

Evaluation of post-surgical complications between “Rendez-vous” technique vs standard care in patients with choledocholithiasis

Evaluación de complicaciones posquirúrgicas de la técnica «Rendez-vous» vs el manejo estándar en pacientes con coledocolitiasis

Osvaldo C. Barraza-Leones¹, Juan F. Coronado-Sarmiento^{2*}, Eduardo Valdivieso-Rueda³, Óscar J. Barrera-León³, and Enrique C. Ramos-Clason⁴

¹Departamento de Cirugía General, Universidad del Sinú EBZ, Seccional Cartagena, Colombia; ²Departamento de Cirugía, Universidad de La Sabana, Seccional Chía, Colombia; ³Departamento de Cirugía Gastrointestinal, Latin American Gastrointestinal Endoscopy Training Center, Bucaramanga, Colombia/Santiago de Chile, Chile; ⁴Coordinación de Investigaciones, Posgrados Médico-Quirúrgicos, Universidad del Sinú EBZ, Seccional Cartagena, Colombia

Abstract

Background: “Rendez-vous” (RV) technique is a mixed-technique which uses both laparoscopic and endoscopic skills; however, the evidence is contradictory regarding the implementation of this technique or the 2-step sequential technique (endoscopic retrograde cholangiopancreatography [ERCP] followed by laparoscopic cholecystectomy [LC]) in the management of cholecysto-choledocholithiasis. **Objective:** To estimate the association between the implementation of RV technique and the presence of post-surgical complications as primary outcome, using as comparator the 2-step sequential technique. **Method:** An observational, analytical, retrospective study was conducted, using as exposed cohort the medical records from patients with a diagnosis of cholelithiasis, cholecystitis, or mild biliary pancreatitis. The exposed cohort underwent RV technique, while the unexposed cohort were those which underwent two step technique. **Results:** There was a lower post-surgical complication rate in the RV group (0%) compared with the 10.1% ($p = 0.3617$) in the control group. Also, RV technique showed a lesser hospitalization time ($p = 0.0377$) and a lesser post-surgical hospitalization time ($p < 0.0001$). **Conclusions:** RV technique is superior when compared with the 2-step sequential technique (ERCP followed by LC), based on a better surgical success rate, a fewer complications rate and less hospitalization time.

Keywords: “Rendez-vous”. ERCP. Laparoscopic cholecystectomy. Surgical complications.

Resumen

Antecedentes: La técnica de «Rendez-vous» (RV) es una técnica mixta en la que se combinan las habilidades endoscópicas y laparoscópicas. La evidencia es contradictoria respecto al uso de RV frente a la técnica secuencial en dos tiempos (colangiopancreatografía retrógrada endoscópica [CPRE] seguida de colecistectomía laparoscópica [CL]) para el manejo de la colelito-coledocolitiasis. **Objetivo:** Estimar la asociación entre el uso de la técnica RV y la presencia de complicaciones posquirúrgicas como desenlace primario, en comparación con la técnica secuencial. **Método:** Se realizó un estudio observacional analítico retrospectivo que tomó como cohorte expuesta las historias clínicas de pacientes con diagnóstico de colelitis, colecistitis o pancreatitis leve de origen biliar sometidos a la técnica RV, y se compararon con registros en los que se realice

*Correspondence:

Juan F. Coronado-Sarmiento
E-mail: juanfcs13@gmail.com

Date of reception: 02-03-2021

Date of acceptance: 21-06-2021

DOI: 10.24875/CIRUE.M21000643

Cir Cir (Eng). 2024;92(3):323-329

Contents available at PubMed

www.cirugiaycirujanos.com

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la técnica de dos tiempos. **Resultados:** La tasa de complicaciones posquirúrgicas en el grupo de RV fue del 0%, frente al 10.1% ($p = 0.3617$) en el grupo control. Además, la RV presentó menor tiempo de hospitalización global ($p = 0.0377$) y posquirúrgica ($p < 0.0001$). **Conclusiones:** La técnica RV es superior a la técnica secuencial de CPRE seguida de CL, por su mayor tasa de éxito, menor tasa de complicaciones y menor tiempo hospitalario.

Palabras clave: «Rendez-vous». CPRE. Colectistomía laparoscópica. Complicaciones quirúrgicas.

