33-0.44)	0.38 (0.34-0.44)	0.37 (0.33-0.44)	0.30
Postoperative	0.32 (0.29-0.36)	0.33 (0.30-0.36)	0.31 (0.29-0.34)	0.53
Aptt, s				
Baseline	45 (34-54)	44 (34-54)	45 (36-68)	0.43
Postoperative	36 (30-41)	36 (31-41)	35 (30-41)	0.80
Δ/s × 100	84 (71-100)	83 (72-99)	84 (61-111)	0.92

(*continued*)

Table 1 (*continued*)

	All n = 143	FFP n = 90 (63%)	Omniplasma n = 53 (37%)	p Value
Pt, s				
Baseline	13 (12-15)	13 (12-15)	14 (12-16)	0.45
Postoperative	15 (15-16)	15 (14-17)	15 (15-16)	0.93
Δ/s × 100	120 (111-128)	121 (111-126)	117 (87-133)	0.84
INR				
Baseline	1 (1-1)	1 (1-1)	1 (1-1)	0.61
Postoperative	1 (1-1)	1 (1-1)		
Fibrinogen, g/L				
Baseline	2 (2-2)	2 (2-3)	2 (2-2)	0.25
Postoperative	2 (2-2)	2 (2-2)	2 (1-2)	0.19
Δ/s × 100	83 (74-120)	84 (71-100)	81 (74-140)	0.84
Intraoperative ROTEM				
FIBTEM	8 (6-10)	8 (7-11)	7 (3-8)	0.11
EXTEM MCF	54 (43-58)	56 (48-59)	50 (39-53)	0.04
EXTEM CT	87 (73-103)	86 (73-104)	90 (78-111)	0.64
EXTEM CFT	90 (82-160)	87 (77-141)	144 (88-289)	0.11
INTEM	1191 (307-4,711)	1191 (317-5,007)	1091 (298-4,465)	0.58
HEBTEM	284 (265-321)	273 (253-316)	302 (285-325)	0.13

Abbreviations: ACT, activated clotting time; Aptt, activated partial thromboplastin time; ASD, atrial septal defect; ASO, arterial switch operation; BMI, body mass index; CFT, clot formation time; CPB, cardiopulmonary bypass; EEC, extracorporeal circulation; FFP, fresh frozen plasma; Hb, hemoglobin; HcT, hematocrit; INR, international normalized ratio; MCF, maximum clot firmness; PICU, pediatric intensive care unit; PRISM, pediatric risk of mortality; Pt, prothrombin time; RBC, red blood cell; ROTEM, rotational thromboelastometry; TXA, tranexamic acid; VSD, ventricular septal defect.

Statistical Analysis

Statistical analyses were performed using SPSS Statistics software, version 26 (IBM SPSS, Inc, Armonk, NY). Normally distributed continuous variables were expressed as mean and SD, and nonnormally distributed as median and IQR. Categorical variables were expressed as frequencies and percentages (n [%]). Comparisons between CPB priming with FFP and Omniplasma were made with the Fisher exact test for categorical variables and with either the Mann−Whiney *U* test or *t* test for continuous variables where appropriate. The authors converted all appropriate variables to units per kilogram to adjust for possible weight interaction with the given dosage. Univariate logistic regression analysis was performed for all primary and secondary outcome parameters to assess the association with the used CPB priming agent. The authors performed multivariate logistic regression analysis adjusted for sex, weight, and intervention type with the combined and individual primary endpoints, as well as all variables with a p value of < 0.10 in univariate logistic regression analyses.

Results

From January 2019 to October 2021, 144 surgical procedures were performed with the support of CPB. The priming agent was unknown during 1 procedure, which was excluded from the analysis. The final analyses were done with the data of 143 procedures in 129 children. FFP was used in 90 (63%) and Omniplasma in 53 (37%) surgical procedures for CPB priming. Baseline characteristics are presented in Table 1. Of the 129 children, 121 were discharged alive from the PICU (7 children died in the FFP and 1 in the Omniplasma group). The median age at surgery was 123 days (IQR: 13-203), and 70% of the study population were female.

