Fetal Diagnosis and Therapy

Original Paper

Fetal Diagn Ther 2020;47:682–688
DOI: 10.1159/000508044

Received: January 3, 2020
Accepted: April 20, 2020
Published online: July 6, 2020

Fetoscopic Laser Ablation Therapy for Type II Vasa Previa

Ramen H. Chmait[a] Valerian Catanzarite[b] Andrew H. Chon[a] Lisa M. Korst[c] Arlyn Llanes[a] Joseph G. Ouzounian[a]

[a]Division of Maternal-Fetal Medicine, Department of Obstetrics and Gynecology, Keck School of Medicine, University of Southern California, Los Angeles, CA, USA; [b]San Diego Perinatal Center, Rady Children's Specialists of San Diego, San Diego, CA, USA; [c]Childbirth Research Associates, Los Angeles, CA, USA

Keywords
Vasa previa · Fetoscopy · Laser · Fetal surgery · Fetal therapy

Abstract
Background: In type II vasa previa, fetoscopic laser ablation has the potential to avoid prolonged hospitalization, elective prematurity, and cesarean delivery associated with traditional conservative management. ***Objective:*** To assess the feasibility and to report perinatal outcomes of type II vasa previa patients treated via fetoscopic laser ablation. ***Study Design:*** This is a retrospective descriptive study of all women with vasa previa treated with laser at our center between 2006 and 2019. After 2010, laser ablation of vasa previa was only offered after 31 gestational weeks. Continuous variables are expressed as means ± SD. ***Results:*** 33 patients were evaluated for laser ablation of suspected vasa previa. Fifteen were not candidates (7 had type I vasa previa and 8 had no vasa previa), and the 18 remaining had type II vasa previa. Ten (56%) elected to undergo in utero laser ablation of the vasa previa vessel(s), which was successful in all patients. The mean gestational age (GA) at the time of the procedure was 28.8 ± 5.4 weeks, and the total operative time was 48.1 ± 21.3 min; there were no perioperative complications. The number of vessels lasered were distributed as follows: 1 (2 cases), 2 (5 cases), and 3 (3 cases). All patients except for 1 were subsequently managed as outpatients. The mean GA at delivery was 35.5 ± 3.2 weeks, and vaginal delivery occurred in 5 cases. The 5 patients with singletons who underwent laser ablation for primary diagnosis of type II vasa previa after the protocol change in 2010 had the following outcomes: mean GA of surgery was 32.5 ± 0.8 weeks, mean GA at delivery was 38.1 ± 1.4 weeks, vaginal delivery occurred in all cases, mean birth weight was 2,965 ± 596 g, and none were admitted to the neonatal intensive care unit. ***Conclusion:*** This cohort represents the largest number of vasa previa cases treated via in utero laser reported to date. Laser occlusion of type II vasa previa was technically achievable in all cases and resulted in favorable outcomes.

Part of this study was presented in Oral Concurrent Session 9 (abstract #99) at the 40th Annual Pregnancy Meeting of the Society for Maternal-Fetal Medicine in Grapevine (TX, USA) on February 3–8, 2020.

karger@karger.com
www.karger.com/fdt

Karger

Ramen H. Chmait
Keck School of Medicine, University of Southern California
39 Congress Street, Suite 302
Pasadena, CA 91105 (USA)
chmait@usc.edu

Introduction

Vasa previa is defined as the presence of fetal blood vessels that course within the fetal membranes, unprotected by underlying placenta, and reside in close proximity or directly over the internal cervical os [1]. The precise distance that these vessels must be from the cervix to be considered a vasa previa is not standardized, although a threshold of within 2 cm has been proposed [1, 2]. Three types of vasa previa have been described [1, 3, 4]: type I occurs when there is a single placental lobe with a velamentous cord insertion; type II occurs when the placenta contains a succenturiate lobe or is multilobed, and fetal vessels connecting 2 lobes course over or near the cervix; and type III occurs when a fetal vessel runs within the membranes over or near the cervix, unassociated with a velamentous cord insertion or bilobed placenta [5]. Because the exposed fetal vessels are neither supported by underlying placenta nor surrounded by Wharton's jelly, rupture of the fetal membranes may concurrently rupture the vessels resulting in fetal exsanguination and injury or death [3, 4, 6].