Introduction

Cholelithiasis is the presence of masses (stones) composed of cholesterol or bilirubin located in the gallbladder, affecting 10% up to 20% of the adult population in the United States¹. Of the total cases, 11% up to 20% correspond to symptomatic stones^{2,3}, and laparoscopic cholecystectomy (LC) is the reference technique for their treatment^{4,5}. Choledocholithiasis is defined as the migration of these stones to the biliary tree, occurring in 10% up to 15% of patients undergoing cholecystectomy. In this case, endoscopic retrograde cholangiopancreatography (ERCP) followed by LC is the most widely used sequential procedure for its resolution. The diagnosis and treatment approach for these pathologies depend on multiple factors, including the level of suspicion of choledocholithiasis, the patient's hemodynamic status, available resources, patient preferences, and the expertise of professionals⁶.

Among the available resources is the "Rendez-vous" (RV) technique, a mixed technique that combines endoscopic and laparoscopic skills to extract retained stones from the common bile duct and perform LC in the same surgical act. This maneuver reduces cannulation time and the complications associated with endoscopic manipulation of major duodenal papilla⁷.

Back in 1993, Deslandres et al.⁸ were the first ones to report this combined laparo-endoscopic treatment, consisting of the transcystic insertion of a guidewire to reach the ampulla of Vater, facilitating cannulation, and eventual sphincterotomy and endoscopic extraction with a basket or balloon of the retained stones in the bile duct. Its implementation began in 1994 with 12 patients^{9,10} and became known as RV from 1997¹¹. In our case, the implemented technique is to perform a partial LC, dissecting the Calot's triangle, placing a clip at the level of the cystic artery and locating the cystic duct, then placing a distal clip and making a partial section of the cystic duct. Through the subxiphoid port, an Olsen clamp is placed, positioning it in the performed section, and through this, a 0.89 mm diameter and 450 cm long hydrophilic tip guidewire is

passed, moving it until it reaches the ampulla of Vater and thus the duodenal lumen. Subsequently, with the minimal necessary insufflation, the duodenoscope is moved to the second portion of the duodenum, and having the guidewire under direct vision, with a free tip of approximately 5 cm to 7 cm, it is looped using a polypectomy snare about 2 cm to 3 cm proximal to the papilla, to have a margin of maneuverability whenever there is traction. Once trapped, the guidewire is placed outside the working channel of the duodenoscope, and the entire sphincterotome is inserted into the common bile duct. After placing it, the sphincterotomy is performed and the sphincterotome is replaced by a Dormia basket to extract the stones. This is followed by successive and withdrawal reviews, confirming the bile duct permeability with bile output, and radiologically with cholangiography in search for filling defects. At the end of the ERCP, the insufflated air is aspirated, and the machine is withdrawn, reducing the distension of loops as much as possible, so the surgeon can conclude the LC.

Currently, the 2-stage technique is the most widely used by most surgeons in their routine clinical practice, despite evidence from prospective randomized clinical trials suggesting the superiority of single-stage management (RV), with significant variables including a higher stone extraction rate, shorter lengths of time, faster recovery times, greater comfort and convenience for the patient, and a lower complication rate, particularly of pancreatitis^{12,13}.

In contrast, evaluating the available evidence in retrospective studies, ERCP presents a higher failure rate to cannulate the ampulla of Vater (4-18%), an inadvertent cannulation and injection of contrast medium into the pancreatic duct with the consequent higher pancreatitis rate (2% up to 9%), excessive manipulation of the ampulla of Vater and the bile duct with secondary bleeding (10% up to 30%), and risk of perforation ($< 1\%$)^{14,15}.

Despite the demonstrated benefits of the RV technique, there is evidence showing limitations for its implementation, including greater difficulty in performing LC, longer surgical time, and considerable logistical

needs¹¹, introducing difficulties in structuring the duties of surgeons and endoscopists^{14,17}. Therefore, the present study aims to estimate the development of postoperative complications taking RV technique as an intervention and comparing it with the conventional technique (ERCP + LC).

Method

We conducted an analytical observational study with a retrospective cohort, using as an exposed cohort the medical histories of patients included in the Round List program, who attended various hospital centers in the cities of Bucaramanga and Floridablanca, in Colombia from January 2016 through January 2018 diagnosed with cholelithiasis, cholecystitis or mild biliary pancreatitis, and who clinically presented with a high suspicion of choledocholithiasis based on the presence of very strong predictors (American Society for Gastrointestinal Endoscopy [ASGE] criteria)¹⁸, with subsequent confirmation of the diagnosis by imaging modalities (hepato-biliary ultrasound, contrast-enhanced abdominal CT scan, or magnetic resonance cholangiography). The exposed cohort corresponded to patients who underwent the RV technique, while the non-exposed cohort (control) corresponded to patients who underwent the sequential technique of ERCP followed by LC. The primary endpoint was established as the development of postoperative complications while secondary endpoints were surgical time, ERCP execution time, procedure resolution capacity, and total and postoperative hospitalization times, considering variables such as age, sex, and indication for the technique.

