World J Surg (2021) 45:880–886
https://doi.org/10.1007/s00268-020-05852-0

ORIGINAL SCIENTIFIC REPORT

Randomized Clinical Trial of 14-French (14F) Pigtail Catheters *versus* 28–32F Chest Tubes in the Management of Patients with Traumatic Hemothorax and Hemopneumothorax

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Accepted: 23 October 2020 / Published online: 7 January 2021

Abstract

Introduction Traditional management of traumatic hemothorax/hemopneumothorax (HTX/HPTX) has been insertion of large-bore 32–40 French (Fr) chest tubes (CTs). Retrospective studies have shown 14Fr percutaneous pigtail catheters (PCs) are equally effective as CTs. Our aim was to compare effectiveness between PCs and CTs by performing the first randomized controlled trial (RCT). We hypothesize PCs work equally as well as CTs in management of traumatic HTX/HPTX.

Methods Prospective RCT comparing 14Fr PCs to 28–32Fr CTs for management of traumatic HTX/HPTX from 07/2015 to 01/2018. We excluded patients requiring emergency tube placement or who refused. Primary outcome was failure rate defined as retained HTX or recurrent PTX requiring additional intervention. Secondary outcomes included initial output (IO), tube days and insertion perception experience (IPE) score on a scale of 1–5 (1 = tolerable experience, 5 = worst experience). Unpaired Student's *t*-test, chi-square and Wilcoxon rank-sum test were utilized with significance set at $P < 0.05$.

Results Forty-three patients were enrolled. Baseline characteristics between PC patients ($N = 20$) and CT patients ($N = 23$) were similar. Failure rates (10% PCs vs. 17% CTs, $P = 0.49$) between cohorts were similar. IO (median, 650 milliliters[ml]; interquartile range[IR], 375–1087; for PCs vs. 400 ml; IR, 240–700; for CTs, $P = 0.06$), and tube duration was similar, but PC patients reported lower IPE scores (median, 1, "I can tolerate it"; IR, 1–2) than CT patients (median, 3, "It was a bad experience"; IR, 3–4, $P = 0.001$).

Conclusion In patients with traumatic HTX/HPTX, 14Fr PCs were equally as effective as 28–32Fr CTs with no significant difference in failure rates. PC patients, however, reported a better insertion experience.

www.ClinicalTrials.gov Registration ID: NCT02553434

This manuscript was an Oral Presentation, presented at the 32nd Annual Eastern Association for the Surgery of Trauma Scientific Assembly, January 15–19, 2019 in Austin, TX, USA

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Introduction

Tube thoracostomy remains the mainstay treatment modality for the majority of blunt and penetrating thoracic trauma [1]. Since the development of the first plastic chest tube (CT) by Sherwood Medical in 1961, [2] large-caliber CTs (32–40Fr) have routinely been utilized for drainage of traumatic pneumothorax (PTX) and hemothorax (HTX) using an open cut-down technique [1, 3–6]. However, as the management of the traumatically injured patient continues to evolve, the exclusive use of large-caliber CTs for drainage of traumatic PTX and HTX has been recently challenged.

Pigtail catheters (PCs) are small-caliber (14Fr) catheters capable of being placed at the bedside in a percutaneous manner [3]. Although there is a generous body of literature demonstrating the effectiveness of PCs to drain pleural effusions [7, 8] and PTX, [6, 9, 10] the literature is still limited on the effectiveness of small-caliber catheters to drain traumatic HTX. Previous studies have shown PCs had the same effectiveness as large-caliber CTs for draining blood from a traumatic HTX or hemopneumothorax (HPTX) [3, 11]; however, these studies were observational or retrospective in nature and there still remains a great deal of skepticism among physicians as to whether or not small-caliber catheters are able to adequately drain blood.

The aim of our study was to compare the effectiveness between 14Fr PCs and 28–32Fr CTs in the management of traumatic HTX/HPTX by performing the first randomized controlled trial (RCT). We hypothesized PCs would be as equally effective as CTs in the management of patients with traumatic HTX/HPTX.

Methods

This study was registered with ClinicalTrials.gov (identifier: NCT02553434). It was approved by the institutional review board of the University of Arizona. All patients, or their next of kin, provided informed consent before inclusion.

