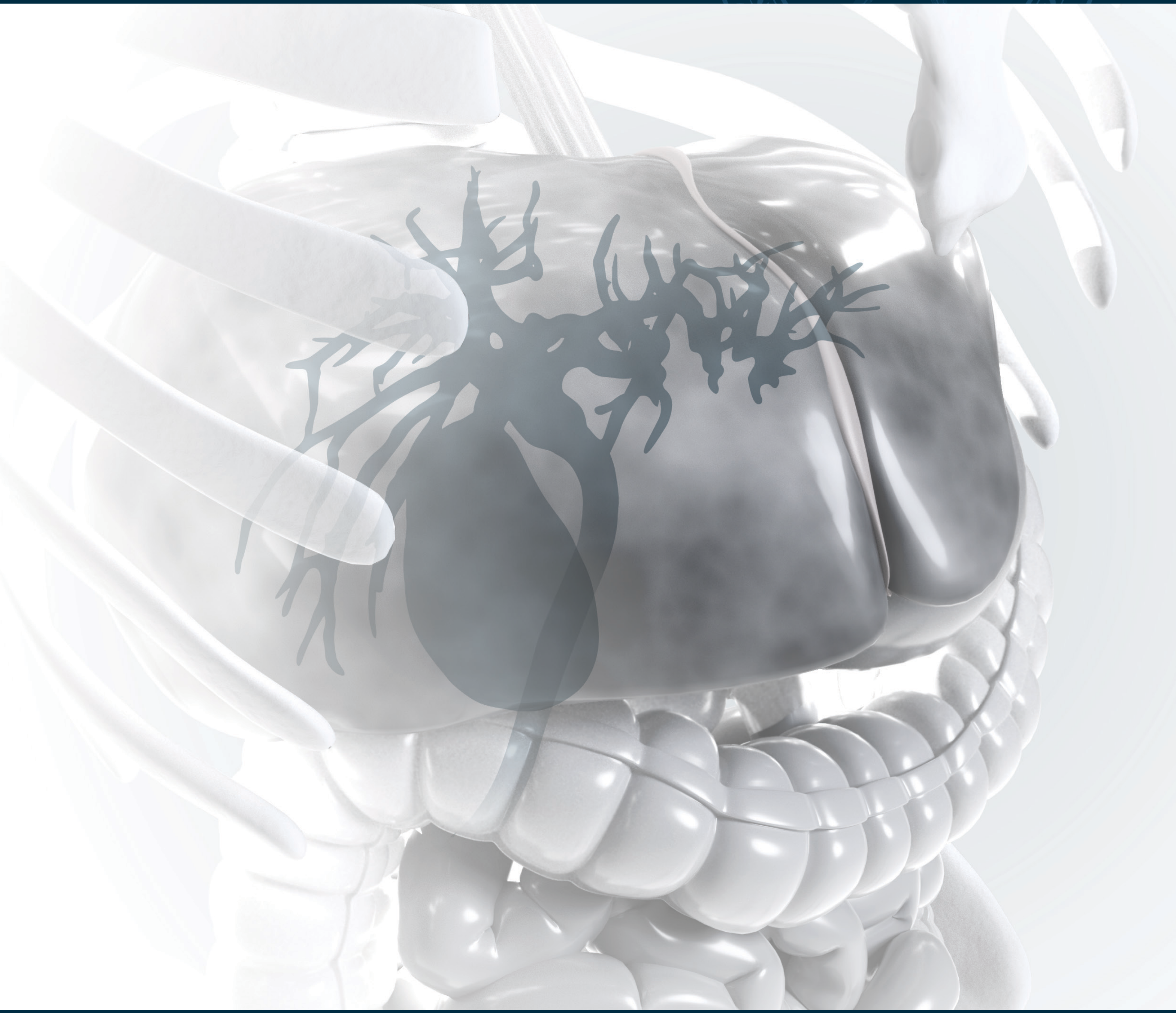
Clinical Dossier:

PowerWire® Pulse RF Guidewire Use in Biliary Interventions



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Introduction to Biliary Strictures

Biliary strictures are abnormal narrowings in the bile ducts that can impede the flow of bile from the liver to the small intestine[22]. Biliary strictures can be due to benign and malignant etiologies. Benign (non-malignant) strictures represent around 30% of biliary strictures and typically arise from bile duct injury, surgical complications, chronic inflammation (e.g., primary sclerosing cholangitis, pancreatitis)[2]. Benign strictures are routinely managed with procedures like stenting, percutaneous biliary drain placement, and/or dilatation[7,9,22]. Delayed recognition and treatment can lead to secondary biliary cirrhosis[24].

Causes

Malignant Strictures: Malignant strictures can be classified into distal strictures (caused by cancers such as pancreatic adenocarcinoma) or proximal strictures (caused by cancers such as hilar cholangiocarcinoma)[11,17,22].

Surgical Complications: Post-surgical strictures often result from procedures like cholecystectomy or liver transplantation. Approximately 7% of patients have a biliary stricture following liver transplant[6]. Scar tissue formation at the anastomosis can constrict the bile ducts[21].

