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FIRST IN HUMAN EXPERIENCE WITH SWIFT SYNC: A NOVEL ATRIO-VENTRICULAR SEQUENTIAL TEMPORARY PACING CATHETER

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Abstract

Background. Current temporary transvenous pacemaker catheters lack sequential atrioventricular (AV) pacing in synchrony. Therefore, a catheter that could provide sequential AV pacing and maintain synchrony may be useful for patients in sinus rhythm who need temporary pacing. **Objective.** The purpose of this study was to describe the first in human experience with a novel temporary AV sequential pacing catheter (TAVSP). **Methods.** We prospectively identified eligible patients undergoing elective cardiac catheterization in whom the TAVSP catheter was delivered and used for temporary AV sequential pacing. Safety endpoints and device performance data were obtained. **Results.** Ten subjects were screened and enrolled in the study. TAVSP was delivered in all ten subjects, and AV sequential synchronous pacing was successfully obtained. The pacing catheter achieved an excellent pacing threshold and impedance in all ten patients except for one. There were no adverse events during the pacing procedure. **Conclusion.** Temporary AV sequential pacing using TAVSP catheter is safe and feasible and may be an alternative to conventional temporary pacing catheters to maintain AV synchrony during temporary pacing.

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Institutional Review Board (IRB) approval was obtained and every patient in the study obtained informed consent.. This study complies with HIPPA and all patient identifiers have been removed

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Background.

Current temporary transvenous pacemaker catheters lack sequential atrioventricular (AV) pacing in synchrony. Therefore, a catheter that could provide sequential AV pacing and maintain synchrony may be useful for patients in sinus rhythm who need temporary pacing.

Objective.

The purpose of this study was to describe the first in human experience with a novel temporary AV sequential pacing catheter (TAVSP).

Methods.

We prospectively identified eligible patients undergoing elective cardiac catheterization in whom the TAVSP catheter was delivered and used for temporary AV sequential pacing. Safety endpoints and device performance data were obtained.

Results.

Ten subjects were screened and enrolled in the study. TAVSP was delivered in all ten subjects, and AV sequential synchronous pacing was successfully obtained. The pacing catheter achieved an excellent pacing threshold and impedance in all ten patients except for one. There were no adverse events during the pacing procedure.

Conclusion.

Temporary AV sequential pacing using TAVSP catheter is safe and feasible and may be an alternative to conventional temporary pacing catheters to maintain AV synchrony during temporary pacing.

INTRODUCTION

Temporary cardiac pacing is required in patients with brady-arrhythmias. Medical conditions such as myocardial infarction, infections, electrolytes disturbance, cardiac trauma, and primary cardiac conduction system disease can cause abnormalities in initiating and propagating the normal electrical impulse throughout the heart(1). In specific cardiac procedures, such as open-heart surgery and transcatheter valve replacement, temporary cardiac pacing is frequently utilized. (2)

Currently, temporary transvenous pacemaker catheters only pace the ventricle and lack atrioventricular (AV) synchrony in patients with intact sinus rhythm. When the heart is paced in an AV synchronized manner, it is estimated to increase stroke volume by 50% in normal hearts and increase the cardiac index by 25-30%[2]compared to ventricular-only pacing. AV synchronization performs better at maintaining proper cardiac output than ventricular pacing alone and is essential in achieving optimal cardiovascular hemodynamics(3).

There is a need for an easily insertable and positionable trans-venous AV sequential temporary pacing catheter. All patients who require temporary pacing would ideally benefit from AV pace and tract capacity, except for those in atrial fibrillation. Currently, temporary AV sequential pacing requires the placement of two separate leads in the right atrium and ventricle. Moreover, lead dislodgement, particularly in the atrium, is frequently encountered unless an active fixation atrial lead is used.

We describe a new temporary AV sequential system that can be advanced into the right heart from the jugular vein with ease and swiftly allow for AV sequential pacing. Also described is acute in man trial showing its feasibility and efficacy.

