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Radial sphincterotomy in endoscopic retrograde cholangiopancreatography for the management of choledocholithiasis of large elements, institutional experience

Esfinterotomía radial en colangiopancreatografía retrógrada endoscópica para manejo de coledocolitiasis de grandes elementos, experiencia institucional

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Keywords: choledocholithiasis, large stones, endoscopic retrograde cholangiopancreatography, radial sphincterotomy, common bile duct.

Palabras clave: *coledocolitiasis, litos de gran tamaño, colangiopancreatografía retrógrada endoscópica, esfinterotomía radial, vía biliar común.*

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ABSTRACT

Introduction: sphincterotomy is commonly used to remove stones from the bile duct and has a high success rate in stones < 10 mm; however, this decreases when larger stones appear; applying the radial sphincterotomy technique increases the surface area of the bile duct outlet, so its usefulness in the extraction of stones with large elements is the subject of this study. **Objective:** to describe the experience of using radial sphincterotomy in large element choledocholithiasis in our hospital. **Material and methods:** a longitudinal, retrospective, observational, and clinical study in patients diagnosed with large element choledocholithiasis who underwent endoscopic retrograde cholangiopancreatography and radial sphincterotomy between April 2021 and April 2023. Study variables: incidence, age at diagnosis, sphincterotomy results, and complications. **Results:** 35 records of patients diagnosed with large element choledocholithiasis were reviewed. An institutional incidence of 13% was obtained. The average age at diagnosis was 58.2 years. It was satisfactory in 85% of the cases. Complications occurred in 8% of cases, pancreatitis being the most common. **Conclusions:** radial sphincterotomy presents percentage gains in the geometric area compared to conventional sphincterotomy, which is why it has proven helpful in managing stones > 10 mm in the bile duct without increasing the rate of complications in this hospital.

RESUMEN

Introducción: *la esfinterotomía es comúnmente utilizada para remover litos de la vía biliar y tiene una alta tasa de éxito en litos < 10 mm; sin embargo, ésta disminuye al presentarse litos de mayor tamaño; aplicando la técnica de esfinterotomía radial se presenta un aumento en el área de superficie de salida de la vía biliar, por lo que su utilidad en la extracción de litos de grandes elementos es el tema de este estudio.* ***Objetivo:*** *describir la experiencia en el uso de esfinterotomía radial en coledocolitiasis de grandes elementos en nuestro centro hospitalario.* ***Material y métodos:*** *estudio retrospectivo, observacional y clínico en pacientes con diagnóstico de coledocolitiasis de grandes elementos sometidos a colangiopancreatografía retrógrada endoscópica a los cuales se les realizó esfinterotomía radial entre los meses de abril de 2021 a abril de 2023. Variables de estudio: incidencia, edad al momento de diagnóstico, resultado de esfinterotomía y complicaciones.* ***Resultados:*** *se revisaron 35 expedientes de pacientes con diagnóstico de coledocolitiasis de grandes elementos. Se obtuvo una incidencia institucional de 13%. Edad promedio al momento del diagnóstico 58.2 años. Fue satisfactoria en 85% de los casos. Se presentaron complicaciones en 8% de los casos, la más común fue la pancreatitis.* ***Conclusiones:*** *la esfinterotomía radial, presenta porcentajes de ganancia en el área geométrica en comparación con la esfinterotomía convencional, por lo que ha demostrado utilidad para manejo de litos > 10 mm en la vía biliar, sin aumentar la tasa de complicaciones en este centro hospitalario.*

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Abbreviation:
ERCP = endoscopic retrograde cholangiopancreatography.