Management of vasa previa is individualized based on the presence or absence of symptoms, history of spontaneous preterm birth, and patient distance from the hospital [1, 3]. The natural history of prenatally diagnosed vasa previa has been described. Migration of these vessels away from the internal cervical os during the pregnancy has been documented in 14–39% of cases, with earlier gestational age (GA) at diagnosis increasing the likelihood of resolution [7–9]. In cases where vasa previa persists, antenatal considerations include timing of treatment with corticosteroids, possible hospitalization at a GA of 30–34 weeks with heightened antenatal monitoring, and planned cesarean delivery at a GA of 34–36 weeks [1, 10, 11]. Such measures and accurate prenatal diagnosis have led to a mean GA at delivery of 35 weeks and fetal mortality rates <5% [2, 7, 8, 12].

There is a subset of vasa previa patients (non-type I) who may be candidates for fetoscopic laser ablation of the vasa previa vessels [13]. As discussed in a recent review, potential advantages of successful in utero treatment include: elimination of the risk for fetal exsanguination with rupture of membranes; the possibility for outpatient management; avoidance of iatrogenic preterm delivery; and the possibility of a vaginal delivery [13]. Although a few individual cases of fetoscopic laser ablation of type II vasa previa have been reported [14–17], the available data on the feasibility and utility of this treatment option is limited, and this management strategy remains investigational.

The aims of this study were to assess the feasibility of this treatment option and to report perinatal outcomes of type II vasa previa patients treated via fetoscopic laser ablation.

Material and Methods

A retrospective cohort study of women with type II vasa previa treated with laser ablation at our center from 2006 to 2019 was conducted. Patients may have been referred for laser ablation of vasa previa, or vasa previa may have been noted upon evaluation for other conditions, primarily the twin-twin transfusion syndrome (TTTS).

All patients underwent a preoperative comprehensive ultrasound examination, including the assessment of fetal anatomy, fetal Doppler waveforms, and cervical length via endovaginal ultrasound. The endovaginal probe was placed in the anterior fornix to visualize the entirety of the cervix and the lower uterine segment. A vasa previa was suspected if one or more vessel(s) unsupported by underlying placenta was noted crossing over or in close proximity to the internal cervical os. The number/size (diameter) of vessels and the distance to the internal cervical os were recorded. The vessel type (artery versus vein) was confirmed via color and pulsed-wave Doppler. The vasa previa was then classified as type I if the vasa previa arose directly from a velamentous cord insertion, or type II if it bridged separate lobes of a bilobed or succenturiate placenta. None of the referred patients had type III vasa previa. The location and position of the placenta relative to the cervix was assessed via transabdominal and endovaginal ultrasound. The relative location of the vasa previa vessel(s) to the placental edges and to the placental cord insertion site was mapped.

Patients with a type I vasa previa were not considered candidates for laser ablation because the risk of fetal demise as a result of lasering a major fetal vessel directly connecting the umbilical cord to the placenta was deemed too high. Patients identified with a type II vasa previa were offered the following: (1) expectant management, with hospitalized bed rest starting from a GA between 28 and 32 weeks until delivery, and cesarean delivery at a GA of approximately 35 weeks; (2) pregnancy termination; or (3) diagnostic fetoscopy and possible laser ablation of the vasa previa. It was emphasized to the patient that, should she elect to proceed with possible laser ablation, that a "diagnostic" fetoscopy would be performed to assess therapy feasibility and determine if the vasa previa vessels appeared to support a significant portion of the placenta. Evaluation of placental territory was a qualitative determination, based on the relative amount of placental tissue perfused by the offending vessels. If the vasa previa vessels were deemed to be perfusing a significant segment of placenta (roughly >10%), then the laser ablation would not be performed. The patients provided consent for possible emergent cesarean delivery should fetal compromise be detected during intraoperative ultrasound.

After 2010, to mitigate against the risks of prematurity, laser ablation of vasa previa was offered only after a GA of 31 weeks.