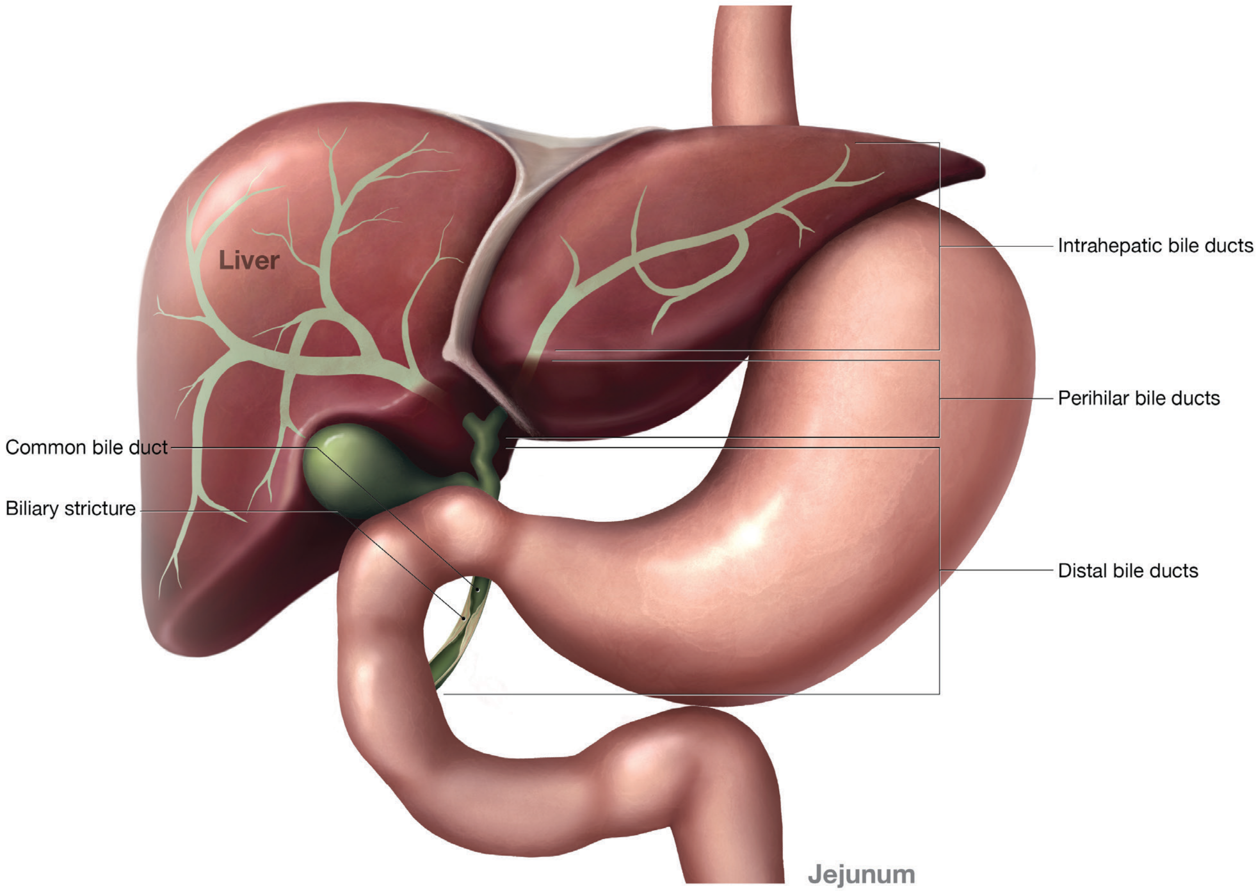
Trauma: Injury to the bile ducts from accidents or interventions such as endoscopic or percutaneous treatments can also lead to benign strictures[4].

Infections: Recurrent episodes of acute cholangitis (infection of the bile ducts) can lead to scar tissue formation[7].

Inflammatory Diseases: Conditions such as chronic pancreatitis and chronic inflammation of the bile ducts (e.g., primary sclerosing cholangitis) can cause benign biliary strictures[21].

Biliary Stones: Choledocholithiasis (stone in the common bile duct) or hepatolithiasis (stone in the hepatic ducts) can also lead to benign biliary strictures[11,12].

Background



Biliary strictures and occlusions, particularly those resulting from complex surgical procedures such as hepaticojejunostomy, pose significant clinical challenges due to their anatomical location and the risk of complications[7,8]. Traditional methods like endoscopic retrograde cholangiopancreatography (ERCP) and percutaneous transhepatic or transjejunal biliary drainage are established methods of treatment. However, the management of these patients is complex due to multiple factors, leading to prolonged complications, such as bile leaks or recurrent obstructions[7,16].

Impact on Patients

Bile Flow Obstruction[10,21]

Jaundice: Accumulation of bilirubin in the blood leads to yellowing of the skin and eyes.

Pruritus: Severe itching caused by bile salts deposited in the skin.

Dark Urine and Pale Stools: Due to impaired bile flow, urine may become darker, and stools may become lighter.

Digestive Issues[23]

Malabsorption: Impaired bile flow can hinder the digestion and absorption of fats, leading to nutritional deficiencies.

Abdominal Pain: Blockage of bile ducts can lead to significant discomfort and pain.

Infection and Inflammation[18]

Cholangitis: Acute infection of the bile ducts due to stasis of bile can cause fever, chills, and systemic illness. Acute cholangitis is a medical emergency and has high mortality and morbidity if left untreated[25].

Chronic Inflammation: Persistent strictures can lead to chronic inflammation and further damage to the bile ducts.

Complications[17]

Biliary Leaks: Strictures can lead to leaks where bile escapes into the abdominal cavity, causing peritonitis and other serious complications. Intrahepatic and extrahepatic bilomas (which can become infected and form abscesses) can form due to obstruction of antegrade flow of bile.

Biliary Cirrhosis: Long-term strictures can result in liver damage and secondary biliary cirrhosis due to ongoing bile duct obstruction and injury. This can be severe enough to necessitate liver transplantation[24].

Quality of Life

Increased Healthcare Needs: Recurrent hospitalizations and interventions can affect the patient's quality of life.

Psychological Impact: Chronic illness and its complications can lead to stress, anxiety, and depression.

Effective management of biliary strictures often involves interventions to relieve the obstruction, restore bile flow, and address any complications that arise[16].

Difficulties in Treating Biliary Strictures

Fibrosis and Scar Tissue: Many biliary strictures develop significant fibrosis, which leads to dense and hardened tissue[13,15].

Inflammation and Edema: Inflammatory processes within the bile ducts can lead to swelling and thickening of the duct walls, further narrowing the lumen[13,18].

Altered Anatomy: Previous surgeries, such as biliary reconstructions and biliary-enteric anastomoses may alter the normal anatomy of the bile ducts, complicating the access path for gastroenterology and interventional radiology[7].

Narrow Lumen: The lumen (inner diameter) of the bile duct can become extremely narrow or obliterated due to the stricture[7].

Location of the Stricture: Strictures in difficult-to-reach areas, such as the intrahepatic bile ducts or near previous surgical sites can be complex to manage sometimes requiring rendezvous (combination) procedures with interventional radiology and gastroenterology[7].

Malignant vs. Benign Strictures: While malignant strictures often progress aggressively and lead to tissue destruction, benign strictures tend to cause dense scarring[9,12,15,17].

Limited Visualization: Endoscopic techniques rely on visualizing the stricture through imaging or direct scope views. However, in some cases, poor visualization due to bile, blood, or the positioning of the stricture can further complicate the procedure[19,22].

