



Research Article

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## Indications Of Stenting in ERCP: Single Center Experience

Dr. Hadeel Waleed Abdulrahman\*<sup>1</sup>, Dr. Maktoum Kawan Jassem <sup>2</sup>.

1. General surgery specialist, Alnuman teaching hospital, Baghdad, Iraq.
2. General surgery specialist, Alkarkh general hospital, Baghdad, Iraq.

**Corresponding Author: Dr. Hadeel Waleed Abdulrahman**, General surgery specialist, Alnuman teaching hospital, Baghdad, Iraq.

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**Abstract**

**Objectives:** To identify the indications of stents in ERCP. whether for benign or malignant conditions in patients who were managed in the ERCP unit at Baghdad Teaching Hospital.

**Background:** Endoscopic stent insertion has become the gold standard for patients who presented with variable benign and malignant biliary disorders so endoscopically placed stents are essential treatment for most benign strictures and are the primary palliative measures for unresectable malignant strictures. **Methods:** There were 103 patients with variable benign and malignant biliary disorders who were referred to the E.R.C.R. Unit at Baghdad Teaching Hospital during the period between August 1,2011, to August 1, 2012, enrolled in this prospective study. Patients' demographic data were recorded including whether the patients were referred for palliation or for cure, the indication, the number of stents, site of stent, the duration of stenting whether temporary or permanent. The patients were followed for the need to replace the stent or to add another one or the need for surgical intervention. **Results:** 103 patients who had undergone E.R.C.P. stenting were evaluated: 49 patients were female & 54 were male, the range was between 60-69 years. In this study we found that the most common indication of stents in E.R.C.P. was for malignant biliary obstruction (n= 69 patients ,66.99%), Followed by the benign biliary obstruction ( n=34 patients ,33.009 % ) ; among the malignant indications, cancer the head of pancreas was the most common (n=26 patients, 25.24%) followed by cholangiocarcinoma (n=18 patients ,17.47 %), the ampullary and the peri - ampullary carcinoma (n=16 patients ,15.53%), Klatskin's tumor (n=7patients ,6.79 %) and carcinoma of the gallbladder (n=2 patients ,1.94 %).

**Conclusion:** Malignant biliary obstructions were the most common indication of stents in ERCP.

**Key words:** Obstructive jaundice, ERCP indication, common bile duct obstruction, biliary tumor.

## Introduction

The development of non – operative stenting techniques has initiated a new era in the treatment of advanced malignant biliary obstructions. Patients who would normally have been turned down for bypass surgery because of extensive disease or who are unfit for an operation, can now be offered biliary decompression by either percutaneous trans hepatic or endoscopic route. [1,2,3,4]. Endoscopic stenting, the more recent of two techniques, was initially limited to the standard duodenoscope which allowed placement of only small size stents (5 – 7 F) and was associated with a high incidence of blockage and Cholangitis; the situation has now changed with the availability of the large channel (3.8 mm and 4.2 mm) duodenoscopes. [2,5,6,7]. Biliary stenting is used to treat biliary obstruction that could be caused by benign or malignant conditions. The malignant indications of stenting include CA. head pancreas, the most common indication. [7, 10, 11, 12], cholangial carcinoma, ampullary and peri – ampullary CA, CA. G.B, primary liver cancer invading the common bile duct, Klatskin's tumor, metastasis from the colon, esophagus, Lung and breast that can cause extrinsic compression of the biliary tree. here biliary stenting is indicated for palliative drainage of cholangitis and to relieve jaundice and pruritis and in patients who are candidates for neoadjuvant chemotherapy which is precluded by jaundice also for those in whom surgical management is likely to be delayed for 1-2 weeks due to limited availability or the need for neo-adjuvant therapy. [6, 7, 8, 9, 10, 11]. The Nonmalignant (benign) cause of biliary strictures that indicate stenting included : [7, 11,12,14,15 ] Iatrogenic ( post – op – strictures) , accounting for 80 % of benign conditions , pancreatitis ( inflammatory , auto – immune , post-ERCP) , biliary stones , primary sclerosing cholangitis , radiation therapy , and anastomotic strictures following liver transplantation .[7,11,13,16,17,18]. In these benign conditions, the placement of stent is temporary, in which sometimes multiple plastic stents are required to provide successful drainage and accurate biliary patency . Biliary stents are of two types: the plastic and the metallic (S.E.M.S) which is either covered, partially covered, and uncovered, the covering is made of polymer, a translucent silicone polymer on the inside of the stents mesh. Each type of stent has its characteristic features and complications ; the plastic stents are not expandable ( fixed size ) , so they can easily be blocked leading to early cholangitis , so they provide shorter biliary patency therefore they need frequent replacement nearly every three months , so they are used for temporary indications ; while the covered Metallic stents are self-expanding , have longer stent patency and they have minor occurrence of early cholangitis but they cannot be removed as they cannot resist tissue and tumor in growth , so they are permanent stents, used for palliative drainage of Unrespectable malignant obstructions and when blockage occurs , a new plastic stent should be placed through it , this compares with the covered S.E.M.S. that can resist tissue and tumor in growth.[10,19,20,21,22]

**Aim of the study:** To identify the most common indications of stents in ERCP, whether it is for benign or malignant biliary obstruction in patients who presented with variable benign and malignant biliary disorders to the ERCP unit at Baghdad teaching hospital.