Inclusion criteria

Patients older than 18 years with a diagnosis of cholelithiasis, cholecystitis, or mild biliary pancreatitis (Atlanta criteria¹⁹, at least, 1 of the 3) diagnosed with choledocholithiasis confirmed by imaging modalities (ultrasound, CT scan, magnetic resonance imaging) and clinically with the presence of very strong predictors (ASGE classification) for choledocholithiasis.

Exclusion criteria

Patients younger than 18 years or with, at least, 1 of the following conditions: moderate-to-severe pancreatitis (Atlanta criteria¹⁹), cholangitis, endoscopic or

imaging findings of neoplasm, porcelain gallbladder, primary choledocholithiasis, Mirizzi syndrome, biliary fistula, or ASA (American Society of Anesthesiologists) III/IV categorization²⁰.

Statistical analysis

Descriptive analysis was performed by calculating absolute and relative frequencies for qualitative variables, and for quantitative variables, median central tendency measures with their respective dispersion measure (interquartile range [IQR]) were used due to the non-parametric nature of these variables, estimated using the the Shapiro-Wilk test. To compare clinical characteristics and postoperative outcomes, the chi-square test or Fisher's exact test were used for qualitative variables as needed; quantitative variables were compared using the Mann-Whitney U test and a p values < 0.05 were considered statistically significant. Finally, crude and adjusted relative risks (RR) by Poisson regression with their respective 95% confidence intervals (CI95%) were estimated to analyze the association of the technique with the occurrence of complications.

Results

The study was conducted with a population of 127 patients, 91% of whom were women and 9%, men. The mean age was 48 years (IQR, 30-66; p = 0.942¹) in the RV group and 50 years (IQR, 30-66; p = 0.942¹) in the ERCP followed by the LC group. Of all the patients, 14.1% underwent RV, 83.3% of whom were women and 16.7%, men. The remaining 85.9% underwent the sequential technique of ERCP followed by LC, 76.2% of whom were women and 23.8%, men (Table 1).

In the RV group, the main indication for performing the surgical procedure was choledocholithiasis in 88.9% of participants (p = 0.019¹), 6 of whom (p = 0.361⁵) concomitantly had cholelithiasis. A total of 11.1% of participants (p = 0.019¹) concomitantly had mild biliary pancreatitis. In the control group, the main indication was choledocholithiasis in 100% of participants (p = 0.019¹), 23 of whom (p = 0.361⁵) concomitantly had cholecystitis, yet no patients with pancreatitis were included.

When evaluating the rate of endoscopic stone extraction, 100% of patients (p = 0.684⁴) who underwent the RV technique had a favorable outcome vs 98.1% (p = 0.684⁴) of the control group. In 1.8% of patients

Table 1. General characteristics of the study cohorts

Characteristic	RV group (n = 18)	n (%)	ERCP + LC group (n = 109)	n (%)	p
Age, years, mean (range)	48 (30-55)	-	50 (30-66)	-	0.9421
Gender	-	-	-	-	-
Female	15 (83.3)	-	83 (76.2)	-	0.7622
Male	3 (16.7)	-	26 (23.8)	-	0.9520

LC: laparoscopic cholecystectomy; ERCP: endoscopic retrograde cholangiopancreatography; RV: "rendez-vous".

($p = 0.563^9$), complete stone extraction was not achieved, considering it a failed procedure, with subsequent insertion of a biliary stent.

Regarding procedural complications, no complications occurred in the RV group, while in the control group, the complication rate was 10.1% ($p = 0.361^7$), and 4.6% of patients ($p = 0.355^7$) presented with pancreatitis, 1.8% ($p = 0.563^9$) perforation, and 3.7% ($p = 0.410^7$) with bleeding (Table 2).

Regarding the overall length of stay, the RV group had a mean of 7 days (IQR, 5-10; $p = 0.037^7$) and the control group a mean of 9 days (IQR, 7-12; $p = 0.037^7$). The postoperative length of stay was 2 days (IQR, 1-2; $p < 0.000^1$) in the RV group vs 4 days (IQR, 2-6; $p < 0.000^1$) in the control group.