Patient inclusion and exclusion

Patients were evaluated at Banner-University of Arizona Medical Center, a level I trauma center, from July 2015 through January 2018. Eligible patients included those $\geq$ 18 years of age who suffered traumatic HTX/HPTX requiring drainage. Chest trauma can result in the combination of both a HTX and PTX. Therefore, patients presenting with a combined HPTX were only enrolled in the study if the HTX component was substantial enough for drainage based on chest X-ray (CXR) or computed tomography. If the HTX component was small and the drainage tube was being placed primarily for the PTX portion, the patient was not enrolled. The decision to place the catheter was the discretion of the treating physician, which was supported by CXR and/or computed tomography scan. Hemithorax blood volumes $\geq$ 300 mL according to computed tomography volumetric calculation were desired based on previous studies suggesting the best HTX/HPTX drainage occurs at this volume [12]. However, not all studied patients received computed tomography scans quantifying this amount as sometimes it was obvious on CXR or ultrasonography. Because of this, it was the discretion of the treating physician to enroll and place the drainage catheter prior to computed tomography using clinical judgment to assess whether there was significant blood in the chest to drain. Exclusion criteria included emergency placement of the catheter due to hemodynamic instability (patient was in extremis or unable to provide consent due to the physiologic stress produced by the traumatic injuries), the catheter was placed in the operating room when the patient was under anesthesia or the patient declined enrollment.

Randomization

Patients were randomized using a block-of-four randomization method into 1 of the 2 treatment groups utilizing a sealed envelope method. At priori, we prepared 50 slips of paper; half written for 14Fr PCs (Cook Critical Care, Bloomington, Indiana, USA) and the other half for 28Fr–32Fr CTs (our institution does not stock any 36Fr–40Fr CTs). We then divided the slips into groups of four (2 PCs and 2 CTs), and placed them into individual opaque envelopes. The envelopes were then thoroughly shuffled. Once a patient that met inclusion criteria agreed to participate and consent was obtained, the top envelope of the block of four was opened and the treatment arm (PC or CT) was revealed.

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Placement of PCs or CTs

Both PCs and CTs were inserted under sterile conditions at bedside by the attending trauma surgeon or a surgical resident under direct supervision. Antibiotics were not routinely administered for placement of the drainage tube. One percent lidocaine was given for local anesthetic along with an intravenous analgesic of choice for systemic analgesia. We did not standardize the dosage, quantity, or type of analgesic medication or local anesthetic to better imitate the real-life setting. Pigtail catheters were inserted using the modified Seldinger technique at the 4th or 5th intercostal space, anterior- or mid-axillary line. Chest tubes were inserted by the traditional cut-down method at the 4th or 5th intercostal space, mid-axillary line. A CXR was performed after each procedure to evaluate tube position and confirm resolution of the HTX/HPTX. The tube was left on continues suction at −20 mmHg. The remaining tube management and secondary interventions were left to the discretion of the rounding attending trauma surgeon. At our institution, eight trauma surgeons routinely crossover for management of patients with traumatic HTX/HPTX, therefore not one surgeon is only managing PC patients and vice versa. Given there is no standardization of chest catheter management in the current literature, this cross-over allows for better imitation of real-world clinical practice and accounts for any variability present with tube management. Prior to the implementation of a secondary intervention when a possible retained HTX (rHTX) was suspected, a repeated chest computed tomography scan or ultrasound was obtained for confirmation.

Data collection

Baseline characteristics were collected including age, gender, mechanism of injury (blunt *versus* penetrating), number of rib fractures, presence of flail chest, Injury Severity Score (ISS), chest Abbreviated Injury Scale score (c-AIS) and number of days from the time of injury when the tube was inserted. Primary outcome measured was failure rates for the drainage catheter. We defined failure as a rHTX (radiographically apparent hemothorax after tube thoracostomy) or recurrent PTX (PTX still present after initial tube thoracostomy or development of PTX after initial tube removal) that required additional intervention including second catheter insertion, thrombolysis, or video-assisted thoracoscopy surgery (VATS). At our institution, VATS was primarily used to manage rHTX. Secondary outcomes included initial drainage output (milliliters, mL) 30 min after the tube was inserted. Furthermore, 24 h (hr), 48 h and 72 h tube output, total tube days, ventilator days, intensive care unit (ICU) and hospital length of stay (HLOS) and insertion perception experience (IPE) scores were recorded. The IPE was assessed 30 min after PC or CT insertion. The IPE score (institutionally created, unvalidated score) is an ordinal scale from 1 to 5 as listed below:

1 = It was okay, I can tolerate it, I can do it again.
2 = It was okay, but I don't want to go through this again.
3 = It was a bad experience for me.
4 = It was a worse experience for me.
5 = It was the worst experience of my life!

