





Endoscopic appearance of major duodenal papilla influences biliary cannulation immediate complications and underlying diagnosis

Aspecto endoscópico de la papila duodenal mayor influye en la cannulación biliar complicaciones inmediatas y diagnóstico subyacente

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Abstract

Introduction: ERCP is the primary treatment for benign and malignant pancreatic-biliary diseases. Procedure success and safety depend on indication. The research examined how endoscopic presence of the main duodenal papilla affects ERCP bile duct cannulation. **Method:** 226 cases This study included adult Iraqi male and female hospitalised patients over 18. These individuals seek hospital ERCP for extrahepatic biliary blockage from various causes. The incidence of problematic cannulation and the correlation of papilla type with age, gender, underlying diagnosis, and acute problems were the main outcome measures. **Results:** This research includes 226 male and female subjects over 18. 87 (38.5%) male, 139 (61.5%) female, aged 19–101. 86.5% (n=96) of female type 1 and type 4 papilla patients had common bile duct stones. Most ERCPs were for common bile duct stones (72.6%). Type 1 ampulla (49%), type 2 (16.4%). Difficult biliary cannulation was 53.1% (n=120), with type 4 papilla being the hardest (92.3%; n=36) and type 1 being the easiest (83.8%; n=93). Precuts were done in 36.3% (n=82) of instances, largely with type 4 papilla (76.9%; n=30) and acute complications in 15% (n=34), predominantly bleeding (97.1%; n=33) and mostly with type 2 (32.4%; n=12). **Conclusion:** the gender of patient and underlying diagnosis associated with shape of papilla while the age not. Type 1 papilla is the most common type. The shape of papilla significantly affects the difficulty of biliary cannulation, the use of precut and immediate complications.

Keywords: biliary cannulation, Endoscopic retrograde cholangiopancreatography, major duodenal papilla, pancreatic duct cannulation.

Resumen

Introducción: La CPRE es el principal tratamiento de las enfermedades pancreático-biliares benignas y malignas. El éxito y la seguridad del procedimiento dependen de la indicación. La investigación examinó cómo la presencia endoscópica de la papila duodenal principal afecta la canulación del conducto biliar por CPRE. **Método:** 226 casos Este estudio incluyó a pacientes iraquíes adultos, hombres y mujeres, hospitalizados mayores de 18 años. Estos individuos solicitan CPRE hospitalaria por obstrucción biliar extrahepática por diversas causas. Las principales medidas de resultado fueron la incidencia de canulación problemática y la correlación del tipo de papila con la edad, el sexo, el diagnóstico subyacente y los problemas agudos. **Resultados:** Esta investigación incluye 226 sujetos masculinos y femeninos mayores de 18 años. 87 (38,5%) hombres, 139 (61,5%) mujeres, de 19 a 101 años. El 86,5% (n=96) de las pacientes con papila tipo 1 y tipo 4 del sexo femenino tenían cálculos en el conducto biliar común. La mayoría de las CPRE fueron por cálculos en el colédoco (72,6%). Ampolla tipo 1 (49%), tipo 2 (16,4%). La canulación biliar difícil fue del 53,1% (n=120), siendo la papila tipo 4 la más dura (92,3%; n=36) y el tipo 1 la más fácil (83,8%; n=93). Se realizaron precortes en el 36,3 % (n=82) de los casos, en gran parte con papila tipo 4 (76,9 %; n=30) y complicaciones agudas en el 15 % (n=34), predominantemente hemorrágicas (97,1 %; n=33.) y mayoritariamente con tipo 2 (32,4%; n=12). **Conclusión:** el género del paciente y el diagnóstico subyacente asociado con la forma de la papila mientras que la edad no. La papila tipo 1 es el tipo más común. La forma de la papila afecta significativamente la dificultad de la canulación biliar, el uso de precorte y las complicaciones inmediatas.

Palabras clave: canulación biliar, colangiopancreatografía retrógrada endoscópica, papila duodenal mayor, canulación del conducto pancreático.