Fetoscopy was conducted under local anesthesia and maternal sedation with the neonatal team on stand-by. Instillation of warm normal saline or lactated Ringer's solution through an 18-gauge needle was performed to facilitate surgical access and improve vi-

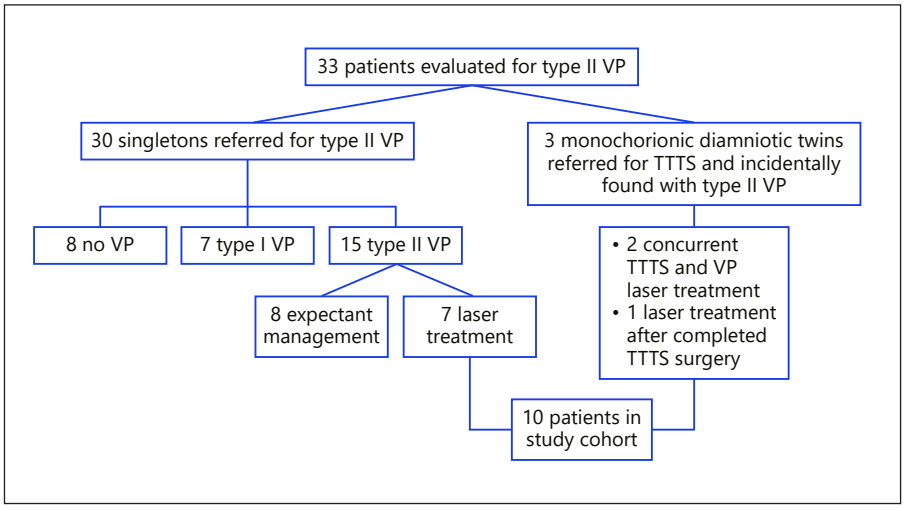

Fig. 1. Distribution of patients evaluated for type II vasa previa (VP) between 2006 and 2019. TTTS, twin-twin transfusion syndrome.

sualization. A 3.8-mm trocar was then inserted under direct ultrasound guidance into the amniotic cavity. The fetal head was externally displaced with the assistance of maternal positional changes (i.e., Trendelenburg position, lateral tilt) from the lower uterine segment for better visualization of the internal os. The vasa previa vessels were identified endoscopically with a 3.3-mm 30° or 70° diagnostic endoscope (Richard Wolf, Inc., Vernon Hills, IL, USA). Placental mapping by fetoscopy to qualitatively assess the extent of the placenta supported by these vessels was performed. If the individual placental territory supported by the vasa previa vessels was not deemed substantial, then laser ablation was performed. The diagnostic endoscope was exchanged for a 3.3-mm 0° operating endoscope with a 5-Fr operating channel, through which a 600-μm non-contact YAG laser fiber (Surgical Laser Technologies, Montgomeryville, PA, USA) was passed. The vasa previa vessels were photocoagulated, using Nd:Yag laser energy at 20–40 W, both in the proximal segment and distal segment to the internal cervical os. Approximately 3–4 cm of the vessel length measured from the internal cervical os in either direction was photocoagulated. Laser photocoagulation of the vasa previa vessel was not performed in the region directly over the cervix. After completion of the laser ablation, an intraoperative endovaginal ultrasound examination with color Doppler was used to confirm successful ablation. An amnioreduction was performed to normalize the amniotic fluid volume, and the trocar was removed. The procedure was performed with continuous ultrasound imaging to monitor fetal heart rate. Total operative time was defined as the time from initial skin incision to completed laser ablation and removal of the trocar from the uterus.

The patient was kept in the hospital overnight to monitor fetal heart rate and uterine contractions. A bedside ultrasound examination was performed the following day to assess fetal well-being. An endovaginal ultrasound examination with color Doppler was done to confirm ablation of the vasa previa. The patient was then discharged home under the care of her obstetrician. The patient was also informed that she was a candidate for vaginal delivery at term.

Prospectively collected data included the following: maternal demographics, perioperative data, and delivery outcomes. Patient characteristics and outcome data are described for the entire group of patients, and for the subset of patients with singletons treated from 2010 onwards, when there was a protocol change to offer laser ablation of type II vasa previa after 31 weeks of gestation. All data were examined using SAS statistical software (version 9.3). All analyses were two sided, and descriptive statistics are presented with continuous variables expressed as means ± SD. Informed consent was obtained from all study participants. This study was approved by the Institutional Review Board of the University of Southern California for the Health Sciences campus.