Inability to Cross the Stricture: In most cases, gastroenterology and/or interventional radiology can cross the stricture using routine wire/catheter techniques. However, there are cases where the stricture cannot be crossed. In these scenarios, a stent inferior to the stricture (placed by GI) has no value. An external biliary drain can be placed by interventional radiology to decompress the biliary tree. There are four key issues with external biliary drains:

- The patient must have the external biliary drain attached to a bag all the time with copious amounts of bilious output that can lead to dehydration and electrolyte imbalances.
- There is a significant risk of drain dislodgement as the internal securement mechanism of the drain (pigtail) does not form inside the small intestine.
- As the stricture is not crossed, no diagnostic (e.g., biopsy) or therapeutic intervention (e.g., cholangioplasty) can be performed on the stricture.
- Internalization of the external biliary drain with plastic or metal stents requires access across the stricture. If the stricture is not crossed, these patients can require life-long drains.

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Introducing the PowerWire® Pulse Radiofrequency (RF) Guidewire

The PowerWire® Pulse Radiofrequency (RF) Guidewire is cleared in the United States to cut and coagulate soft tissue.

The PowerWire® Pulse RF Guidewire presents a novel solution that combines the mechanical properties of a standard guidewire with the cutting capabilities of RF energy. This dual functionality allows for precise RF puncture and tract formation, providing a minimally invasive alternative in procedures such as crossing, for patients who are not candidates for more extensive surgical repairs[3].

Uses [1,2,3,5,6]

The PowerWire® Pulse RF Guidewire enables precise soft tissue puncture including the crossing of biliary strictures, recanalization of extrahepatic and perihilar biliary tracts, and creating new biliary pathways. The RF wire's minimally invasive approach offers an effective alternative to traditional surgical interventions, with a favorable safety profile.

Once the guidewire is successfully navigated through the benign occlusion, subsequent balloon dilation or stenting can help restore bile flow.

Key Publications

1. Close et al. - Percutaneous Hepaticojejunostomy Using a Radiofrequency Wire for Management of a Postoperative Bile Leak [1]

Study Overview:

A 63-year-old female had right lobe cholangiocarcinoma and underwent an extended right hepatectomy and Roux-en-Y left lateral duct hepaticojejunostomy reconstruction. Postoperatively, she developed a bile leak, leading to complications such as a large abdominal abscess, septic shock, and Escherichia coli bacteremia. Despite initial interventions, including external drainage and antibiotic therapy, the patient experienced persistent issues with a subhepatic biloma and infection, necessitating further procedures.

The technique described in this case involves the use of a PowerWire® Pulse RF Guidewire to puncture the bowel wall to perform a percutaneous transhepatic biliary-enteric anastomosis and gain access to the Roux limb. The procedure allowed for the creation of a connection between the biliary tree and the bowel, providing definitive treatment for the patient's biliary leak and preventing future biloma or infection.

Performance:

Radiofrequency puncture was successfully used to gain access into the Roux limb. The authors note the RF wire's precision and predictability in creating controlled punctures without the need for excessive force. The authors state that the choice to use the RF guidewire system in this case was based on the device's excellent maneuverability, consistent tissue destruction, and its ability to easily traverse virtually any type of tissue. It combines the steerability of a low-friction guide catheter with the delivery of RF energy. The PowerWire® Pulse RF Guidewire demonstrates the ability to both guide and cut through fibrotic or stenotic tissue, even in cases where conventional techniques have failed.

Safety:

Close et al. report favorable safety outcomes in cases where the PowerWire® Pulse RF Wire was used, with no significant complications directly attributed to the device. Safety is ensured through careful wire positioning and controlled RF energy delivery, minimizing collateral tissue damage. In addition, the author's note that having a distal target (balloon in the Roux limb in this case) is key to ensure safety in these cases.

Patient Outcomes:

At the 3-month follow-up, imaging revealed a slightly narrowed passage between the duct and bowel lumen, with no signs of an anastomotic leak.

The RF wire resolved a bile leak following a failed hepaticojejunostomy, restoring bile drainage and resolving the patient's condition.

2. Dai et al. - Percutaneous Creation of a Choledocho-choledochostomy for Bile Duct Injury [2]

Study Overview:

A 64-year-old woman presented a bile duct occlusion following a right hepatectomy. Conventional techniques including ERCP, and percutaneous guidewire attempts to reconnect the left main bile duct to the common bile duct were unsuccessful in restoring bile flow. The choledocho-choledochostomy from the left bile duct to the common hepatic duct was created by advancing the PowerWire® Pulse RF Guidewire through a Cobra catheter guided by contrast injection from a nasobiliary drain placed in the common hepatic duct.

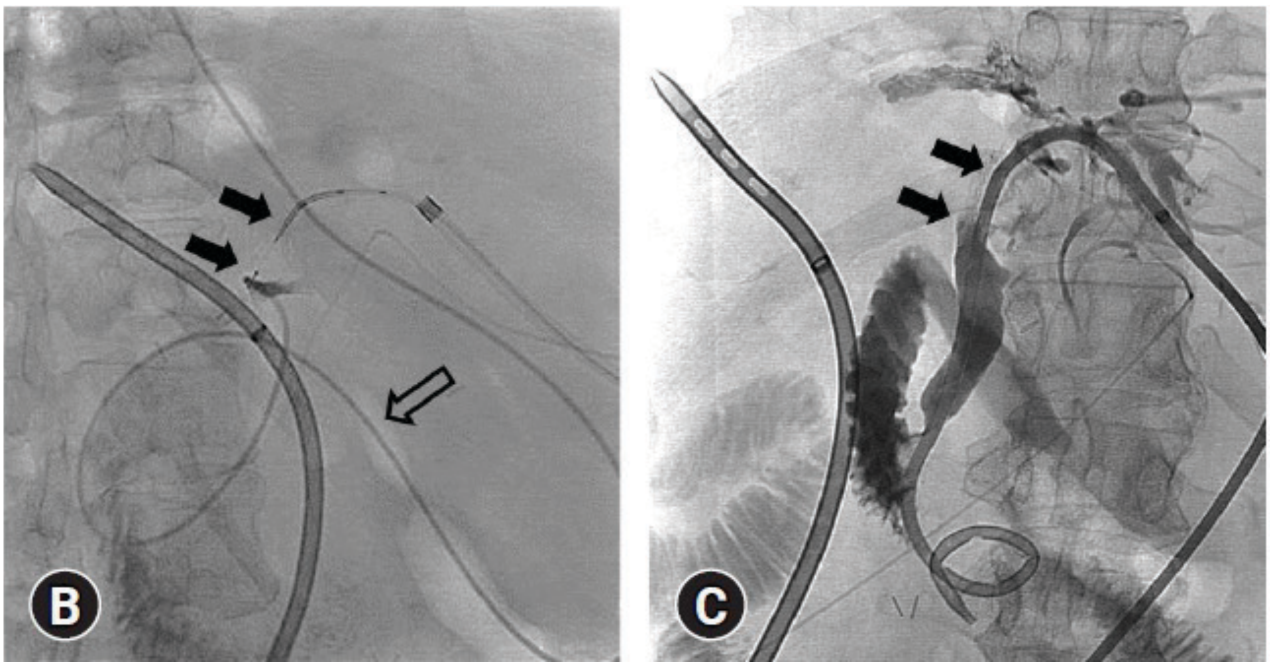

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Figure 2b. The RF wire (black arrows) passes from the excluded left biliary tree to the stump of the left main duct, opacified with iodinated contrast injected through a nasobiliary drain (open arrow). A 3 French catheter lies within the left portal venous system.