Children with procedures in which FFP was used for priming the CPB were younger, shorter, weighed less, and had a higher Pediatric Risk of Mortality II score at PICU admission than those in whom Omniplasma was used. FFP was used more frequently during arterial switch interventions, and CPB perfusion time was generally longer.

Perioperatively, total UFH and protamine administration were lower in the FFP group. When adjusted for body weight, significantly more UFH per kilogram was administered in the FFP group. In the FFP group, patients were administered more milliliters of RBC per kilogram body weight (78 *v* 55 mL, p = 0.02).

The postoperative ACT (125 *v* 118 seconds, p = 0.01) and preoperative versus postoperative delta ACT (90% *v* 94%, p = 0.03) were the only coagulation variables that statistically significantly differed between the groups.

PICU mortality and number of days mechanical ventilation recorded did not differ between the groups. Total chest-drain production in the first 24 hours of PICU admission was higher in the Omniplasma group, but production per kilogram body weight did not differ between groups.

The combined endpoint was met in 18 patients (20%) in the FFP group and in 6 patients (11%) in the Omniplasma group, which was not statistically significant. A thromboembolic complication was present after 6 (4.2%) procedures in individual patients. Hemorrhagic complications were present in 15 (10.4%) individual patients. The most prevalent thromboembolic complications were peripheral venous

Table 2
Logistic Regression Analyses for Association With Omniplasma

	Univariate Logistic Regression Crude OR (95% CI)	Multivariate Logistic Regression Adjusted OR (95% CI)*
Primary endpoints		
Combined endpoint	1.96 (0.73-5.29)	1.43 (0.48-4.25)
Thromboembolic	2.56 (0.69-9.54)	1.13 (0.16-8.21)
Hemorrhagic	1.17 (0.21-6.71)	2.33 (0.57-9.53)
Mortality	2.08 (0.55-7.94)	1.06 (0.25-4.50)
Secondary endpoints		
PICU		
Chest-drain production, mL/24 h	1.00 (0.99-1.00)	
Length of stay, d	1.00 (1.00-1.00)	
Mechanical ventilator, d	1.03 (1.01-1.05)	
Transfusion		
Blood, mL	1.00 (0.99-1.00)	
Platelets, mL	0.99 (0.99-1.00)	
Laboratory tests		
ACT, postop, s	0.99 (0.97-0.99)†	0.99 (0.98-1.01)
ACT, postop Δ/s, %	1.03 (1.00-1.05)†	1.03 (0.99-1.05)
Hb, postop, mmol/L	0.94 (0.68-1.31)	
HcT, Δ/postop, %	1.61 (0.00-1707.71)	
Hb/HcT, postop	2.84 (0.15-55.69)	
Aptt, Δ/s, %	1.00 (0.98-1.02)	
Pt, Δ/s, %	1.00 (0.97-1.02)	
Fibrinogen, Δ/s, %	1.00 (1.00-1.01)	
Medication		
Heparin, IU	1.00 (1.00-1.00)	
Heparin IU/kg	0.99 (0.99-1.00)†	1.00 (1.00-1.00)
Protamine, IU	1.00 (1.00-1.00)	
Protamine, IU/kg	0.99 (0.99-1.00)	
Fibrinogen, mg	1.00 (0.99-1.00)	

Abbreviations: ACT, activated clotting time; Aptt, activated partial thromboplastin time;
CPB, cardiopulmonary bypass; Hb, hemoglobin; HcT, hematocrit; INR, international normalized ratio; OR, odds ratio; PICU, pediatric intensive care unit; Postop, postoperative; Pt, prothrombin time; RBC, red blood cell; TXA, tranexamic acid.

* Adjusted for sex, weight, and intervention type.

† p value of < 0.10.

thromboembolic complications. The most prevalent hemorrhagic complications were postoperative re-bleeds, which required reexploration.

The results of the univariate logistic regression analysis are shown in Table 2. Omniplasma for CPB priming was associated with decreased UFH administration per kg body weight, a higher preoperative and postoperative ACT discrepancy, and a lower postoperative ACT value. However, none of these variables remained statistically significant after multivariate logistic regression analysis. The combined primary endpoint or its individual components were not associated with the used CPB priming agent.