Results

From 2006 to 2019, a total of 33 women were evaluated for vasa previa treatment (Fig. 1). Thirty women with singleton pregnancies were primarily referred for management of the suspected vasa previa. Of these 30 patients, 8 had no vasa previa, 7 had type I vasa previa, and 15 had confirmed type II vasa previa. Seven (46.7%) of the 15 confirmed type II vasa previa patients were singleton gestations and elected to undergo in utero laser treatment. The additional 3 patients in this cohort were monochorionic diamniotic twin gestations referred primarily for TTTS treatment and were incidentally diagnosed with type II vasa previa, and all 3 elected to undergo in utero laser treatment, yielding a total of 10 cases reported in this study. The distribution of these cases by year of treatment was as follows: 2007 (1); 2008 (1); 2009 (1); 2013 (2); 2016 (1); 2018 (3); and 2019 (1). The TTTS patients were treated for vasa previa in 2008, 2013, and 2018. Two were treated at the same time as the laser surgery for TTTS (both were Quintero stage III donor), and 1 (Quintero stage II) was discovered postoperatively and laser occluded in a second surgery, as described in detail previously [16].

Table 1. Characteristics of the entire cohort (n = 10) and of a subgroup of singletons treated after protocol change in 2010 when laser occlusion of primary vasa previa was performed after 31 weeks of gestational age (GA) (n = 5)

Patient characteristics	All patients (n = 10)	Subgroup with singletons treated after 2010 (n = 5)
Multiparous	5 (50.0%)	3 (60.0%)
Age, years	33.3±6.7 34.5 (21.0–43.0)	36.4±5.9 37.0 (27.0–43.0)
History of prior cesarean delivery	1 (10.0%)	0 (0%)
Delivery mode cesarean delivery	5 (50.0%)	0 (0%)
GA at first evaluation for vasa previa, weeks	23.8±5.4 22.4 (16.7–33.6)	28.0±4.3 28.6 (22.3–33.6)
GA at surgery, weeks	28.8±5.4 31.3 (17.9–33.7)	32.5±0.8 32.9 (31.7–33.7)
Referral to vasa previa surgery latency, weeks	5.0±3.5 4.8 (0.1–10.0)	4.5±3.8 3.1 (0.1–10.0)
Post-laser hospitalization	1 (10.0%)	0 (0%)
Closest vessel to internal os, cm	0.68±0.63[a] 0.75 (0.00–1.50)[a]	1.23±0.26[b] 1.20 (1.00–1.50)[b]
Diameter of the largest vessel, cm	0.25±0.08[a] 0.26 (0.10–0.36)[a]	0.30±0.05 0.28 (0.24–0.36)
Operative time, min	48.1±21.3 46.5 (26.0–98.0)	58.4±23.5 54.0 (35.0–98.0)
Laser, J	9,792±5,748[a] 9,167 (1,960–19,067)[a]	11,923±5,739 10,968 (5,575–19,067)
Latency from surgery to delivery, weeks	6.7±3.4 6.3 (2.3–14.7)	5.5±2.1 5.4 (2.3–7.6)
GA at delivery, weeks	35.5±3.2 35.5 (29.3–39.4)	38.1±1.4 38.1 (36.0–39.4)

Values are presented as n (%), mean ± SD, or median (range).
[a] n = 8: 2 patients did not have these data prospectively collected.
[b] n = 4: 1 patient did not have these data prospectively collected.

Patient characteristics for these 10 patients are presented in Table 1. In all 10 cases, fetoscopic mapping of the vasa previa vessels was performed, and in all cases, the vessels were deemed acceptable for ablation because they did not appear to support a major portion of the placenta. Laser ablation of the vasa previa vessel(s) was successful in all patients. The mean GA at the time of the procedure was 28.8 ± 5.4 weeks. The number of vessels lasered was distributed as follows: 1 (2 cases), 2 (5 cases), and 3 (3 cases). The types of vessels lasered were: artery (1 case); vein (1 case): and both (8 cases). The mean total operative time was 48.1 ± 21.3 min. There were no perioperative complications. No intraoperative fetal heart rate decelerations occurred. No patients had iatrogenic preterm premature rupture of membranes.