Figure 2c. A 10 French percutaneous biliary drainage catheter passes from the left biliary tree through the newly created choledocho-choledochostomy (black arrows) and into the duodenum.

Performance:

The PowerWire® Pulse RF Guidewire was successful in safely puncturing the biliary occlusion which had been resistant to other recanalization techniques, and creating a choledocho-choledochostomy.

The authors state that the use of an RF wire allows operators to plot a controlled path towards a target.

The use of the wire provided a controlled method for creating a biliary anastomosis and avoided the need for open surgical intervention, which posed significant risks for the patient. This method can provide an alternative to major surgical repair of iatrogenic biliary injury.

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2. Dai et al. - Percutaneous Creation of a Choledocho-choledochostomy for Bile Duct Injury [2]

Safety:

The use of the PowerWire® Pulse RF wire in this procedure was associated with a favorable safety profile, with no complications such as bleeding, bile leak, bowel perforation, or pseudoaneurysm observed. Having a distal target (contrast opacification of the duct by the nasobiliary tube in this case) and a catheter in the portal vein to ensure live knowledge of the relationship of the vessel relative to the RF wire trajectory enhanced safety in this case.

Patient Outcomes:

Bile drainage was restored, with the percutaneous biliary drain output at 300 mL/24 hours and the biloma drainage reduced to 13 mL/24 hours. The patient's death, 19 days post-procedure, was due to anuric renal failure and was unrelated to the RF wire or the procedure itself.

Restoration of bile duct continuity using radiofrequency can provide an alternative to major surgical repair of iatrogenic biliary injury, improving patient quality of life.

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3. Guimaraes et al. - Successful Recanalization of Bile Duct Occlusion with a Radiofrequency Puncture Wire Technique [3]

Study Overview:

The five patients in the study faced various bile duct issues, including severe blockages, complicated strictures, and post-surgical injuries. The biliary occlusions presented in this study were very hard in nature, suggesting the presence of scar tissue. In all cases, prior attempts to restore bile duct access using various methods, including a 5-F, 40-cm-long catheter with a stiff angled shaft, an 80-cm-long, 0.035-inch conventional guidewire, or an 80-cm-long, 0.018-inch guidewire with an angled intermediate shaft were unsuccessful.

Typically, bile duct occlusions require percutaneous or open surgical interventions, however the RF puncture technique using the PowerWire® Pulse RF Guidewire offered a minimally invasive alternative approach.

The RF guidewire was delivered percutaneously via a transhepatic biliary route, and RF energy was used to cross the occluded duct segments. Balloon cholangioplasty was followed to dilate the ducts, and internal-external biliary drains were placed to maintain duct patency.

Performance:

Technical success in recanalization was defined as the effective puncture and passage through the blockage, followed by balloon dilation and placement of internal-external biliary drainage, all without complications. All five patients showed technical success. In two cases, initial attempts led to incomplete success, necessitating follow-up procedures that achieved full recanalization. No immediate or delayed complications were reported, and all patients eventually had their biliary catheters removed.

The PowerWire® Pulse RF Guidewire was successful in cutting through the fibrous scar tissue, thereby creating new biliary ducts or anastomoses, enabling further treatment procedures.

Authors note that a combination of a short steerable catheter, such as the 5 French Kumpe catheter, with a straight RF guidewire provides a better and more predictable tool for recanalizing difficult lesions. However, they also caution that using a semi-curved RF wire with a straight or semi-curved diagnostic angiographic catheter has a higher chance of creating false tracts due to less precise wire advancement.

Safety:

Safety outcomes for the RF wire were notably positive. RF puncture did not lead to any clinically significant complications in this sample of patients with no immediate or delayed procedure-related clinical complications observed.

In one patient, authors noted the formation of a false passage leading to the portal vein and another to the retroperitoneal space. However, this did not lead to any clinical issues or notable bleeding.

3. Guimaraes et al. - Successful Recanalization of Bile Duct Occlusion with a Radiofrequency Puncture Wire Technique [3]

Patient Outcomes:

The average follow-up duration was 13 months, with a range of 11 to 16 months. Throughout this period, all patients received percutaneous cholangioplasty with balloon dilation and had internal-external biliary drain catheters placed. By the time of the report, none of the patients required internal-external drains, and all were free of biliary drain catheters.

4. McDevit et al. - Interventional Radiology-Operated Choledochoscopy-Guided Radiofrequency Wire and Holmium Laser Ablations May Facilitate Treatment and Long-Term Patency of Benign Biliary Strictures [5]

Study Overview:

A 68-year-old post-liver transplant patient presented recurrent anastomotic biliary strictures comprised of abundant white fibrotic tissue. The stricture had caused four failed capping trials with an indwelling drain in place for over two years.

After direct visualization with a choledochoscope, the PowerWire® Pulse RF Guidewire was positioned at the fibrotic bands in the stricture, and RF energy was applied. The fibrous tissue was successfully released, as confirmed by choledochoscopy, and followed by balloon dilation for further stricture management.

Performance:

The authors state that the RF guidewire provided a definitive treatment for a recalcitrant biliary stricture. Its use under choledochoscopic guidance allows for real-time monitoring of the puncture process and potential complications.

The authors mention a need for a minimally invasive and definitive procedure to shorten the duration of indwelling catheter.

Safety:

No adverse events were observed during or after the procedure. Additionally, there was no increase in bilirubin levels or any signs of cholangitis, either in laboratory tests or clinical evaluations, following the procedure.

The biliary drain was removed 57 days post-procedure, and as of day 417, the patient remained stricture-free. The technique, however, carries a risk of complications as the RF wire can easily pass through tissue layers. Extra caution is to be taken by users, given the delicate nature of a chronically inflamed biliary system.

Due to high complication rates with conventional serial dilation protocols, the authors mention a need for a minimally invasive and definitive procedure to shorten the duration of indwelling catheter.