Regarding surgical times, ERCP took 34 minutes (IQR, 26-50; $p = 0.939^9$) in the RV group vs 35 minutes (IQR, 22-60; $p = 0.939^9$) in the control group; LC took 100 minutes (IQR, 90-104; $p = 0.000^8$) in the RV group vs 70 minutes (IQR, 52-90; $p = 0.000^8$) in the control group. The overall surgical time was 131 minutes (IQR, 120-160; $p = 0.015^6$) in the RV group vs 110 minutes (IQR, 84-150; $p = 0.015^6$) in the control group (Table 2). Notably, the crude association between the RV technique and the sequential ERCP followed by LC technique was only statistically significant when comparing LC surgical time (crude RR, 1.44; 95%CI, 0.45-4.64; adjusted RR, 1.78; 95%CI, 0.31-10.31) with total surgical time (crude RR, 1.37; 95%CI, 0.44-4.25; adjusted RR, 1.03; 95%CI, 0.19-5.63). In the rest of the items, no statistically significant data were observed (Table 3).

Discussion

ERCP followed by LC is currently the reference technique^{4,5,21} for the resolution of choledocholithiasis

associated with cholelithiasis, cholecystitis, and biliary pancreatitis; however, the best resolution strategy is still debated.

Several studies^{8,15} have demonstrated the superiority of the RV technique due to its high success rate, high stone elimination rate, low complication rate, shorter lengths of stay, and the need for only 1 surgical act. One of the factors supporting its implementation is the theory that, after endoscopic sphincterotomy during ERCP, biliary contamination through the ascent of jejunal bacteria²² can lead to inflammation of the hepatoduodenal ligament, obstructing laparoscopic dissection of Calot's triangle and making LC difficult in a second surgical time; however, recent evidence has shown that this is not an independent predictor factor of difficult cholecystectomy²³.

On the other hand, the RV technique has been discussed because, in retrospective studies, it has been shown to significantly increase operating room time, in addition to requiring qualified and trained operators²⁴, and presents intraoperative difficulties specific to the technique, such as the supine position, which makes cannulation of the papilla difficult, or intestinal endoscopic insufflation, which interferes with LC. Therefore, Basso et al.²⁵, finding benefits in the application of the RV technique, considered it important to perform a total dissection of the gallbladder before performing the endoscopic procedure, to reduce the technical difficulty after intestinal insufflation with the endoscope. Other recommendations include using a laparoscopic intestinal clamp applied to the first jejunal loop²⁶, or minimizing inflation and prolonging aspiration before removing the endoscope²⁷, thus facilitating the implementation of this technique.

Now, comparing the clinical outcomes of the 2 techniques, regarding the endoscopic stone extraction rate in retrospective studies, ERCP has a cannulation failure rate that can reach up to 18%¹⁴, while with the RV technique it is $< 1\%$, with a sequential technique failure rate of 12.3% vs 0.7% for the RV technique ($p = 0.001$)^{27,28}. In relation to the success rate, reports for the RV technique vary between 90% and 100% vs the 82%-96% achieved by the sequential ERCP followed by LC technique²⁶, but with an incomplete stone elimination risk of up to 20% with the latter, due to the inability to cannulate the ampulla of Vater^{14,15}. In our study, when comparing the endoscopic stone extraction rate, a 100% resolution was evidenced in patients who underwent the RV technique vs 98.1% in the control group; however, this remaining 1.9% required 2 surgical acts to resolve their biliary

Table 2. Comparison of clinical outcomes observed in the study cohorts

Outcome	RV group (n = 18)	n (%)	ERCP + LC group (n = 109)	n (%)	p
Endoscopic stone extraction	18 (100.0)	-	108 (99.1)	-	0.6844
Stent insertion	0 (0.0)	-	2 (1.8)	-	0.5639
ERCP complication	0 (0.0)	-	11 (10.1)	-	0.3617
Pancreatitis	0 (0.0)	-	5 (4.6)	-	0.3557
Perforation	0 (0.0)	-	2 (1.8)	-	0.5639
Bleeding	0 (0.0)	-	4 (3.7)	-	0.4107
Overall length of stay (days), mean (range)	7 (5-10)	-	9 (7-12)	-	0.0377
Postoperative length of stay (days), mean (range)	2 (1-2)	-	4 (2-6)	-	< 0.0001
ERCP surgical time, min, mean (range)	34 (26-50)	-	35 (22-60)	-	0.9390
LC surgical time, min, mean (range)	100 (90-104)	-	70 (52-90)	-	0.0008
Overall surgical time, min, mean (range)	131 (120-160)	-	110 (84-150)	-	0.0156

LC: laparoscopic cholecystectomy; ERCP: endoscopic retrograde cholangiopancreatography; RV: “rendez-vous”.