A special mention is necessary regarding the presence of type II vasa previa with TTTS, which occurred in 3 cases in this cohort. This clinical scenario is not unexpected, as vasa previa is more common in multifetal gestations [18, 19]. In 2 of these cases, the vasa previa was identified prior to laser surgery for TTTS, and laser ablation of the communicating vessels and the vasa previa vessels were done at the same time. In both cases, the procedure was technically successful. In the third case, the

vasa previa was diagnosed postoperatively, and a subsequent surgery was done later in the pregnancy to occlude the vasa previa vessels after cervical shortening and preterm labor symptoms developed [16].

Nine patients were subsequently managed as outpatients, and 1 patient with twins in preterm labor was managed as an inpatient, as described previously [16]. Postoperative fetal Doppler assessments were normal. The mean GA of delivery was 35.5 ± 3.2 weeks, and vaginal delivery occurred in 5 cases. The indications for cesarean delivery were (3) twin gestations, (1) planned repeat cesarean, and (1) preeclampisa with severe features remote from delivery. The perinatal survival rate of this cohort was 100% (13 of 13). The 3 TTTS patients delivered at 29.3, 32.6, and 34.4 weeks. Donor and recipient twins from all 3 TTTS cases were admitted to the neonatal intensive care unit (NICU); 1 singleton requiring intubation was also admitted to the NICU.

After the protocol change in 2010, in which laser ablation of the type II vasa previa vessels was delayed until after completion of 31 weeks GA, 5 laser ablations for singletons with the primary diagnosis of type II vasa previa (TTTS patients excluded) were performed. Patient characteristics of this subgroup are presented in Table 1. For this subgroup, the mean GA at surgery was 32.5 ± 0.8 weeks, the mean GA at delivery was 38.1 ± 1.4 weeks, vaginal delivery occurred in all cases, birth weight was 2,965 ± 596 g, and no newborns were admitted to the NICU. The only neonatal complication recorded was for 1 newborn with hyperbilirubinemia that required phototherapy.

Comments

In this cohort, which represents the largest number of patients with vasa previa treated in utero via laser occlusion published to date, the laser surgery was technically achievable in all cases and resulted in overall favorable outcomes. After protocol change in 2010, which mandated laser occlusion of the vasa previa vessels after reaching a GA of 31 weeks, all patients treated primarily for vasa previa delivered vaginally at a mean GA of 38 weeks without perinatal complications.

The current management strategies for prenatally detected vasa previa include prolonged inpatient surveillance, preterm delivery prior to labor or rupture of membranes, and delivery via cesarean section [1, 11]. Although the risk for perinatal mortality is substantially reduced by prenatal recognition of the vasa previa and adoption of this management strategy, the presence of a vasa previa still poses perinatal risks from prematurity and the rare case of rupture of the vasa previa prior to the scheduled preterm cesarean section delivery [2, 20]. In a retrospective multicenter study, Swank et al. [20] reported that sudden rupture of the fetal vessel occurred in 1 of 47 prenatally diagnosed vasa previa cases. Bronsteen et al. [2] reported 3 perinatal deaths in 56 patients with a prenatal diagnosis of vasa previa despite emergent delivery. Catanzarite et al. [5] reported only 1 perinatal death, which was attributed to cardiac disease, among 96 patients treated over a 12-year period. However, in this series, urgent delivery was required before 34 weeks in 9/77 singletons and 11/19 twins.

Laser ablation of a type II vasa previa, which is currently an investigational treatment option, reduces the need for hospitalized surveillance and prescribed bed rest, allows for the possibility of a vaginal delivery at term, and provides relief to both the mother and health care providers. In this cohort, all but 1 twin patient was managed as outpatient after laser ablation. The overall vaginal delivery rate was 50%, but after protocol change (laser ablation >31 weeks GA) and exclusion of the twin cases, the vaginal delivery rate was 100%. Furthermore, the definitive treatment that laser occlusion provides, which was confirmed via postoperative endovaginal ultrasound in all cases in this cohort, eliminates the diagnostic dilemma that antepartum vaginal bleeding often creates [11, 12, 21]. For instance, in a series of 155 vasa previa cases (61 diagnosed prenatally), 56 had third trimester bleeding and only 3/56 (5%) of these had a test performed to determine whether the blood was of maternal or fetal origin [12].