5. Robins et al. - Percutaneous Biliary Neo-anastomosis or Neo-duct Creation Using Radiofrequency Wires [6]

Study Overview:

Five patients, aged 10 to 69, were treated between May 2019 and April 2021. Traditional methods for crossing the biliary occlusion including conventional catheters, wires, and endoscopic techniques had failed, leading to the consideration of the PowerWire® Pulse RF Guidewire to cross the stricture.

The procedure began with percutaneous access to the biliary system. A guide wire was inserted and positioned across the stricture or obstruction. The RF wire was advanced under imaging guidance to cross the stricture and is used to create a new duct (neo-duct) (1 case) or neo-anastomosis (4 cases) by puncturing the fibrotic tissue and facilitating the formation of a new channel for bile flow. Through-and-through access was obtained by snaring the RF wire upon crossing stricture from the jejunum below, confirming the successful creation of the new pathway. This technique was aimed at restoring biliary drainage and bypassing obstructions.

The illustrations (Fig. 5a and 5b) below pertain to a 49-year-old female with gastric cancer status post-Roux-en-Y that presented a benign biliary stricture (patient 5). A hepaticojejunostomy biliary-enteric anastomosis was created.

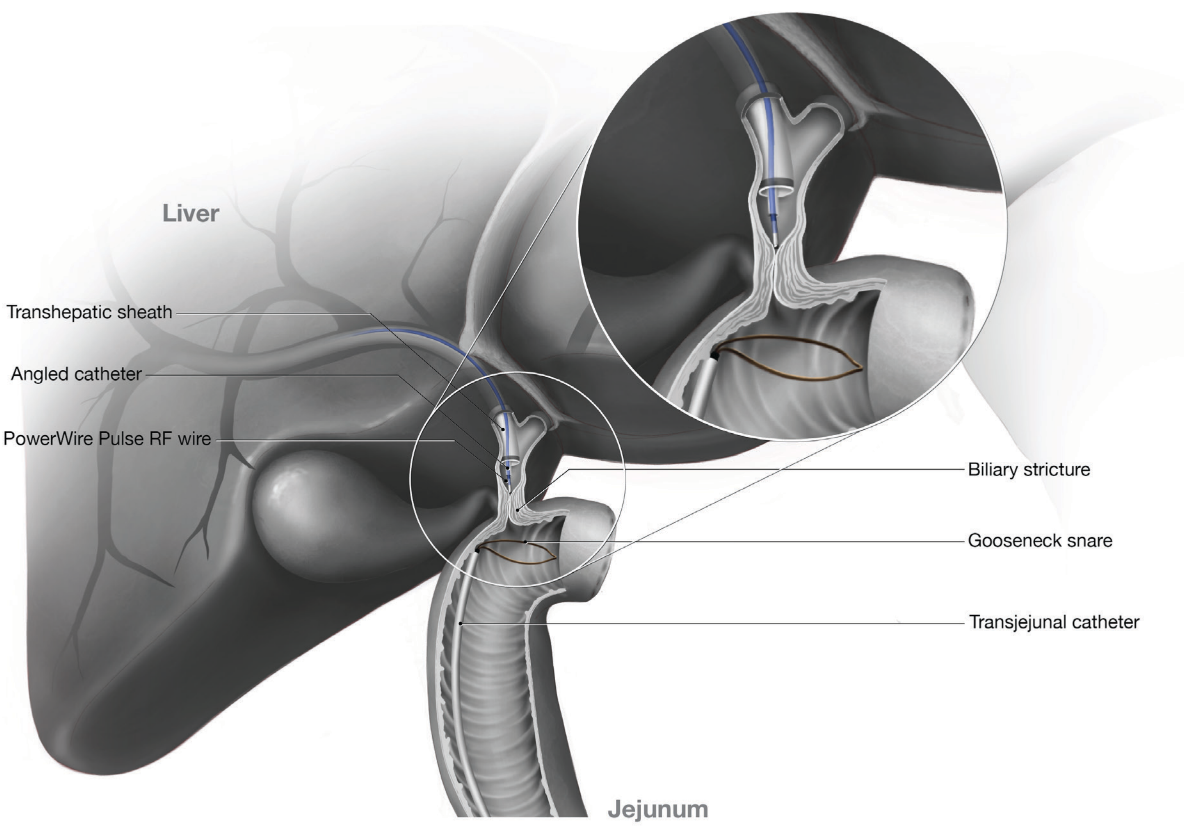

Figure 5a. Illustration of the cholangiogram depicting a snare placed in the jejunal loop through the transjejunal catheter. The RF wire was advanced to the stricture through an angled catheter placed via transhepatic access.