METHODS

Study Design

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This first-in-human, prospective, single-center, and single-arm study assessed the feasibility and safety of a new temporary AV sequential system in patients undergoing cardiac catheterization. Swift Sync Inc sponsored the study. This study was based on positive outcomes from a pilot animal study. All patients were enrolled, and studies were completed in a single center in Asuncion, Paraguay, in May of 2018. Institutional Review Board approval was granted, and every patient obtained informed consent.

Study Population

We identified patients 18 years or older undergoing elective right and left heart catheterization and capable of providing informed consent. Major exclusion criteria were as follows: age less than 18 years, unable to provide informed consent, any form of atrial fibrillation, presence of implantable cardiac pacemaker and acute coronary syndrome, cardiac tamponade, cardiogenic shock, massive pulmonary embolism, or any other medical unstable emergency as an indication for cardiac catheterization procedure.

Device Description and Procedural Technique

We studied a novel temporary AV sequential pacing catheter (TAVSP) (Swift Sync Inc. Miami, Florida) deployed percutaneously via a transjugular approach. It consists of a plurality of pre-formed, pre-shaped, resilient insulated nitinol wires bundled together in a tubular and flexible retaining sheath. Venous access is obtained in the right internal jugular vein using standard techniques, and an 8F introducer is inserted. The catheter is delivered to the right ventricle like any other temporary ventricular pacing catheter (4). Once the sheath is retracted, the nitinol wires can spread and deploy in the right ventricle and right atrium, assuring endocardial contact. Because of nitinol's capacity to seek a pre-shaped form (metal memory), they spread out and contact the endocardial surfaces inside the cardiac chambers. Each wire has a ball tip designed to minimize trauma to the endocardium and provide a high current density for myocardial capture. The unipolar electrodes also provided sufficient surface area to ensure adequate sensing. These are the leads of the pacing catheter. Swift Sync pacing catheter current design has three ventricular leads, one distal (-) lead that will seat at the distal end of the right ventricle, the other two ventricular leads one (+) and one (-) spread at a 180-degree angle in the opposite direction making contact with the right ventricular endocardium at any time. The catheter has four additional atrial leads, two (+) and two (-) spreading at 90-degree angles and in opposite directions allowing right atrial wall contact at any time (Figure 1 & 2). Nitinol leads are radiopaque to allow for fluoroscopic visualization. The unique design of the catheter and the leads guarantees endocardium wall contact at any time during the cardiac cycle.

Study Endpoints

The study's primary endpoints were the successful deployment of the device and pacing capture in AV sequential synchrony. Safety endpoints included major adverse cardiac events, any cardiac arrhythmia requiring cardioversion, and pericardial effusion with or without associated cardiac tamponade.

Data Analysis

We evaluated the procedure time in all patients. We also evaluated the impedance, the electrical capture threshold, and the current of atrial and ventricular leads. Data collected were summarized using descriptive statistics. All data were manually entered into a database in Microsoft Excel.

RESULTS

Ten subjects requiring a diagnostic right and left heart catheterization were screened and enrolled in the study. All ten subjects were successfully paced in AV sequential synchrony with the TAVPS catheter (Table 1). The duration of time that the pacing catheter was left in the patient averaged 24 minutes (range of 10-48 minutes), including positioning, deployment, the pacing of the right ventricle, right atrium, synchronous atrioventricular pacing, and removal. That sequence was followed in all cases. Four catheters were inserted and positioned without fluoroscopy; five were done with fluoroscopy guidance and one with the use of echocardiography.

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Echocardiography showed a mean ventricular longitudinal dimension of 6.1 cm, mean right atrial minor dimension of 4.1 cm, and mean right atrial area of 15.89cm^2 (ranging from 8.21cm^2 to 26.60cm^2) (Table 2). All subjects were assessed for any complications with trans thoracic echocardiogram at all times during the procedure. There were no adverse events during the pacing procedure. At discharge the following day, there were no adverse events reported. Patients were followed up as per standard of care after discharge.