Discussion

The major finding of the authors' study was that Omniplasma (SD-plasma) was not associated with an increased risk for thromboembolic or hemorrhagic complications or death in pediatric patients undergoing cardiac surgery.

Omniplasma has several potential advantages over FFP, such as reduced viral transmission, fewer immune-mediated reactions, and a more stable consistency of coagulation factors.[1,3-6,13,14] On the other hand, some studies suggested an increased coagulation potential of Omniplasma due to reduced factor V, α2-antiplasmin, and free protein S levels.[10,15]

The children in the Omniplasma group were statistically significantly older and bigger, possibly due to the initial cautious use of Omniplasma in very young patients. Pediatric patients in the Omniplasma group had lower postoperative ACT levels, consistent with another observational study comparing FFP with an equivalent of Omniplasma (OctaplasLG).[16] This was also consistent with earlier studies in which coagulation markers such as international normalized ratio and activated partial thromboplastin time were significantly lower in patients receiving Omniplasma compared to FFP.[14,16,17] The lower postoperative ACT levels could be an indicator of the prothrombotic properties of Omniplasma. Although statistically significant, the difference between groups was minor, and clinical relevance could be questioned. In contrast, chest drain production in the first 24 hours of PICU admission was significantly higher in the Omniplasma group. The latter correlation may be affected by the performed surgical intervention, which was more complex, because of the differences in the preferred chosen plasma product between different interventions and patient characteristics in case both Omniplasma and FFP were available. To analyze this, the authors performed a post hoc analysis, which showed no statistically significant correlation between chest drain production and the used plasma product when analyzing each intervention type (atrial septal defect or ventricular septal defect repair, arterial switch surgery, and other interventions) separately, in addition to that chest drain production per kilogram did not differ between groups.

The authors found an increased total administered UFH in the Omniplasma group, but the correlation vector reversed when UFH was expressed as IU per kg body weight, resulting in decreased administration of UFH/kg in the Omniplasma group. When analyses were performed for every intervention type separately, this correlation vanished in patients undergoing atrial septal defect or ventricular septal defect repair repair and arterial switch surgery. Still, it persisted in the 'other' intervention group.

Study Limitations

This study had several limitations, including known limitations of observational cohort studies, such as incomplete datasets and the risk of invalid data due to the lack of strict protocols. Another limitation was the potential effect of practice variation between individual care teams involved regarding the quantity of the administered blood products and relevant medication. However, anticoagulation protocols in the authors' center were well-formulated, and post hoc analysis showed that the used plasma product for CPB priming was

distributed equally among anesthesiologists. The study authors were able to obtain intraoperative rotational thromboelastometry values; however, the number of missing values was high. Therefore, results could differ from actual values.

The incidence of thromboembolic and hemorrhagic complications was low. This could make it difficult to show statistically significant differences between the groups. Lastly, the authors did not screen routinely for thromboembolic complications, and, therefore, they reported only clinically apparent thromboembolic complications. It is known that critically ill patients are generally at risk for thromboembolic complications, although the majority of them are asymptomatic.[18,19] Consequently, the authors could have underestimated the incidence of thrombotic complications. However, it could be argued that asymptomatic thromboembolic complications are less clinically relevant.

Conclusion

SD-plasma/Omniplasma used for CPB priming was not associated with an increased risk for thromboembolic and hemorrhagic complications or death in neonates and infants undergoing cardiac surgery. Based on these results, SD-plasma/Omniplasma seems to be safe for use in this population. However, a prospective randomized controlled trial would be needed to confirm this hypothesis.

Declaration of competing interest

None.

CRediT authorship contribution statement

Olivier van Minnen: Conceptualization, Data curation, Formal analysis, Methodology, Writing – original draft, Writing – review & editing. **Walter M. van den Bergh:** Conceptualization, Formal analysis, Writing – original draft, Writing – review & editing. **Ryan E. Accord:** Conceptualization, Methodology, Writing – review & editing. **Dedré Buys:** Conceptualization, Data curation, Formal analysis, Methodology, Writing – review & editing. **Sascha Meier:** Conceptualization, Data curation, Formal analysis, Methodology, Writing – original draft, Writing – review & editing.

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