5. Robins et al. - Percutaneous Biliary Neo-anastomosis or Neo-duct Creation Using Radiofrequency Wires [6]

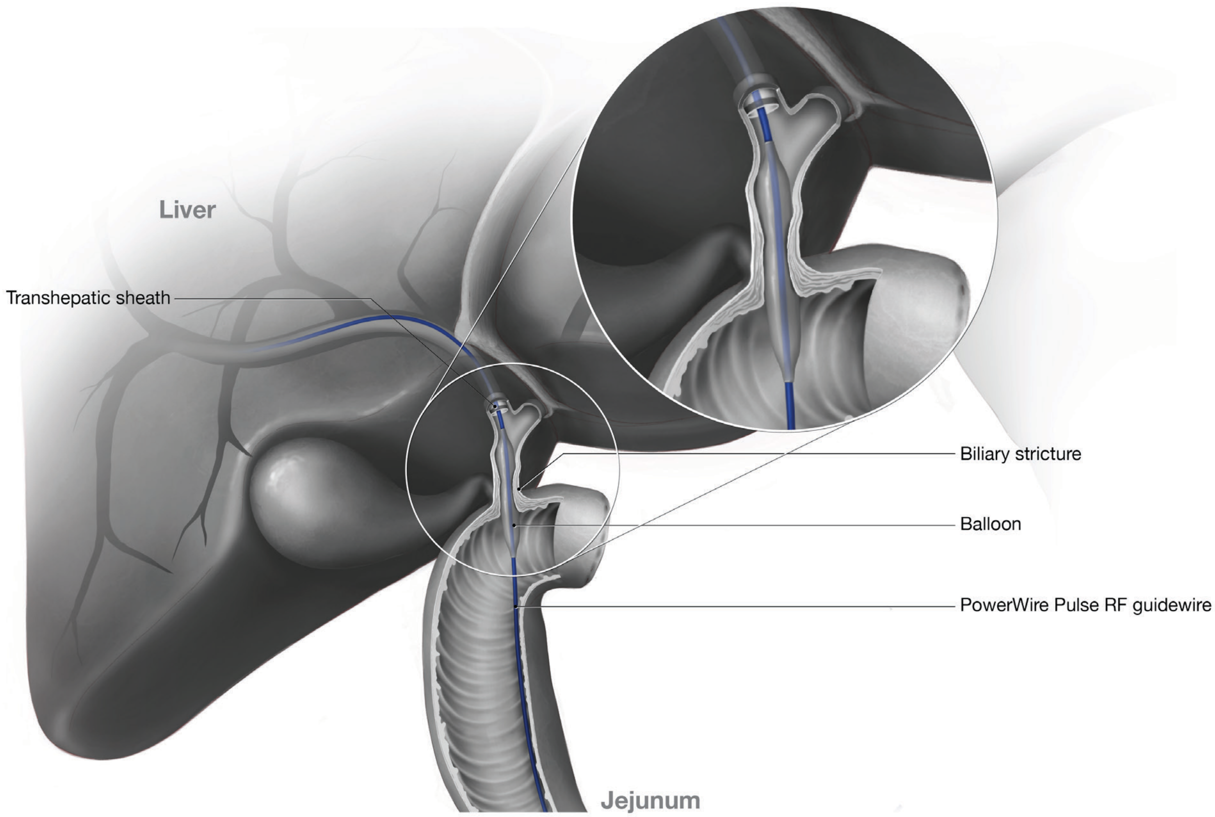

Figure 5b. Illustration of the cholangiogram depicting a balloon being used to dilate the neo-anastomosis for an internal–external biliary drain to then be placed.

Performance:

The procedure was technically successful in all five cases, enabling successful access through strictures.

In patients 1 and 2, a peroral endoscope was advanced to either the biliary-enteric anastomosis or the biliary stricture. The PowerWire® Pulse RF Guidewire was advanced into the distal target, which was visible via peroral endoscopy. The endoscopic view confirmed that the tip of the RF wire was correctly positioned within the bowel without percutaneous bowel access. This procedure aimed to navigate through the stricture and establish the desired access or drainage.

For patients 3, 4, and 5 (Fig. 5a and 5b), the RF wire was effectively passed through the stricture and snared from below the bowel using through-and-through access.

The neo-duct and neo-anastomoses remained patent in all patients, with follow-up periods ranging from 4 to 11 months.

5. Robins et al. - Percutaneous Biliary Neo-anastomosis or Neo-duct Creation Using Radiofrequency Wires [6]

Safety:

There were no RF-related complications or deaths related to the procedure in these patients. One patient experienced a recurrent stricture that necessitated replacing the biliary drain, but this did not require using the RF wire to cross the anastomosis. Additionally, two out of five patients reported pain from the internal-external biliary drain. The authors note the importance of knowing the relationship between blood vessels and other adjacent structures while advancing the RF wire. This can be performed by carefully reviewing pre-procedure cross-sectional imaging. In high-risk cases, the hepatic artery or portal vein can be catheterized to confirm that these vessels are not in the path of the RF wire tract. The authors also highlight the importance of having a distal target to advance the RF wire towards.

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PowerWire® Pulse RF Guidewire Techniques

A summary of techniques, safety, results, benefits, and disadvantages are discussed below.

The PowerWire® Pulse RF Guidewire technique involves several key procedural steps:

Imaging and Access: Visualization of the biliary anatomy via fluoroscopy or endoscopy to guide the RF wire to the occlusion or stricture.

RF Guidewire Advancement: The RF guidewire is inserted percutaneously and advanced to the target site, where RF energy is applied in controlled bursts to cut through fibrotic soft tissue. Techniques such as using a snare through a transjejunal catheter or opacifying the distal target area with contrast can enhance visualization, aiding accurate advancement to the target site.

Tract Creation: RF energy is applied to cut through soft tissue. The RF wire enables passage through fibrous strictures by delivering focused radiofrequency to puncture through the target tissue, thereby facilitating the creation of a patent biliary channel. This technique can be employed to recanalize an occluded duct or aid in the formation of a biliary anastomosis. Prior to dilation, it is essential to confirm that no critical vascular structures—such as the hepatic artery or portal vein—have been inadvertently crossed. Following successful traversal, adjunctive procedures including balloon dilation and stent placement may be performed as necessary to maintain bile flow.

Post-Procedure Management: After the tract is established, balloon dilation follows. Biliary drainage is maintained via a percutaneous catheter or stent placement to prevent recurrence. These drains or stents can be exchanged or upsized as needed to help the neo-duct or neo-anastomosis form with an acceptable diameter.

Clinical Imaging of Procedural Techniques: The images (a-g) below showcase techniques from an unpublished case courtesy of Dr. Ahsun Riaz, Northwestern Medical Group, Vascular and Interventional Radiology.

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This case presents a 58-year-old woman post-living donor liver transplant with two hepaticojejunostomies. The inferior anastomosis was accessible via a retrograde approach through the modified Hutson loop, while the superior anastomosis could not be identified using a transjejunal approach. Access was obtained percutaneously to enter this system. The steps including use of the RF wire are demonstrated below in Figure 6.

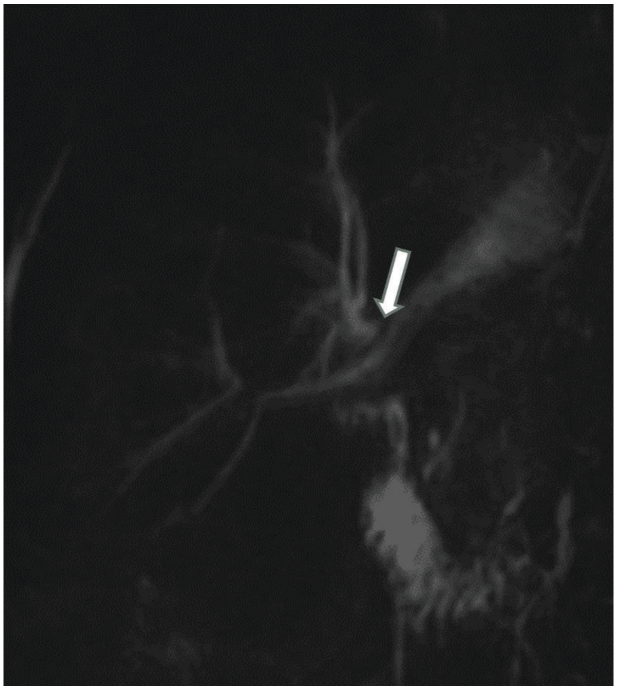

Figure 6a. Coronal MRCP image demonstrating the completely occluded superior right anastomosis (white arrow).