In all ten patients, the pacing catheter achieved an excellent pacing threshold and impedance except for one. (Table 1). Patient number 7 had adequate thresholds and impedance in the ventricular leads but poor performance in the atrial leads.

DISCUSSION

This study reports the first-in-human experience with the Swift Sync temporary pacing catheter, a novel device implanted via the internal jugular vein approach to provide temporary atrioventricular synchronous pacing. We demonstrated the feasibility and initial safety of the study device in patients undergoing elective cardiac catheterization procedures. The catheter was successfully delivered and retrieved in all patients and achieved adequate pacing thresholds in all patients, although it required one patient higher MA to pace atrium. . There were no deaths, major adverse cardiac events, or device-related adverse events.

Impaired electromechanical coupling at any level (atrioventricular, interventricular, and intraventricular) can worsen cardiac performance and heart failure symptoms. Conversely, improving electromechanical dyssynchrony and restoring the physiologic AV relationship results in improved myocardial performance, reduced severity of mitral regurgitation, and ultimately increased cardiac output (1). These hemodynamics benefits are desirable in patients needing temporary pacing, particularly those with impaired hemodynamics, such as cardiogenic shock, myocardial infarction with right ventricular involvement, left ventricular hypertrophy, or decompensated heart failure.

Nearly all temporary pacing is done trans-venously with a single bipolar catheter, which is floated or advanced into the right ventricle (5). This only allows ventricular pacing without atrial pacing and tracking or AV synchrony. Furthermore, these catheters displace easily. Even with active fixation, there can be complications such as loss of pacing capture or potential ventricular perforation(6). We believe TAVSP catheter design with multiple unipolar expanding leads will improve endocardial contact and catheter stability.

AV synchrony is obtained during cardiac surgery by directly suturing temporary transcutaneous leads to the epicardium(7). These leads are then connected to an external cardiac pacer box, and AV synchrony can be achieved. However, these leads are not without potential complications. There are reports of infections, myocardial damage, ventricular arrhythmia, and cardiac perforations with these leads(8). In addition, removing the leads can be complicated, as highlighted by the published tragic case of Neal Armstrong (the first astronaut to walk on the Moon), who died of cardiac tamponade immediately following the removal of his epicardial transcutaneous leads. There were no device-related adverse events in our study. The atraumatic round tip of the lead was designed to minimize chamber perforation and erosion. The profile size of the TAVPS is comparable with some of the commercially available temporary pacing venous catheters.

This acute first in man study has limitations. This early feasibility study aimed to gather information on the device's ease of deployment and performance. We did not compare TAVPS to any other standard temporary pacing catheters with a single-arm design. Furthermore, we did not measure the hemodynamics effects of atrioventricular pacing using our device. Additionally, this initial experience was performed in patients with no need for temporary pacing. TAVPS still needs to be evaluated in patients with indications for temporary pacing and varied hemodynamic conditions. Although we did not observe any adverse device-related event, definitive conclusions about safety cannot be drawn due to the small number of patients.

CONCLUSIONS

This first-in-human experience demonstrated the feasibility and initial safety of the Swift Sync AV sequential temporary pacing catheter; a single catheter was capable of AV pacing and sensing.