INTRODUCTION

The high worldwide prevalence of gallbladder stones (10-20%) has conferred an inherent risk of developing choledocholithiasis, followed by primary choledocholithiasis, which has an incidence of 4-10% of the population. Endoscopic retrograde cholangiopancreatography (ERCP), as a diagnostic and therapeutic tool, began to be used in 1968, followed by the first sphincterotomy in 1974, becoming the gold standard in the management of common bile duct stones as it is a highly effective, minimally invasive, and safe procedure. Common duct stone removal techniques include sphincterotomy, mechanical lithotripsy, papillary balloon dilatation, and cholangioscopy-guided lithotripsy.[1] However, several factors make stone removal difficult, including large stones, which is defined as a stone greater than or equal to 10 mm. Because of this, the risk of a failed ERCP, with no possibility of removing the common bile duct stone, is 10-15%. Anatomically, Oddi's sphincter is divided into bile duct and pancreatic sphincter, followed by a common segment and the ampulla. The latter is usually located in the second portion of the duodenum and appears as a nodular prominence on the lateral wall. It is a site where sphincterotomy is performed in search of access to the bile duct to remove the duodenum. This technique has been widely described and has been shown to be close to 100% effective in stones smaller than 10 mm. However, the success rate decreases up to 12% in stones larger than 15 mm.[2] Therefore, the management of large choledocholithiasis still represents a challenge and involves the risk of advanced endoscopic techniques or surgery with bile duct exploration, which, if unsuccessful, will lead to the development of complications such as cholangitis and sepsis in the patient. The aim of this study is to present the experience in a hospital center for the management of large element choledocholithiasis with radial sphincterotomy.

MATERIAL AND METHODS

Objective: to describe the experience in using radial sphincterotomy during endoscopic retrograde cholangiopancreatography (ERCP) to manage large element choledocholithiasis in our hospital center. In a retrospective, observational, and clinical study performed in patients diagnosed with large element choledocholithiasis, from April 2021 to April 2023, 252 endoscopic retrograde cholangiopancreatography (ERCP) procedures were performed. The diagnosis was confirmed at the time of the procedure during cannulation and fluoroscopy of the biliary tract. Patients with common bile duct stones > 15 mm who underwent radial sphincterotomy were included. The information was obtained from medical records and notes, and endoscopic reports.

Variables analyzed: incidence, sex, age at diagnosis, sphincterotomy result, and complications.

Statistical analysis: for data management, means between independent groups were recorded, and a parametric statistical test was applied. Categorical variables are reported in frequency and percentages.

RESULTS

Of the 252 patients who underwent ERCP, 35 were found and included in this report. They had a diagnosis of large element choledocholithiasis, presenting an incidence of 13%; 25 of the cases were women, and only 10 were men. The average age at presentation was 58.2 years; however, the age ranged from 20 to 91. All subjects underwent endoscopic retrograde cholangiopancreatography (ERCP), with the same frequency of 15 mm lithiasis with 13 cases and 13 cases of 20 mm lithiasis; the rest ranged from 14 to 25 mm. Radial sphincterotomy was performed in all patients. The removal of common bile duct stones was successful in 30 cases, while the stone could not be removed in five patients, which corresponds to a success rate of 85%. In most cases (33), a balloon was used to remove the stone. Only in two cases was a Dormia basket used. Complications were reported in only three patients, two of whom

developed pancreatitis, while one of them developed cholangitis.

DISCUSSION

Choledocholithiasis most frequently results from the migration of bile from the gallbladder into the biliary tree. They are formed as a consequence of cholesterol saturation in the bile, inadequate bile salt function, and decreased contractility of the biliary epithelium.[3] One of the risk factors for the development of lithiasis is related to being female; 25 of the 35 files analyzed belonged to this group, while the remaining ten were male, as reported in our study, age over 40 years, obesity, and rapid weight loss.[4] Choledocholithiasis has a concomitant incidence with gallbladder lithiasis of 7-12%. The size of the stones varies from small (1-2 mm) to large (15-30 mm); this study focused on stones > 14 mm, with 15- and 20-mm stones being more frequent comprising 75% *(Figure 1)*. Their management represents an important clinical problem. Endoscopic retrograde cholangiopancreatography (ERCP) with the use of a Dormia basket or balloon has become the standard management for this condition, and it is estimated that 85-95%[5] of choledocholithiasis resolved satisfactorily by this endoscopic method.