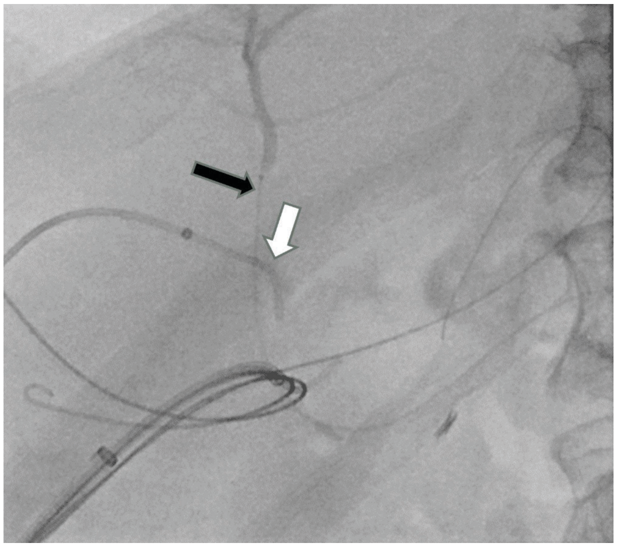

Figure 6c. A 5-French angled catheter was placed into the bile duct (white arrow). A microcatheter was placed into the right hepatic artery (black arrow) to ensure there was no damage to the hepatic artery while using the PowerWire® Pulse RF Guidewire.

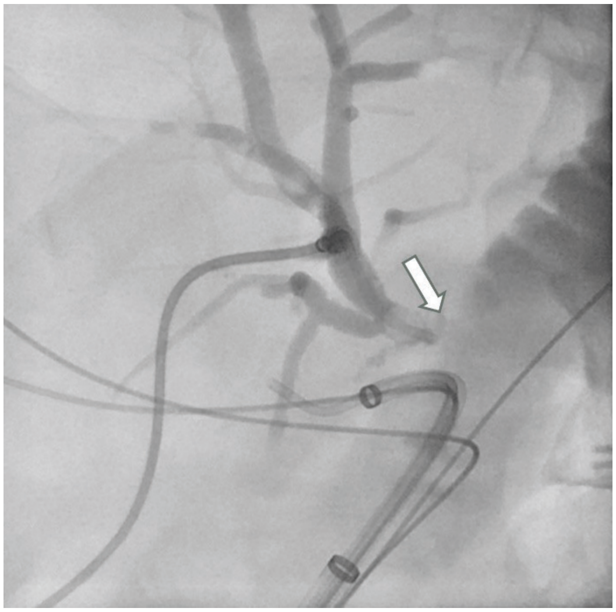

Figure 6b. Percutaneous access of the superior biliary system with a complete occlusion of this anastomosis (white arrow).

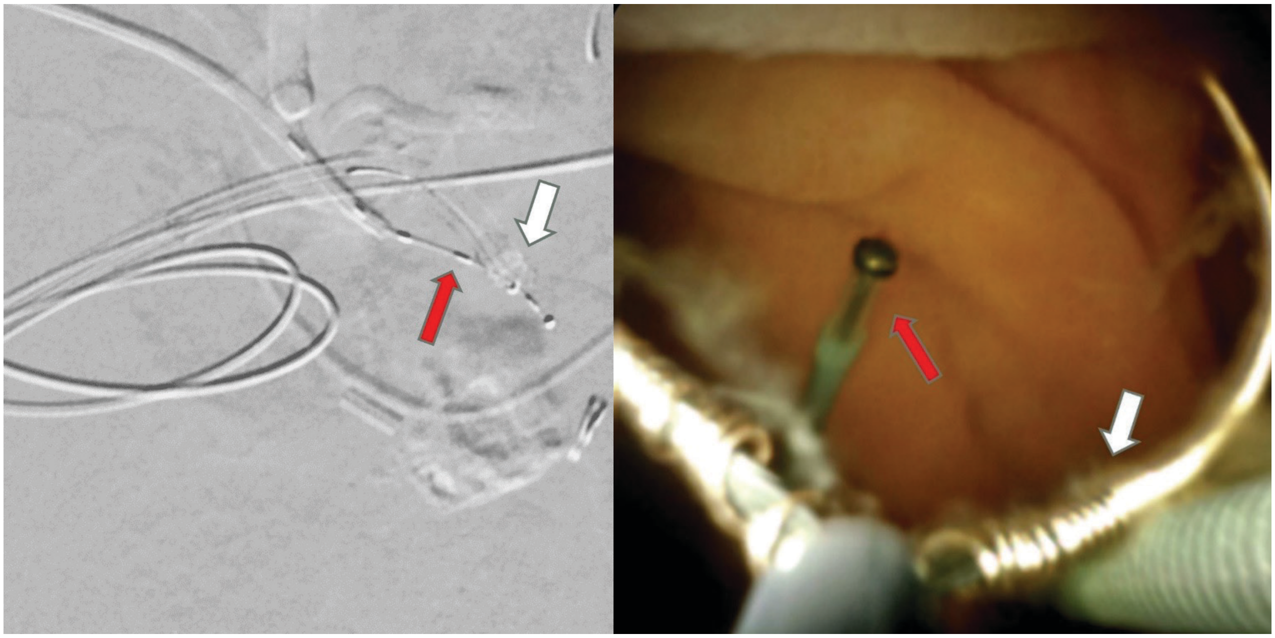

Figure 6d. Fluoroscopic and endoscopic view of an endoscope with snare in the jejunum (white arrow) using a transjejunal puncture (Hutson loop). The snare advanced through the endoscope and served as the target. The RF wire (red arrow) was then advanced into the jejunum to create a neo-anastomosis under fluoroscopic and endoscopic guidance.