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FIGURES

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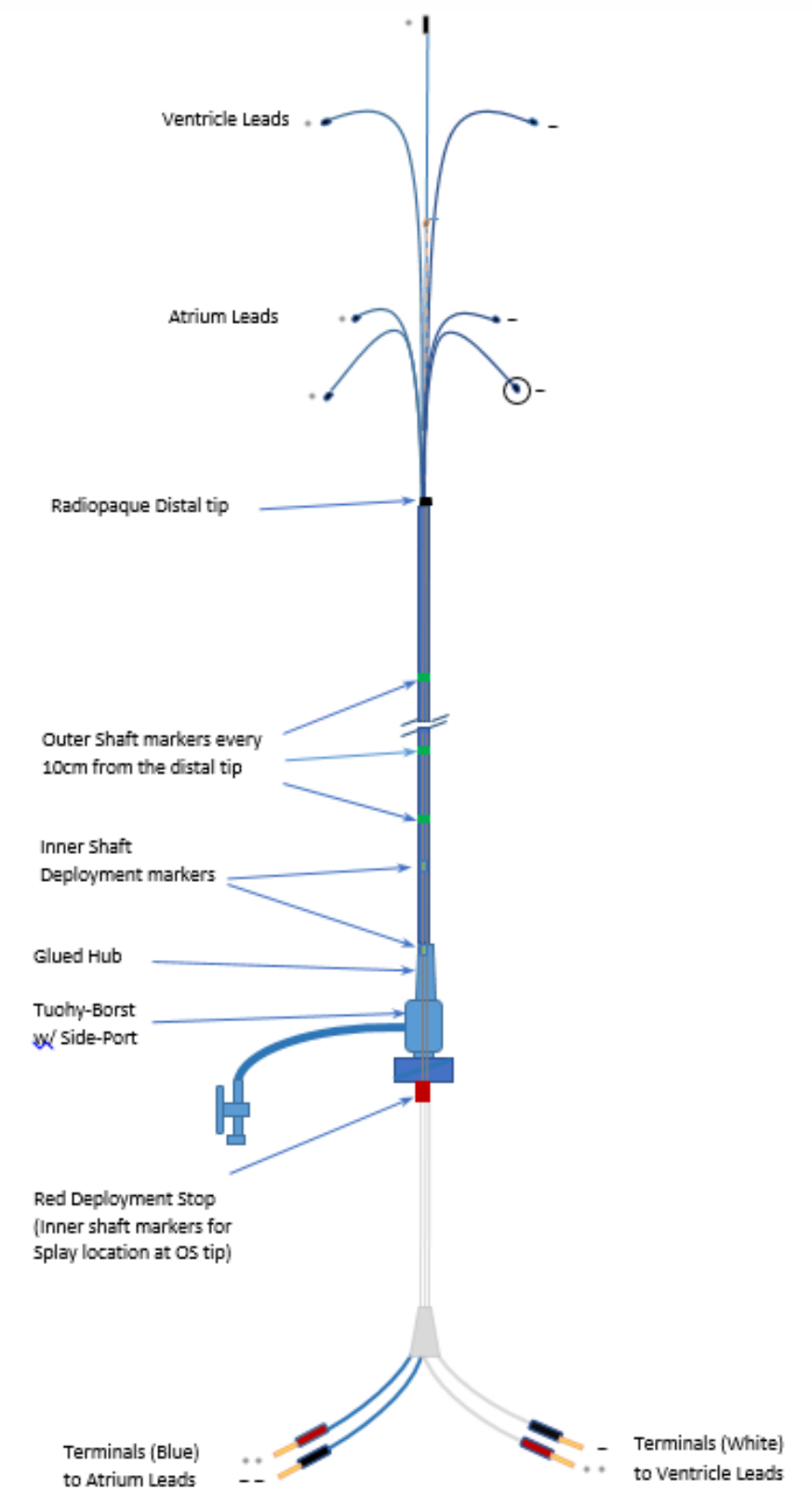

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Figure 1: Swift Sync AV Sequential Pacing Catheter (TAVPS)