Statistical analysis

To estimate the sample size, we used primary end-point failure rate to calculate the needed sample size. The existing literature, including our 2 prior studies comparing PCs to CTs for draining traumatic HTX/HPTX, estimated the failure rate for CTs to be 15–30% [3, 11, 12]. Previous observational and retrospective studies reported PC failure rates between 8–21% [3, 11]. Since prior studies have shown PCs and CTs had similar efficacy for draining traumatic HTX/HPTX, this was structured to be a non-inferiority trial with a one-sided test, 80% power and $P = 0.05$ [3, 11]. Therefore, we used 15% failure rate for CTs as a reference and a preset Δ of 15 (< 30% failure rate and still within the range of failure reported in the literature) for PCs. It was determined a sample size of 95 patients in each arm would be required for adequate power analysis for this study. However, after performing an interim analysis, we found our primary outcome, failure rate, to reach an appropriate non-inferiority result. Furthermore, statistically significant findings had been obtained for our secondary outcomes for this sample size. Due to a long enrollment period (30 months) as well as limited resources, the decision was made to conclude the study early since outcomes had been met.

Continuous variables were expressed as mean (Standard Deviation, SD) or median (Interquartile Range, IQR). Categorical variables were expressed as proportions or percentages. For between-group comparisons, Student's *t*-test was used for continuous normally distributed data, the Wilcoxon rank-sum test for non-normally distributed data and χ^2 test for categorical data. For statistical analysis, STATA version 14 (College Station, Texas) was used. Two-sided $P < 0.05$ was considered statistically significant.