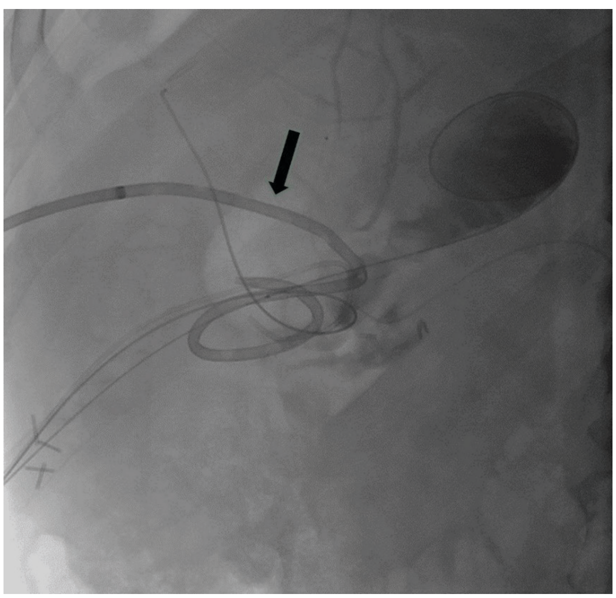

Figure 6e. A 5-French angled catheter was placed into the bile duct (white arrow). A microcatheter was placed into the right hepatic artery (black arrow) to ensure there was no damage to the hepatic artery while using the PowerWire® Pulse RF Guidewire.

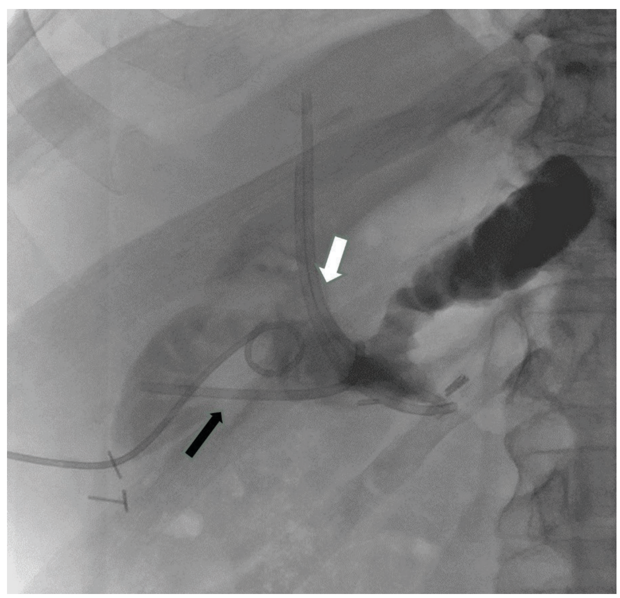

Figure 6f. Six weeks following the neo-anastomosis creation, the PTBD was replaced by two parallel plastic Cotton-Leung stents (white arrow). The black arrow points to the Cotton-Leung stent in the patent inferior biliary system.

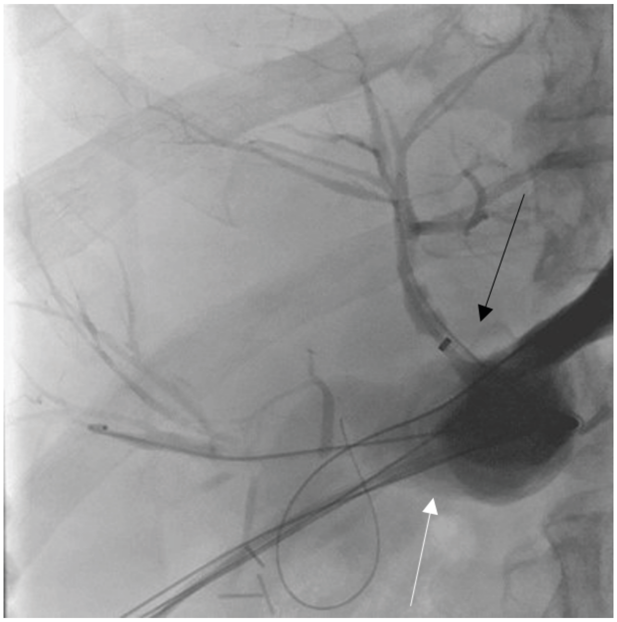

Figure 6g. Twelve weeks following the neo-anastomosis creation, the final cholangiogram demonstrates patency of the two anastomoses (black and white arrows). The stents were removed at this time.

Results [1,2,3,5,6]**:**

Technical Success: The clinical literature reports a 100% technical success rate with the PowerWire® Pulse RF Guidewire to cut through soft tissue in biliary interventions, resulting in both recanalizing strictures and creating neo-ducts/neo-anastomosis.

Long-Term Patency: The use of RF puncture in biliary interventions has been reported to lead to long-term patency of treated bile ducts, reducing the need for repeat procedures[5].

Safety [1,2,3,5,6]**:**

Complications: Reported complication rates are low but may include bile leakage, minor bleeding, or infection at the puncture site.

Post-Procedure Care: Close monitoring is required post-procedure to ensure that bile ducts remain patent, and no new obstructions develop. Laboratory values such as alkaline phosphatase and total/direct bilirubin levels can be used as markers for recurrent stenosis.

Benefits:

Minimally Invasive: The PowerWire® Pulse RF Guidewire provides a less invasive option for patients unresponsive to conventional techniques that are not suitable for surgery[1,3].

Cut Through Soft Tissue: Authors have reported that RF Puncture can be effective in cutting through soft tissue in cases of recurrent benign strictures or obstructions where other techniques have failed[1,2,3,5,6].

Convert External Drains to Internal External Drains: This helps with internal drainage of bile leading to decreased fluid-electrolyte losses, secures the drain to decrease dislodgement, and helps do procedures to decreased drain dwell time.

Cost: Use of the PowerWire® Pulse RF Guidewire System in an interventional setting is less costly than open surgery[20]. Additionally, open revision of the biliary-enteric anastomosis is not possible in some cases. This procedure can prevent the need for complex surgeries such as a liver transplant.

Drawbacks:

Access to RF puncture technology may be limited to specialized centers with expertise in interventional radiology. Anatomical knowledge of the surrounding critical structures, such as the hepatic artery and portal vein, is essential.

The procedure may be costly compared to traditional methods, depending on the healthcare system[14].

Operators must be skilled in both interventional radiology and the use of RF technology, which may limit the widespread adoption of this technique.

Conclusion [1,2,3,5,6,26]

The PowerWire® Pulse RF Guidewire is indicated to cut through soft tissue, enabling interventional techniques that represent significant advancements in biliary treatments. Its advanced technology allows for precise punctures that have been utilized in cases of complex biliary obstructions and strictures, particularly when conventional techniques prove ineffective. The clinical literature supports the RF guidewire's ability in cutting through soft tissue to recanalize obstructed ducts and create new biliary routes, while maintaining a favorable safety profile. As a minimally invasive alternative to surgery, the procedure using RF puncture technology has offered promising long-term clinical outcomes for patients with challenging biliary conditions. Future studies may further validate its use across a wider patient population.

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