Endoscopic retrograde cholangiopancreatography (ERCP) is a widely discussed procedure, primarily in the context of bile duct cannulation. A variety of technical and patient-related factors influence the success of cannulation and potential complications^{1-3,4-6}. A significant detail that has been understudied is how the macroscopic appearance of the major duodenal papilla affects cannulation, immediate complications, and the correlation with the underlying diagnosis. ERCP is typically performed in hospital settings, appreciated by physicians, staff, and patients for the convenience and efficiency it provides. Being in a hospital facilitates the procedure for inpatients and allows easy access to facilities for post-procedure observation¹. The procedure is preferred for managing various benign and malignant pancreatic-biliary disorders, with the success and safety largely dependent on the procedure's indication, the physician's skill, and the functionality of the ERCP unit¹. Essential equipment for ERCP includes a dedicated ERCP room and fluoroscopy unit, along with duodenoscopes, biliary cannulas, sphincterotomes, balloon catheters, needle knives, guidewires, stents, and other equipment necessary to execute the procedure and resolve patient issues¹. The process involves advancing a duodenoscope through the mouth, esophagus, and stomach, then into the duodenum. Identification of the papilla and proper access and orientation of the biliary duct are achieved using specific techniques and maneuvers. Biliary access is typically done through sphincterotomy and guidewire usage, followed by contrast agent injection (cholangiogram) to validate the correct position and underlying disorders. Occasionally, access is achieved through needle-knife precut or other maneuvers. However, these actions put the patient at risk of complications such as bleeding, perforation, pancreatitis, and procedure failure²⁻⁶. Until now, the impact of the macroscopic appearance of the major duodenal papilla on cannulation difficulties has not been systematically studied. Before determining this association, it's necessary to have a clear definition of a "difficult bile duct cannulation" to ensure the evaluations of cannulation difficulties are relevant and reproducible. Various definitions have been proposed⁷, but since 2016, the European Society for Gastrointestinal Endoscopy (ESGE)⁸ recommends the definition presented in the Scandinavian Association of Digestive Endoscopy group study. The aim of study is to assess the endoscopic presence of the major duodenal papilla has on the capability to do bile duct cannulation during ERCP.

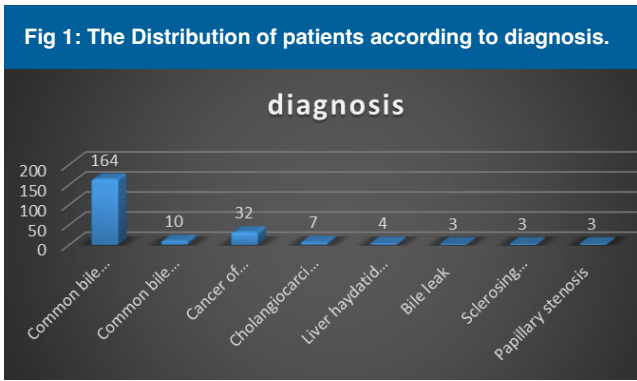
From 1st January 2019 until 1st January 2021 in Iraq, Bagdad, Medical City Complex, Gastroenterology and Hepatology Teaching Hospital, total of 226 cases Iraqi adult patients age more than 18 years old, male and female, hospitalized in this period were studied. Distributed as common bile duct stone (164 cases), common bile duct stricture (10 cases), pancreatic cancer causing obstructive jaundice (32 cases), extra hepatic cholangiocarcinoma (7 cases), liver haydatid cyst with biliary communication (4 cases), post cholecystectomy bile leak (4 cases), sclerosing cholangitis (3 cases) and papillary stenosis (3 cases). Sphincterotomy and guidewire were used for biliary cannulation in the majority of cases. If the guidewire did not advance to the bile duct, pre-cut with needle knife or trans pancreatic sphincterotomy with/without pancreatic stent insertion was applied. ERCP performed with either Olympus EVIS EXERA III CV-190 system or PENTAX video scope EPK-i5000 system. Included in this study patient had to be: More than 18 years old. Intact naïve major duodenal papilla. (A major papilla that has not undergone a prior biliary sphincterotomy). Common bile duct cannulation the desired duct not the pancreatic duct. Exclusion criteria were: Age less than 18 years old. Periampullary diverticulum, Obvious tumors of the papilla, Patient with surgically altered anatomy. The primary outcome measures were the differences in the frequency of difficult cannulation distributed between the types of papilla and association of papilla type with age, gender, underlying diagnosis and immediate complications. Problematic cannulation of bile duct was assessed by 5-5-2 measure: time to effective bile duct cannulation > 5 minutes from first touch of the papilla, effort > 5 contact and passageway of catheter or guidewire to papilla, bile duct or pancreatic duct and 2 or more passage of guidewire to pancreatic duct^{5,9}. Statistical analysis done by SPSS version 23. In categorical variables used frequencies and percentages. In continuous variables used (Means ± SD). ANOVA test used to compare means between three groups or more. Pearson's chi square (X²) and Fisher-exact tests used for association between variables. A p-value of ≤ 0.05 is significant.