Table 3. Crude and adjusted association by poisson regression of the use of the “rendez-vous” technique vs surgical time

Outcome	Crude RR	95% CI	Adjusted RR	95% CI
LC surgical time, min	1.44	0.45-4.64	1.78	0.31-10.31
Overall surgical time, min	1.37	0.44-4.25	1.03	0.19-5.63

LC: laparoscopic cholecystectomy; 95%CI: 95% confidence interval; RR, relative risk.

conditions, initially managed with the placement of a biliary stent and subsequently with a new ERCP time for the endoscopic extraction of the stones.

Rábago et al.²⁹ evaluated morbidity when applying these techniques and found that it was higher with the sequential technique than with the RV technique (23% vs 8.5%), with a need for ERCP repetition of almost 100% more in the sequential technique (10.2% vs 5.2%). In our work, no complications occurred in the RV group, but in the sequential technique, we reported complications in 10.1% of patients, distributed as follows: 4.6% (representing 45=5% of patients with complications) had pancreatitis, but we consider this finding expectable, given the association between ampulla of Vater manipulation and the development of this complication, which does not seem to vary concerning the surgical approach^{28,29}. However, the rate of pancreatitis is significantly higher with conventional ERCP vs the RV technique (12.7% vs 1.7%)³⁰. In our study, the sequential technique had a bleeding rate of

3.7% and a perforation rate of 1.8% (36.6% and 17.8% of the respective total of patients with complications); we consider this derives from the difficulty in cannulating the ampulla of Vater, which represents greater endoscopic manipulation. The RV technique confers a protective effect against these complications, given that cannulation is performed under indirect vision of the bile duct, in relation to the guidewire introduced retrogradely via the cystic duct¹¹.

Regarding ERCP surgical time, in the RV group it was 34 minutes ($p = 0.939^0$) while in the 2-stage technique it was 35 minutes ($p = 0.939^0$), with no statistically significant difference. However, when evaluating the duration of LC, it was longer in the RV group (100 vs 70 minutes) than in the sequential technique group ($p = 0.000^8$), probably related to the technical difficulty of the procedure, which coincides with the literature^{14,28}. Continuing with the length of stay, in our study the overall length of stay with the RV technique was shorter, with a mean of 7 days ($p = 0.037^7$), while with the sequential technique the mean was 9 days ($p = 0.037^7$). The postoperative length of stay was 2 days ($p < 0.000^1$) in the RV group vs 4 days ($p < 0.000^1$) in the control group. This mean difference of 4 days of hospitalization between techniques, in favor of RV represents a cost reduction of approximately €2000 per patient²⁸. Based on this and establishing that in our study the p was statistically significant in favor of the RV technique, we can extrapolate that there was also a lower hospitalization cost.

Additionally, as described in the literature³¹, early management of biliary lithiasis disease reduces readmission rates, improves the technical organization of the procedure³², and increases patient satisfaction, making RV technique the most advantageous therapy when analyzing the ideal management for cholecysto-choledocholithiasis³³.

The RV technique has demonstrated a higher surgical success rate, lower complication rate, shorter lengths of stay, lower costs, and greater patient satisfaction. Despite this, its overall implementation is low for several reasons, the first being the learning curve, as the need to implement an individual learning curve³⁴ is difficult to achieve because this procedure is performed in specialized centers, and it is usual for this management to be joint with the gastroenterology team, raising another difficulty related to the availability of an endoscopy specialist at the time of surgery^{35,36}, or whose second option should be training surgeons in the endoscopic technique³⁵. This, coupled with the need for multidisciplinary intrahospital structuring, facilitates the availability of additional equipment and materials as needed. Moreover, cost benefits have been reported³⁷, although it should be noted that this benefit is only valuable concerning the management of choledocholithiasis, but not when evaluated together with LC.

Conclusions

Cholelithiasis-related choledocholithiasis, cholecystitis, or biliary pancreatitis is a common disease in surgical services. Its management can be performed in 1 or 2 surgical acts. The laparoendoscopic or RV technique has shown superiority concerning a higher resolution rate, lower complication rate, shorter lengths of stay, and greater patient satisfaction. However, more multicentric studies with larger cohorts are needed to establish if there are other benefits, or if other adverse events arise by expanding its use. Similarly, more training is required for surgeons in this technique, based on the benefits it offers, allowing for broader implementation.

Funding

None declared.

Conflicts of interest

None declared.

Ethical disclosures

Protection of human and animal subjects. The authors declare that no experiments were performed on humans or animals for this study.

Confidentiality of data. The authors declare that they have followed the protocols of their work center on the publication of patient data.

Right to privacy and informed consent. The authors have obtained the written informed consent of the patients or subjects mentioned in the article. The corresponding author is in possession of this document.

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