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## Patients and Method

The data were collected by prospective study including 103 patients (49 females and 54 males) who presented with benign and malignant biliary disorders and referred to the E.R.C.P. unit at Baghdad teaching hospital from August / 2011 to August / 2012.

### Data Form included:

The history of the present illness and its duration , history of jaundice , itching , fever , abdominal pain, abdominal mass , weight loss and anorexia , it also include the E.R.C.P. findings, indications for biliary stenting, type , site and the number of stents for each case , duration of stenting whether it is the first or replaced one , the histopathological results of the lesion ; Post – stenting follow up including ( removal, blockage and replacement , referral for surgical intervention ).The stents that are available in the E.R.C.P. unit in our study are: the uncovered S.E.M.S. ( 10 mm x 6cm ) and the plastic one (10 F x 9 cm) , (10 F x 7 cm) and (10F x 12cm) . Usually, the patient was admitted to the hospital prior to the procedure.

**Pre – procedure preparation:** All patients prepared for stenting through ERCP they should have the following investigations:

PCV, RBS, B. urea, Creatinine, LFT, TSB. (direct & indirect), GOT, GPT., alkaline phosphatase, bleeding profile (PT, PTT, INR), virology screening, imaging studies including :(CXR, abdominal U/S, abdominal CT scan and MRCP (according to the case and indication)).

**Medication prior to the procedure (day before):** I.V.fluid , Vit.K.amp , I.V.antibiotics.

Start fasting since midnight (at least 6 hours prior to the procedure).

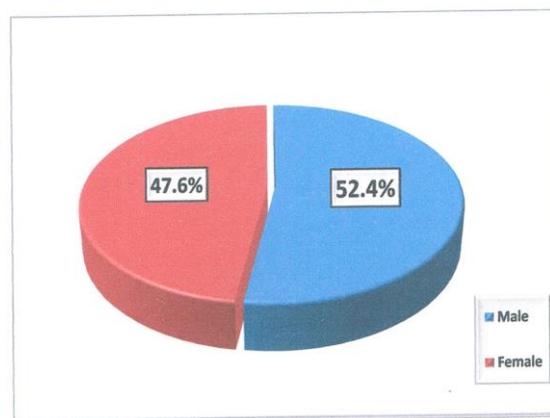
In the E.R.C.P Unit: Prone position, with I.V. canula. Pre E.R.C.P. medication used to be given are 1 cc(5mg) diazepam amp I.V. + 2 cc Buscopan amp. i.v. During the procedure we may repeat the dose of both medications. The patient is attached to the diathermy devise earth by metal plate applied to the calf muscle. Pulse oximeter monitoring is also available during the procedure. The whole procedure is done under supervision of anesthetic doctor available for monitoring. the endoscope is inserted into the patient's mouth, down the esophagus, through the stomach, and into the second part of the duodenum until it reaches the spot where the bile ducts empty. At this point a cannula is inserted through the endoscope and used to inject a contrast dye into the ducts. A series of X – Rays are then taken as the dye moves through the ducts. If the X – rays and the direct visualization through the endoscope show that a biliary stricture exists, a stent can be placed into the duct to relieve the obstruction.

To do this, sphincterotome is inserted into the endoscope and sphincterotomy (a cut into the sphincter of Oddi) is performed to provide access to the bile ducts. In some cases, the biliary stricture may first be dilated using a thin, flexible catheter, followed by a balloon – type device that is inflated. The stent is then inserted into the bile duct. The procedure may last for about 30-60 minutes. The device used is OLYMPUS, LUCERA CV- 260, MODEL Eu 2000.

Post stenting follow up is usually every three months, unless there is fever, pain or Jaundice (signs & Symptoms) that indicate obstruction of the stent at that time reevaluation must be done by: I. biochemical Investigations: P.C.V, L.F.T. (T.S.B. direct and indirect, S.G.o.T, S.G.P.T, S. alkaline phosphatase) , R.F.T. ( B . urea, S. creatinine), II. Radiological study: (abdominal u /s, Abd C.T scan and M.R.C.P.), III. new E.R.C.P.

## Results

A total of 103 patients were enrolled in this study, their age was between (20-85y) and the mean age of them was (58.11±14) year. They were 49 (47.6%) females and 54(52.4%) males, figure 1. The distribution of patients by age group was summarized by table (1).