Results:

The majority of patients were female (61.5%) and age were distributed from 19 years old to 101 years old, mean was (53.40 ± 19.19). The distribution of patients according to study variables including (time to successful bile duct cannulation, number of cannulation attempts and number of MPD cannulation). In general, successful bile duct cannulation was done in less than 5 min. in 52.2% and more than 5 min. in 47.8%, cannulation attempt was less than 5 in 49.1% and more than 5 attempt in 50.9%. MPD cannulation was 0 in 65.9%, once in 18.6% and two or more in 15.5%. The distribution of patients according to study variables including (use of precut to gain biliary access, immediate complication and procedure failure). In general, precut were done in 36.3% of cases and immediate complications occurred in 15% only with 85% no complications from which bleeding is the most common complication that occurred in 33 cases (97.1%) and only one case (2.9%) with perforation. Procedure failure (failure to gained biliary access were 19 cases (8.4%) only.

Table 1: frequency of variables includes in current study.		
Study variables	N	(%)
Age	(53.40 ± 19.19)	(19-101)
Gender		
Male	87	38.5%
Female	139	61.5%
Total	226	100.0%
Time to successful bile duct cannulation (minutes)		
< 5 minutes	118	52.2%
> 5 minutes	108	47.8%
Total	226	100.0%
Number of cannulation attempts		
< 5	111	49.1%
> 5	115	50.9%
Total	226	100.0%
Number of MPD cannulation		
0	149	65.9%
1	42	18.6%
2	35	15.5%
Total	226	100.0%
Use of precut to gain biliary access		
Yes	82	36.3%
No	144	63.7%
Total	226	100.0%
Immediate complication		
Yes	34	15.0%
No	192	85.0%
Total	226	100.0%
Type of complication		
Bleeding	33	97.1%
Bleeding and perforation	1	2.9%
Total	34	100.0%
Procedure failure		
Yes	19	8.4%
No	207	91.6%
Total	226	100.0%

distribution of patients according to diagnosis including (common bile duct stone, common bile duct stricture, Cancer of pancreas, cholangiocarcinoma, liver haydatid cyst, bile leak, sclerosing cholangitis and papillary stenosis). Majority (72.6%) of patients presented with common bile duct stone. As show in fig 1.



The mean differences of age (years) according to type of ampulla including (type 1, type 2, type 3 and type 4). There were no significant differences between means of age according to type of ampulla. As show in table 2.

Table 2: The mean differences of age (years) according to type of ampulla						
Study variable	Type of ampulla	N	Mean	SD	F-test	P-value
Age (years)	1	111	52.30	19.37	2.215	0.087
	2	37	48.27	16.73		
	3	39	56.61	19.25		
	4	39	58.20	19.90		

*P value ≤ 0.05 was significant

Table 3 shows the association between type of ampulla and study variables including (gender and underlying diagnosis of the patients). There was significant association between type of ampulla and study variables. The majority of female patient with type 1 and type 4, were as the majority of male patient with type 3 and slightly type 2. 86.5% of patients with type 1 ampulla had common bile duct stone, stricture (7.7%) in type 3 and type 4, pancreatic cancer with type 3 ampulla, cholangiocarcinoma type 2.

Table 3: Association between type of ampulla and age, gender and underlying diagnosis.

Study variables	Type of Ampulla				Total	χ^2	P-value
	Type 1	Type 2	Type 3	Type 4			
Gender						14.79	0.002*
Male	30 (27.0)	18 (48.6)	23 (59.0)	16 (41.0)	87 (38.5)		
Female	81 (73.0)	19 (51.4)	16 (41.0)	23 (59.0)	139 (61.5)		
Total	111 (100.0)	37	39	39	226 (100.0)		
		(100.0)	(100.0)	(100.0)			
Diagnosis							
Common bile duct stone	96 (86.5)	20 (54.1)	19 (48.7)	29 (74.3)	164 (72.6)		
Common bile duct stricture	2 (1.8)	2 (5.4)	3 (7.7)	3 (7.7)	10 (4.4)		
Cancer pancreas	8 (7.2)	7 (18.9)	12 (30.8)	5 (12.8)	32 (14.2)		
Cholangiocarcinoma	1 (0.9)	3 (8.1)	2 (5.1)	1 (2.6)	7 (3.1)		
Liver haydatid cyst	2 (1.8)	1 (2.7)	1 (2.6)	0 (0.0)	4 (1.8)		<0.001* f
Bile leak	1 (0.9)	2 (5.4)	0 (0.0)	0 (0.0)	3 (1.3)		
Sclerosing cholangitis	0 (0.0)	2 (5.4)	0 (0.0)	1 (2.6)	3 (1.3)		
Papillary stenosis	1 (0.9)	0 (0.0)	2 (5.1)	0 (0.0)	3 (1.3)		
Total	111 (100.0)	37	39	39	226 (100.0)		
		(100.0)	(100.0)	(100.0)			