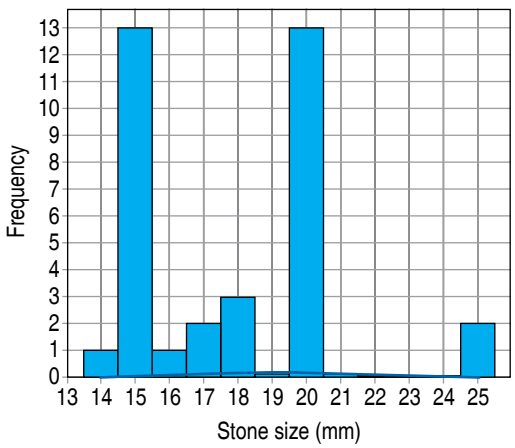

Figure 1: *Frequency of common bile duct stone size.*

Multiple factors have been reported to hinder the success of ERCP removal of lithiasis. It is estimated that approximately 10-15% are related to difficulty in accessing the bile duct (periampullary diverticulum, sigmoid morphology of the common bile duct, postgastrectomy Billroth II anatomy, Roux-en-Y gastrojejunostomy), large number of stones (> 10), large size of stones (> 15 mm), unusual shape of stones or abnormal location (intrahepatic, cystic duct, proximal structures).[6] However, stone size is the most challenging factor, and multiple studies have demonstrated that stone size is inversely proportional to the clearance of the bile duct during ERCP.[7] Successful bile duct stone removal depends on two general principles: decreasing the size of the stone and increasing the surface area of the bile duct outflow orifice.[8] Because of this, sphincterotomy combined with balloon dilatation has become the first-line approach. Standard sphincterotomy has been extensively detailed and consists of an electrocautery incision in the 11, 12, or 1 o'clock direction, depending on the papilla's anatomy and the stone size. Subsequently, a balloon sweep or the use of a cannula can be performed to extract the stone. The maximum length of the incision depends on the length of the longitudinal fold from the papilla to the first transverse fold.[9] The safe, natural anatomic boundaries are around the papilla, which makes it an insufficient incision for large element (< 15 mm) stones. Because of this, in 2020 Kenan Yusif-Zade described and compared the improved method for radial sphincterotomy, in which multiple incisions are performed in a single session towards 11, 12, and 1 o'clock conventional clock positions; this provides a larger total cross-sectional area, at least 1.5 times larger, compared to conventional sphincterotomy.[10] *Figure 2* depicts the radial sphincterotomy surface as proposed in the referenced article, which is bounded by the vertices in the interval [V1-V8]; the area of this surface is taken as A. Similarly, the standard sphincterotomy geometry is formed by the surface of vertices V1, V2, Vn, Vm, V8; the area of this surface is taken as B. To