Many of the technical aspects of laser occlusion of the vasa previa vessels are similar to those encountered in the laser treatment of TTTS. The primary differences relate to GA at treatment. In the case of TTTS, laser surgery is usually performed between 16 and 26 weeks GA [22, 23]. According to our initial experience, we performed laser occlusion of the vasa previa vessels at a similar GA. However, after 2010, we made the decision to perform this procedure after reaching a GA of 31 weeks for the following reasons: (1) there is a possibility of spontaneous resolution of the vasa previa [8, 20]; (2) delay of laser ablation of the vasa previa would pose minimal fetal risk (unlike delay of laser ablation for TTTS), and this delay may mitigate against the procedure-related risks of prematurity; and (3) many patients who elect expectant management start hospitalized surveillance at a GA of 32 weeks, thus offering ther-

apy at this time seemed practical because it would allow for easier transfer of the patient to a center that offers this treatment (prior to the scheduled hospitalization). The challenges of performing laser surgery beyond a GA of 31 weeks include the relatively large size of the fetus, which can limit access to the vessels of interest, and the large caliber of vessels, which require relatively increased laser energy and time to fully occlude.

The potential benefits of laser occlusion of the vasa previa vessels must be weighed against the potential risks of operative fetoscopy [24–26]. Maternal complications are uncommon with fetoscopy, but can include anesthesia risks, benign intraperitoneal amniotic fluid leakage, placental abruption, and chorioamnionitis [25]. The immediate fetal risks include preterm delivery and preterm premature rupture of membranes [24, 26–28], but, as mentioned above, the prematurity risks can be mitigated by postponement of the laser surgery to the latter half of the third trimester. Another procedure-related risk is the possibility of iatrogenic fetal exsanguination secondary to rupture of the vasa previa vessel during laser occlusion. All patients were informed of this risk, and all provided informed consent for the possibility of an emergent cesarean delivery should this complication occur. However, the risk to the fetus would likely be low because the patient is already in the operating room with all necessary staff and equipment readily available. Nevertheless, arrangements for a possible emergent neonatal blood transfusion should be considered with a unit of O negative blood on stand-by. Finally, there is theoretical concern of placental insufficiency if the vasa previa vessels perfuse a substantial amount of placenta. Thus, all patients were counseled that a *diagnostic* fetoscopy would be performed to map out placental territory, and that laser occlusion would only be performed if the corresponding placental territory appeared not to be significant. Placental territory assessment for all cases in this cohort appeared adequate, and all underwent the laser occlusion of the vasa previa vessels with no subsequent evidence of placental insufficiency. It must be acknowledged that this is a qualitative assessment that must be assessed by a fetal surgeon with experience in placental mapping.

The strengths of this study include the fact that it is the largest published cohort of vasa previa patients treated via fetoscopic laser occlusion, an innovative treatment option for a consequential obstetrical complication. The limitations of the study are several. Despite being the largest of its kind, it still describes a relatively small cohort. There is heterogeneity in the patient population and in the timing of laser occlusion. Furthermore, the determination of whether or not the relative amount of placental tissue perfused by the vasa previa vessels was too significant for laser ablation was subjective and not standardized. Finally, this is a retrospective study, with all the limitations inherent therein.

In conclusion, this cohort represents the largest number of type II vasa previa cases treated in utero via laser reported to date. Laser occlusion of type II vasa previa was technically achievable in all cases and resulted in favorable outcomes for both the fetus and the mother. Further studies and ethical scrutiny will be required to determine if this novel surgical treatment provides sufficient benefit to the mother and fetus to justify its procedure-related risks in comparison to those risks encountered with the standard expectant management approach.

Statement of Ethics

The procedures followed were approved by the USC Health Sciences IRB under protocol number HS-16-00468. Written informed consent of patients was obtained. The research complies with guidelines for human studies and was conducted ethically in accordance with the World Medical Association Declaration of Helsinki.

Disclosure Statement

L.M.K. assists with research studies as an independent contractor. The other authors have no conflicts of interest to disclose.

Funding Sources

There are no sources of funding to disclose.

Author Contributions

All named authors, R.H.C., V.C., A.H.C., L.M.K., A.L., and J.G.O., have: (1) made substantial contributions to the conception or design of the work, or to the acquisition, analysis, or interpretation of data for the work; (2) participated in drafting the work or revising it critically for important intellectual content; (3) approved the final version to be published; and (4) agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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