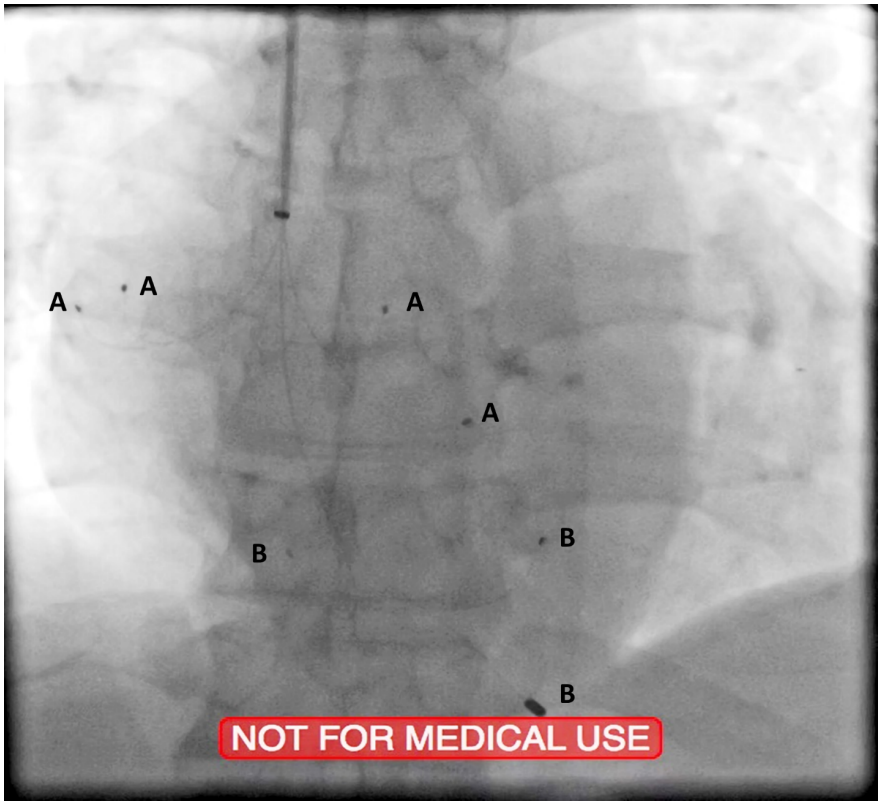

Figure 2: X-Ray of AVPS Atrial leads (A) in the RA and Ventricular leads (B) in RV

TABLES

Table 1: Study sample attributes and conduction and pacing results for first in human

Sex distribution (n=10):	**Sex distribution (n=10):**	**Sex distribution (n=10):**	**Sex distribution (n=10):**
Age (mean):	**Age (mean):**	60	60
Mean	**Mean**	**Mean**	**Mean**
Height	**Height**	**Height**	168cm
Weight	**Weight**	**Weight**	77kg
Baseline HR	**Baseline HR**	**Baseline HR**	69bpm
Subject	**Lead**	**Lead**	**Lead**
01	Atrial	Atrial	Atrial
	RV	RV	RV
02[1]	Atrial	Atrial	Atrial
	RV	RV	RV
03[1]	Atrial	Atrial	Atrial
	RV	RV	RV
04[1]	Atrial	Atrial	Atrial
	RV	RV	RV
05[1]	Atrial	Atrial	Atrial
	RV	RV	RV
06	Atrial	Atrial	Atrial

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	RV	RV	RV
07	Atrial	Atrial	Atrial
	RV	RV	RV
08[2]	Atrial	Atrial	Atrial
	RV	RV	RV
09	Atrial	Atrial	Atrial
	RV	RV	RV
10	Atrial	Atrial	Atrial
	RV	RV	RV
Mean ± SD	Atrial	Atrial	Atrial
	RV	RV	RV

[1] Fluoroscopy was not used during insertion of the AVPS

[2] Echocardiography confirmed position of the AVPS, fluoroscopy was not used during insertion.