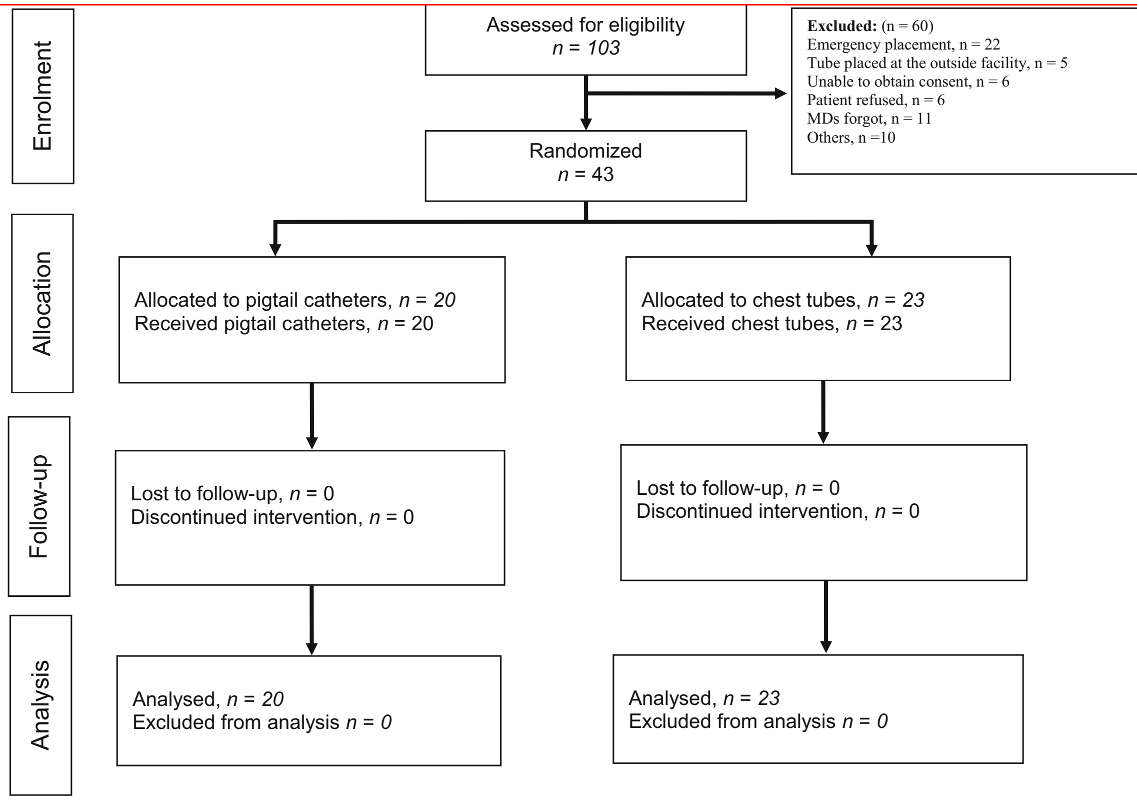

Fig. 1 CONSORT diagram

Results

One-hundred and three patients were screened, of which 43 were enrolled. Twenty patients received PCs and 23 patients received CTs (Fig. 1). There were no significant differences in baseline characteristics between cohorts (Table 1). The majority of mechanisms of injury for both groups was blunt. The primary outcome, failure rate, was similar between the 2 groups. Initial and daily outputs as well as total catheter days were also similar between groups (Table 2).

When analyzing IPE score, PC patients reported lower IPE scores (median = 1, "I can tolerate it"; IQR, 1–2) than CT patients (median = 3, "It was a bad experience"; IQR, 3–4), $P = 0.001$ (Fig. 2). The remaining secondary outcome measures were all similar between groups. Of note, there were no insertion-related complications for any of the 43 patients enrolled (Table 2).

Discussion

In this prospective RCT study, we found 14Fr PCs were equally as effective as CTs (28–32Fr) in the management of patients with traumatic HTX and HPTX in terms of initial drainage output and failure rate. This would suggest that it is not the size of the tube that affects HTX/HPTX drainage, but rather the consistency of the blood itself. Similar to previous studies, [3, 11] the population in our study represented a subset of HTX/HPTX patients who were not in extremis and did not require emergency tube placement as reflected by the median tube insertion days of 2.5 for PCs and 1 for CTs ($P = 0.18$). Unlike prior studies, we did not have the selection biases towards placing more PCs in older trauma patients who suffered more blunt (vs. penetrating) trauma as a result of the randomization process.

Although CTs have long been used for the drainage of HTX, the optimal diameter size is still debated among practicing clinicians [12, 13]. One would theorize that based on Poiseuille's law (flow rate is directly proportional to the fourth power of the internal radius and the pressure difference between the 2 ends of the tube and inversely proportional to the length and viscosity of the fluid),

Table 1 Demographic data and baseline characteristics

	Pigtail catheters (N = 20)	Chest tubes (N = 23)	P
Age (years), mean + SD	62 + 13	55 + 18	0.16
Gender (male), %	85	96	0.23
Blunt, %	95	74	0.06
ISS, mean + SD	17.5 + 6.6	15.8 + 5.9	0.40
C-AIS, median (IQR)	3.5 (3, 4)	4 (3, 4)	0.89
Number of rib fractures, median (IQR)	5 (2.5, 7)	4 (1, 6)	0.50
Flail (yes), %	9	0	0.18
Days from injury tube inserted, median (IQR)	2.5 (1, 5)	1 (1, 2)	0.18

C-AIS chest abbreviated injury scale score, *IQR* interquartile range, *ISS* injury severity score, *SD* standard deviation

*Of the 60 patients excluded, 22 were excluded because of emergent tube placement; they were all young male (age, 35 ± 27) and suffered penetrating trauma. For the remaining 38 patients, baseline characteristics—age (51 + 20), gender (92%), and blunt (71%) were all similar to the study group with P-value not significant

[14, 15] a smaller caliber catheter would not be able to drain blood from the chest as effectively as a larger caliber catheter; however, this difference in flow rate does not seem to have a significant effect clinically. Inaba et al. demonstrated in a review of the 275 patients who received a CT for traumatic HTX/HPTX, there was no difference in efficacy of drainage, complication rates, rHTX rates or need for additional interventions for patients who received a 28–32Fr CT versus 36–40Fr CT [13]. Tanizaki et al. further demonstrated in a 7 year retrospective review, patients requiring emergent CT placement (< 2 h from presentation) had no difference in HTX drainage capability when comparing 20–22Fr CTs to 28Fr CTs. Furthermore, this study suggested when a larger caliber CT was utilized, there was actually a higher incidence of needing a secondary CT [14].