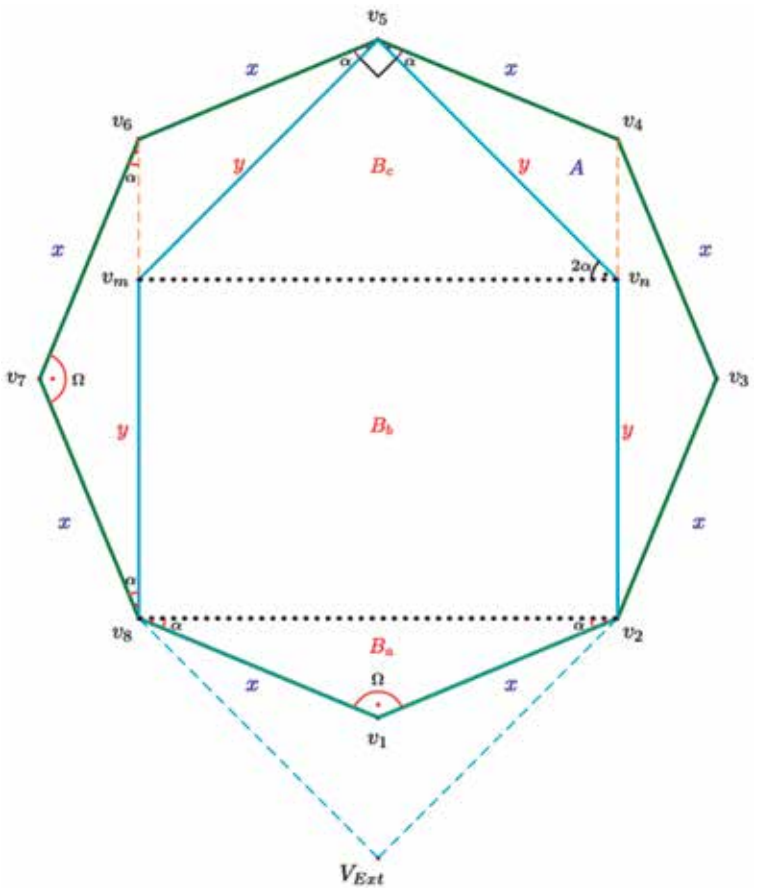

Figure 2: *Geometric comparison of conventional sphincterotomy area vs radial sphincterotomy.*

verify the area gain factor, the trigonometric analysis was replicated to compare areas A and B in much the same way as performed by Kenan Yusif-Zade. The gain σ is defined by the relation (1) *(Figure 3)*, where area A is directly proportional to area B and the gain factor σ. If the edges bounding each vertex vi of A, have length x, and the top four edges of B are worthy, leaving everything a function of a single variable is convenient. We have information: Ω = 135° and α = Ω / 6. It is straightforward to determine the relationship between the variables x and y in *Figure 2*, where the geometric segment bounded by the vertices v2, v3, v4, and v5 is shown. Adding the Euclidean distance vno + ov2 results in equation (2) *(Figure 3)*. Area A is a regular octagon, but with B, dividing each area section into known geometries, Ba, Bb, Bc, and applying corresponding formulas is convenient. From this analysis, equations (3), (4), and (5) are determined *(Figure 3)* for each area section, all as a function of a single variable, the length of edge x. If the gain σ is calculated by the geometric ratio of area A between area B, where B = Ba + Bb + Bc, then the resulting factor is 1.333333..., i.e., the area of A is approximately 4/3 greater than area B, or A represents 33.33% more area than B. Thus, it can be deduced that increasing the sphincter exit area by 1.333333 allows larger volume stones to exit. The success rate demonstrated in this study corresponds to 85%, with satisfaction in 30 procedures concerning the five that were not satisfactory in large element choledocholithiasis, representing a significant increase compared to that reported in the literature, ranging from 15-20%. Like any procedure, it is not exempt from developing complications, and despite the indication and population, mortality and morbidity rates after sphincterotomy are reported in the literature to be approximately 10%.[11] In this regard and in relation to this study, we can define any adverse event related to ERCP in which sphincterotomy was performed as a complication. In the literature, between 7 and 10% of patients undergoing ERCP had any complication[12] which corresponds to the complications presented in the population of this study *(Figure 4)*. Post-ERCP pancreatitis is defined as the presence of abdominal pain and