Table 2: Echocardiographic evaluation

Subject	**RV long diameter (cm)**	**RA minor dimension (cm)**	**RA surface area (cm^2)**
1	8.33	5.64	26.6
2	5.93	2.87	13.1
3	5.15	3.89	14.8
4	7.67	4.41	19.9
5	6.14	4.34	15.65
6	6.16	4.25	23.1
7	5.45	2.61	8.21
8	4.06	3.97	12.2
9	5.63	3.97	14.3
10	6.33	5.62	11

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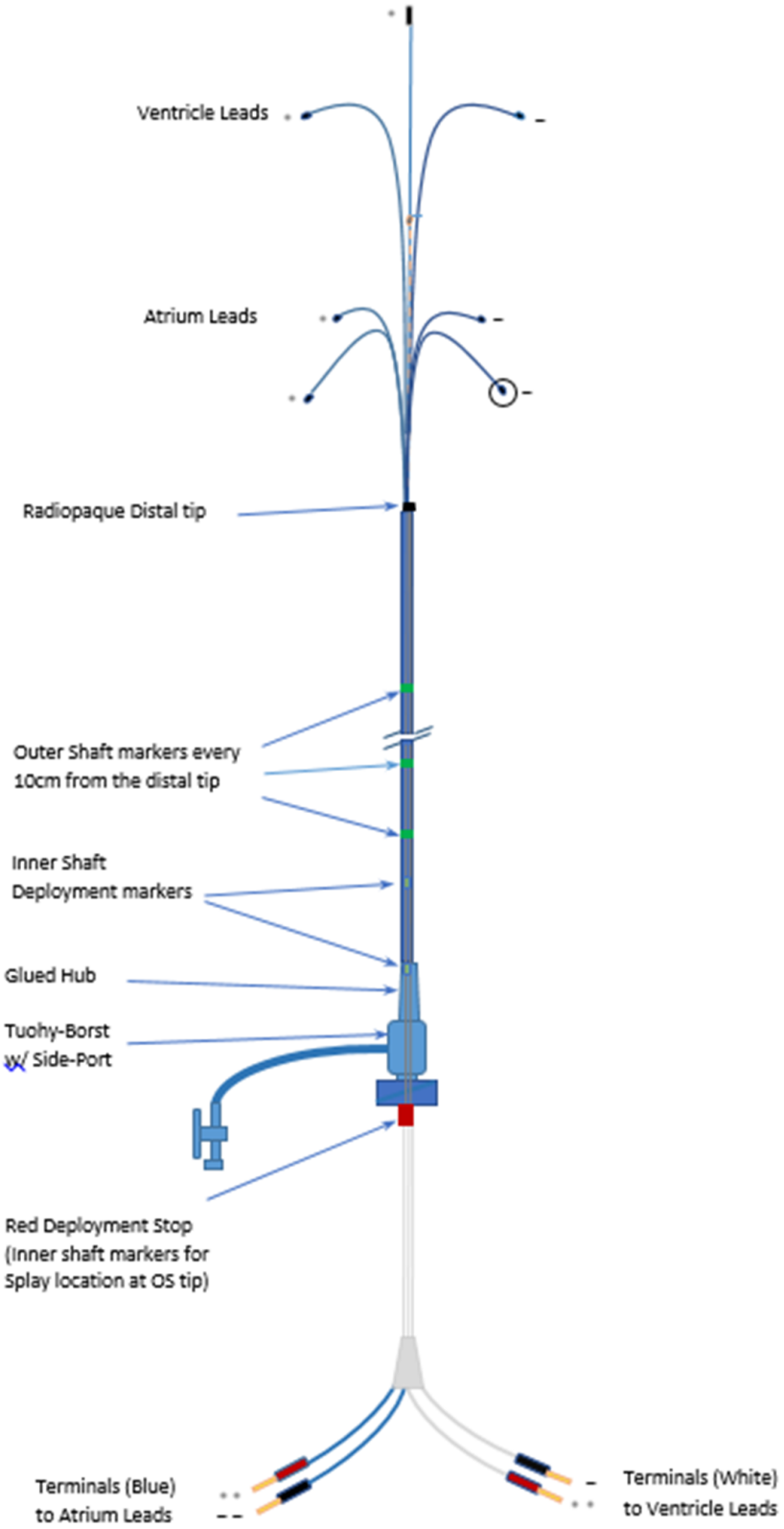

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