Our previous studies spanning a 7 year period did not find any significant differences in terms of initial drainage output and failure rates between PCs and CTs [3, 11]. However, they were observational studies with an observed selection bias toward the placement of PCs in older trauma patients who suffered more blunt (vs. penetrating) trauma [3, 11]. In addition to these clinical studies, Russo et al. demonstrated in an ex vivo swine HTX model that although large-caliber (32Fr) CTs had an initial (within the first 3 min) and total drainage volume greater than that of PCs, this difference was not statistically significant and in fact, PCs were equally as effective as CTs at draining HTX [16].

In this RCT, we also captured the insertion pain perceptions of patients using our own created IPE ordinal score. Based on our results, PC patients reported a lower IPE score than CT patients ("1 = I can tolerate it" vs. "3 = It was a bad experience," P = 0.001). We did not use or capture the standard pain score during insertion in this study because it had previously been published in an RCT that compared PCs to CTs for traumatic PTX, demonstrating PCs had less tube insertion numerical rating pain scores than CTs (3.2 vs. 7.7, $P < 0.001$) [9]. We hypothesized less pain associated with PC insertion had to do with the percutaneous technique resulting in less tissue damage than the open cut-down technique for the CT. Less pain during insertion translated into a better insertion perception experience reported by PC patients. The authors realized IPE score, like a pain score, is the patient's subjective perception that can be influenced by many things including, but not limited to, the patient's emotional state, social background, situational stress and intravenous analgesia and local anesthetic administered during insertion, something we did not standardize in this study.

We also report our overall failure rate of 13.9% (N = 6). This was substantially lower than the 31–33% quoted in the current literature [12, 17, 18]. There may be several reasons for this result. First, the majority of our patients suffered blunt trauma. Based on the current literature, it is still not fully known whether mechanism of injury plays a role as to which patients have a higher risk of developing a rHTX [19]. Secondly, by excluding those patients who were in extremis and those who needed emergency chest drainage, we may have excluded those patients who might be really ill and at higher risk for developing a rHTX. Furthermore, median tube days of 5 or greater has been associated with increased risk of rHTX [19]. However, in our study, median tube days were only 4 for both cohorts, suggesting this may be a reason for the overall decreased failure rates. Lastly, most of our study patients did not have prolonged ventilator days, which has been shown to be

Table 2 Comparison of outcomes

	Pigtail catheters (N = 20)	Chest tubes (N = 23)	P
Failure rate, %, (n)	10 (2)	17 (4)	0.49
Initial output (ml), median (IQR)	650 (375, 1087)	400 (240, 700)	0.06
24 h output	980 (600, 1625)	660 (430, 1000)	0.10
48 h output	300 (110, 424)	225 (90, 400)	0.22
72 h output	50 (0, 200)	130 (0, 260)	0.54
Tube days, median, (days)	4 (3, 5.5)	4 (2, 7)	0.79
IPE score, median (IQR)	1 (1, 2)	3 (3, 4)	0.001
VATS, %	5	9	0.64
Ventilator day, median (IQR)	0 (0, 0.5)	0 (0, 0)	0.30
ICU day, median (IQR)	0 (0, 3.5)	0 (0, 3)	0.86
Hospital length of stay, median, (days)	6.5 (4.5, 10)	7 (3, 9)	0.54

ICU intensive care unit, *IPE* insertion perception score, *IQR* interquartile range, *ml* millimetres, *SD* standard deviation, *VATS* video-assisted thoracoscopy