*P value \leq 0.05 was significant. f: Fisher-exact test.**Table 4: Association between type of ampulla and difficult cannulation parameters**

Study variables	Type of Ampulla				Total	χ^2	P-value
	Type 1	Type 2	Type 3	Type 4			
Time to cannulation							
< 5 minutes	99 (89.2)	9 (24.3)	6 (15.4)	4 (10.3)	118 (52.2)		
> 5 minutes	12 (10.8)	28 (75.7)	33 (84.6)	35 (89.7)	108 (47.8)	121.07	<0.001*
Total	111 (100.0)	37	39	39	226 (100.0)		
		(100.0)	(100.0)	(100.0)			
Number of attempts							
< 5	95 (85.6)	8 (21.6)	4 (10.3)	4 (10.3)	111 (49.1)		
> 5	16 (14.4)	29 (78.4)	35 (89.7)	35 (89.7)	115 (50.9)	117.39	<0.001*
Total	111 (100.0)	37	39	39	226 (100.0)		
		(100.0)	(100.0)	(100.0)			
MPD cannulation							
0	98 (88.3)	15 (40.6)	25 (64.2)	11 (28.2)	149 (65.9)		
1	7 (6.3)	10 (27.0)	7 (17.9)	18 (46.2)	42 (18.6)		
2	6 (5.4)	12 (32.4)	7 (17.9)	10 (25.6)	35 (15.5)	63.74	<0.001*
Total	111 (100.0)	37	39	39	226 (100.0)		
		(100.0)	(100.0)	(100.0)			

*P value \leq 0.05 was significant.**Table 5: Association between type of ampulla and use of precut and immediate complications.**

Study variables	Type of Ampulla				Total	χ^2	P-value
	Type 1	Type 2	Type 3	Type 4			
Use of precut							
Yes	13 (11.7)	20 (54.1)	19 (48.7)	30 (76.9)	82 (36.3)		
No	98 (88.3)	17 (45.9)	20 (51.3)	9 (23.1)	144 (63.7)	64.51	<0.001*
Total	111 (100.0)	37 (100.0)	39 (100.0)	39 (100.0)	226 (100.0)		
Complication							
Yes	3 (2.7)	12 (32.4)	10 (25.6)	9 (23.1)	34 (15.0)		
No	108 (97.3)	25 (67.6)	29 (74.4)	30 (76.9)	192 (85.0)	27.37	<0.001*
Total	111 (100.0)	37 (100.0)	39 (100.0)	39 (100.0)	226 (100.0)		
Failure							
Yes	0 (0.0)	10 (27.0)	6 (15.4)	3 (7.7)	19 (8.4)		
No	111 (100.0)	27 (73.0)	33 (84.6)	36 (92.3)	207 (91.6)		<0.001* f
Total	111 (100.0)	37 (100.0)	39 (100.0)	39 (100.0)	226 (100.0)		

*P value \leq 0.05 was significant. f: Fisher-exact test.

Table 4 shows the association between type of ampulla and study variables including (time to successful bile duct cannulation, number of cannulation attempts and number of MPD cannulation). There was significant association between type of ampulla and study variables. Biliary accessed gained in less than 5 min with type 1 ampulla, whereas most patient with type 4 papilla followed by type 3, type 2 respectively gained in more than 5 min. Un intentional pancreatic duct cannulation mostly with type 2 and type 4 ampulla and less with 3 and least with type1 ampulla.

Table 5 shows the association between type of ampulla and study variables including (use of precut to gain biliary access, immediate complication and procedure failure). There was significant association between type of

ampulla and study variables. Precut mostly performed with type 4 papilla followed by type 2, type 3 and least type 1 papilla. Immediate complications were observed mostly with type 2 papilla followed by type 3 then type 4 ampulla and least with type 1 ampulla. Failure mostly with type 2 papilla.

Table 6 shows the association between type of ampulla and type of biliary cannulation including (difficult biliary cannulation or not difficult biliary cannulation). There was significant association between type of ampulla and type of biliary cannulation. Type 4, type 3 and type 2 papilla respectively was difficult to gained biliary access, as opposite to type 1 papilla were biliary cannulation was easy (83.8%).