$$(1)\ \sigma B = A$$

$$(2)\ y = x(\cos\alpha + \sin\alpha)$$

$$(3)\ B_a = \frac{x^2 \sin\Omega}{2}$$

$$(4)\ B_b = x^2 \frac{\sin\Omega}{\sin\alpha}(\cos\alpha + \sin\alpha)$$

$$(5)\ B_c = x^2 \sin\Omega \cos\alpha\,(\cos\alpha + \sin\alpha)$$

Figure 3: *Trigonometric analysis of area in sphincterotomy.*

elevation of pancreatic enzymes, which usually leads to a course of mild pancreatitis in 42% of cases,[13] both in the literature and in this study. It was found to be the most frequent complication and generally presented in its mild form, with satisfactory resolution with supportive management and allowing patients to leave the hospital an average of three days after the procedure. Hemorrhage is defined as bleeding data such as melena or hematemesis associated with a decrease of 2 g in hemoglobin concentration and did not occur in this group of patients.[14] It is necessary to compare different techniques for bile duct clearance. However, it is worth considering radial sphincterotomy as a therapeutic option, with a high possibility of success in patients with this pathology.

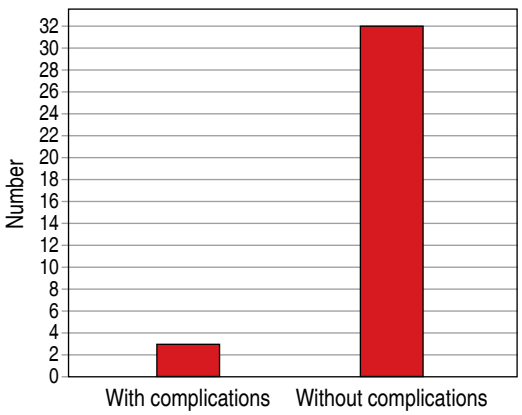

Figure 4: *Frequency of complications.*

CONCLUSIONS

Radial sphincterotomy during the performance of endoscopic retrograde cholangiopancreatography *(Figure 5)* presents an area gain factor of 1.333 demonstrated by replicating the trigonometric analysis, which represents an increase in the surface maneuvering margin, which represents a difference in the diameter of the segment for the extraction of the stone. The mathematical analysis has demonstrated the theoretical increase in the area for extraction. The complication rate is similar and remains within the expected parameters, like conventional sphincterotomy, while the success rate rises to 85% for large element choledocholithiasis in this study. It is convenient to carry out further studies to compare other techniques for biliary tract clearance in cases of large element choledocholithiasis, as well as to know the limit of the tissue enlargement field due to the thickness of the walls and their elasticity without representing risks for the structures involved, nor for the patient.

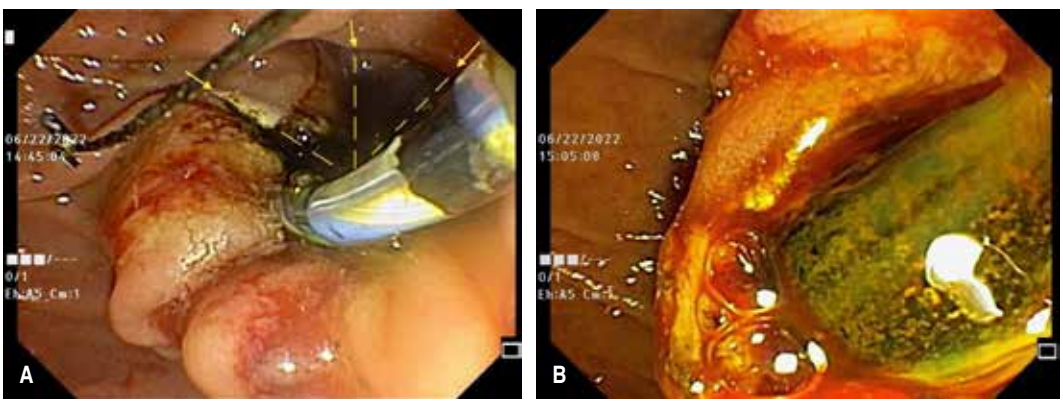

Figure 5: ***A)*** *Radial sphincterotomy technique in endoscopic retrograde cholangiopancreatography.* ***B)*** *Clarification of the biliary tract with the exit of a large bile duct stone through the Oddi sphincter.*

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