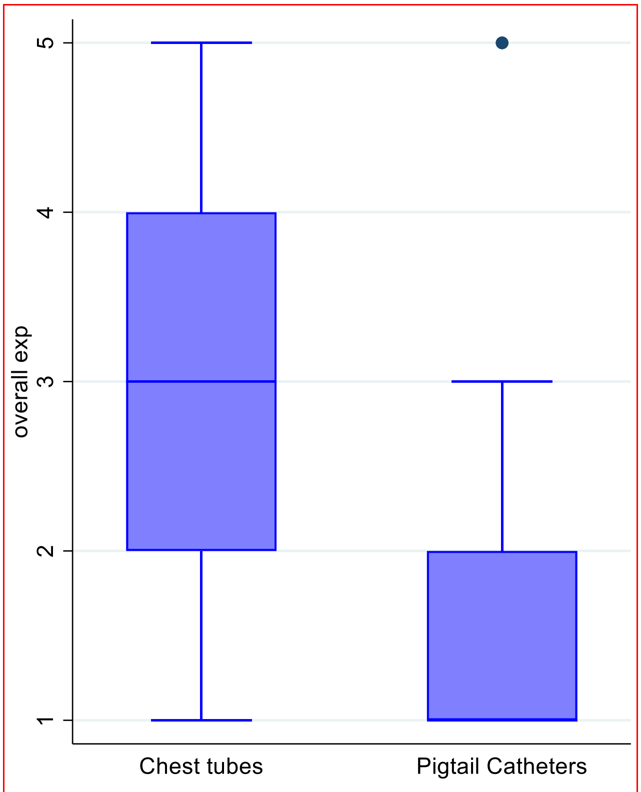

Fig. 2 Insertion Perception Experience (IPE) score (P = 0.001)

another risk factor for development of a rHTX in the current literature [19].

Despite outcomes supporting our hypothesis, there are still limitations of this study. First, this is a single institutional study. Our findings may not be representative or duplicated until a multi-center study is performed or more institutions report on their PC experiences. It was noted that over a 30 month period, only 43 patients were recruited to the study. A multi-center study will surely help obtain a larger enrollment of patients for a better comparison between the 2 types of drainage catheters. Furthermore, the need for a multi-center trial becomes even more important given there is no standardization of chest drainage catheter management in the current literature; therefore, our definition of “failure,” or the degree to which the “failure” is acted upon, may differ across institutions. Second, our PC and CT placement was mostly in a delayed fashion. Therefore, the comparable effectiveness of PCs versus CTs cannot be extrapolated to the emergency placement setting. Tanizaki et al. demonstrated there was no difference between 20–22Fr and 28Fr CT to drain traumatic HTX/HPTX in the emergency setting; however, this was a comparison of cut-down techniques, so their results are not applicable to the PC technique [14]. Third, the IPE utilized an ordinal scale that has never been validated in the previous literature. Just like the Numerical Pain Score used in our previous study, [9] IPE score is subjective and can be affected by several external factors. Fourth, although obtaining a computed tomography scan was encouraged prior to placement of the drainage catheter, it was not required especially if it was obvious on CXR. Therefore, this may have falsely influenced the ability to better assess the volume of blood in the hemithorax prior to drainage tube placement. Lastly, we did not standardize the intravenous analgesic or local anesthetics used during insertion to simulate real-life trauma; therefore, our IPE score findings may be criticized. However, the tissue damage associated with an invasive cut-down technique for CT placement is more likely to justify why CT patients might report worse experiences during CT insertion. Furthermore, tube management was not standardized given the fact there is no standardization in the current literature. Although there was not one single trauma surgeon managing either CTs or PCs at our institution, a large multi-institutional study will help define discrepancies with this process.

Conclusion

The authors found there was no difference between 14Fr PCs and large-caliber (28–32Fr) CTs in their ability to drain a traumatic HTX/HPTX. Furthermore, there was no significant difference in the incidence of failure rates between groups; however, PCs were associated with better patient reported insertion experiences. Given these findings, we prefer 14Fr PCs over large-caliber 28–32Fr CTs for drainage of traumatic HTX/HPTX, at least in a non-emergency situation.

Author contributions This study was registered through the U.S. National Library of Medicine ClinicalTrials.gov. The registration number is NCT02553434. All authors contributed substantially to this research project. All authors were fully involved in this research project and collectively designed, conducted and interpreted the data. Furthermore, all authors reviewed and approved the decision to submit this manuscript for publication in its current form. The institution providing the patient population and data collected was Banner University of Arizona Medical Center in Tucson, AZ.

Compliance with ethical standards

Conflict of interest No authors have any conflicts of interest or funding to disclose at this time. No source of funding was utilized for this study.

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