Table 6: Association between type of ampulla and type of biliary cannulation

Study variables	Type of Ampulla				Total	χ^2	P-value
	Type 1	Type 2	Type 3	Type 4			
Type of biliary cannulation							
Difficult biliary cannulation	18 (16.2)	31 (83.8)	35 (89.7)	36 (92.3)	120 (53.1)	119.72	<0.001*
Not difficult biliary cannulation	93 (83.8)	6 (16.2)	4 (10.3)	3 (7.7)	106 (46.9)		
Total	111 (100.0)	37 (100.0)	39 (100.0)	39 (100.0)	226 (100.0)		

*P value ≤ 0.05 was significant.

Discussion

This study showed 72.6% of cases were common bile duct stone as primary indication of ERCP followed by pancreatic cancer (14.2%), CBD stricture (4.4%), cholangiocarcinoma (3.1%) and others. The most common type of ampulla is type 1 (49% of cases) followed by type 3 and type 4 (17.3%) and least common is type 2 papilla (16.4%). The result was nearly the same percentage as performed in study done by⁴. The association of type of ampulla with age and gender of patients, there was no significant differences between means age of patients according to type of ampulla. The association of type of papilla with difficulty of biliary cannulation according to our study were significant as type 4 (92.3%), type 3(89.7%) and type 2 (83.8%) papilla respectively was difficult. Type 1 papilla was more easy to cannulate than other types (83.8%). In comparison to the articles published by¹⁰, the overall frequency of difficult cannulation was 42%; type 2 papilla (52%) and type 3 (48%) were more frequently difficult to cannulate compared with type 1 papilla (36%). The analysis of each part of definition of difficult biliary cannulation and their association with type of papilla indicate that time to successful bile duct cannulation were less than 5 min in 52.2% overall and majority of type 1

regular ampulla (89.2%) cannulate in less than 5 min as opposite to type 4 and type 3 ampulla in which cannulation time done in more than 5 min in 89.7% and 84.6% of the total cases that take more than 5 min. (47.8%). Cannulation attempt also less than 5 with type 1 ampulla (85.6%) and more than 5 attempts with type 3 and 4 ampullas. Unintentional pancreatic duct cannulation was 0 with type 1 in 88.3% of cases whereas more than 2 times with type 2 ampulla in 32.4% and type 4 about 25.6% of the total percentage of cases with unintentional pancreatic duct cannulation that occurred more than two 15.5%. This signifies the influence of shape of ampulla with time, attempt of biliary cannulation and main pancreatic duct cannulation. In comparison to the study performed by¹¹, the overall frequency of difficult cannulation, regardless of the papilla types, was 34.4%, the type 2 small and retracted papillae have been significantly more difficult to cannulate (66.7%) when compared to both regular papillae and other anatomical variations and type 2 papillae needed significantly more cannulation attempts and more time to cannulate when compared to those with a regular papilla. In ¹² suggest type of ampulla according to protrusion of papilla and found that large papilla most difficult to cannulate. Other study performed by Adler DG suggest the frequency of difficult cannulation by papilla type was as follows: type 2 (52%); type 3 (48%); type 4 (43%); type 1 (36%). The overall frequency of difficult cannulation regardless of papilla type was 42%^{13,14}. Precut papillotomy, overall

performed 36.3 % of cases and immediate complications occurred in 15%. Precut papillotomy /fistulotomy mostly with type 4 ampulla, whereas bleeding occurred mostly with type 2 ampulla and failure of procedure mostly with type 2. this indicate that the shape of ampulla associated with precut use and complications also associated with shape of ampulla in addition to the usage of precut as precut performed mostly with type 4 ampulla and bleeding occurred mostly with type 2 ampulla. Taken together according to Papillary cannulation and sphincterotomy techniques at ERCP: European Society of Gastrointestinal Endoscopy (ESGE) Clinical Guideline¹⁵, and in comparison, with the study performed by¹³, the shape of ampulla significantly affect cannulation rate, technique of cannulation and complications. Use of pre-cut varies from none to as many as 38% of all biliary cannulation attempts in many studies¹⁶. Complications mostly with type 2 papilla (32.4%) followed by type 3 (25.6%), type 4 (23.1%) and least with type 1 (2.7%). Type 2 papilla (27%) most common type in which procedure failed in spite of precut that might be related to small size papilla and difficult to determine accurately the margin of papilla¹⁷.

Conclusions

The gender of patient and underlying diagnosis associated with shape of papilla while the age not. Type 1 papilla is the most common type. The shape of papilla significantly affects the difficulty of biliary cannulation, the use of precut and immediate complications.

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