**Figure 1** Distribution of patients by gender (N=103)

Age group (years)	Gender				Total	
	Female		Male			
20-29	3	75.0%	1	25.0%	4	100%
30-39	4	57.1%	3	42.9%	7	100%
40-49	6	46.2%	7	53.8%	13	100%
50-59	11	45.8%	13	54.2%	24	100%
60-69	13	44.8%	16	55.2%	29	100%
70-79	8	38.1%	13	61.9%	21	100%
≥80	4	80.0%	1	20.0%	5	100%
Total	49	47.6%	54	52.4%	103	100%

**Table (1)** Distribution of patients by age groups and gender

Regarding the indication of stents in E.R.C.P: The most common indication was for malignant biliary disorders 69 patients (66.99%) , and among these CA . head of pancreas was the most common 26 patients (25.24 %) , while the stent was indicated for benign biliary disorders in 34 patients (33.009%) , in which post cholecystectomy bile leak was the most common indication 19 patient (18.44%) as shown in table(2) .The indication of stenting in malignant condition was either for biliary drainage as in those with bacterial cholangitis , to relieve the Jaundice & pruritis or for biliary decompression as in post cholecystectomy leakage.

<b>Biliary disorder</b>	<b>No.</b>	<b>%</b>
<b>Malignant Indications</b>		
CA head Pancreas	26	25.24
Cholangiocarcinoma	18	17.47
Ampullary and peri-ampullary tumor	16	15.53
Klatskin's tumor	7	6.79
CA. G.B.	2	1.94
Total	69	66.99
<b>Benign Indications</b>		
Post cholecystectomy bile leak	19	18.44
C.B.D. stone and benign C.B.D. strictures	15	14.56
Total	34	33.009

**Table (2)** Distribution of patients according to the Indication of stent in E.R.C.P

Regarding the number and the site of stents: some patients need more than one stent, and this can be explained by the anatomy of the biliary tree as distally there is single duct (namely the C.B.D) while proximally there is the bifurcation into Rt. And Lt hepatic ducts; so distal lesions e.g., CA head of pancreas are easily palliated with single stent while proximal lesions e.g., Klatskins tumor (hilar adeno carcinoma) require two or more stents to accomplish drainage of adequate liver volume. as shown in the tables 3,4

No. of stents	No. of patients	Percent
1	86	83.5%
2	15	14.6 %
4	2	1.9 %
total	103	100 %

**Table (3)** Distribution of patients according to the number of stents

Site	No. of patients	Percent
C.B. D	90	87.4 %
C.B.D + C.H. D	2	1.9 %
Rt. and Lt I . H. D.	11	10.7%
Total	103	100%

**Table (4)** Distribution of patients according to the site of stents in the biliary tree.

**Regarding the types of stents: -**

Stent selection is based upon stricture etiology, location, ductal anatomy, and assessment of patient longevity.

Basically, we have two types of stents: the plastic and the metallic (S.E.M.S) (self-expanding metallic stent), the metallic one has several types: the covered, partially covered, and the fully covered. the stents that is available in the E.R.C.P Unit in our study are the uncovered S.E.M.S of size (10 mm X 6 cm) (it is an open-end cylinder of nitinol wire), and the plastic one of 2 sizes (10 F X 9 cm), (10 F X 7 cm) and (10F X 12cm). each type has its own characteristic features and complications as mentioned in the introduction (P.4).

Type of stent	No. of pt.	Percent
Plastic	93	90.3%
Metallic	10	9.7%
Total	103	100%

**Table (5)** Distribution of patient according to the type of stents.

In our study the use of the uncovered S.E.M.S. was limited, it was used only in ten cases :6 cases were CA head pancreas, 2 cases were cholangiocarcinoma, and 2 cases were periampullary tumors, as shown in table (6)

Indications	Metallic stent		Plastic stent	
	No.	%	No.	%
CA head pancreas	6	5.82	20	19.41
Cholangiocarcinoma	2	1.94	16	15.53
Ampullary and periampullary tumors	2	1.94	14	13.59
Klatskin's tumor	0	0.0	7	6.79
CA. G.B.	0	0.0	2	1.94
Post cholecystectomy bile leak	0	0.0	19	18.44
C.B.D.stone and benign C.B.D. strictures	0	0.0	15	14.56
Total	10	9.7	93	90.26

**Table (6):** distribution of patients according to the indications and type of stent

**Regarding the duration of stenting (temporary or permanent):**

The use of stenting in the benign conditions (post cholecystectomy bile leak and benign C.B.D. strictures) was temporary (maximum for up to 12 months) while the use of stenting for the malignant condition was sometimes permanent especially for the cases that are beyond surgery (advanced cases with distant metastasis, and when the patient is unfit for surgery (old ages)).

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Indication	Temporary		Permanent	
	No.	%	No.	%
CA. head pancreas	8	7.76	18	17.47
Cholangio carcinoma	1	0.97	17	16.50
Ampullary and peri-ampullary tumors	6	5.82	10	9.60
Klatskin's tumor	0	0.0	7	6.79
CA. G.B.	0	0.0	2	1.94
Post cholecystectomy bile leak	19	18.44	0	0.0
C.B.D.stone and benign C.B.D. strictures	15	14.56	0	0.0
Total	49	47.57	54	52.42

**Table (7)** Distribution of patients according to the duration of stenting

**Regarding the follow up after stenting: -**

51 patients (49.5%) were managed successfully by biliary stenting without complications.

37patients (35.9%) require stent replacement which was indicated for the plastic stents that need serial follow up every three months.

15 patients (14.6%) need surgical intervention in the form of triple bypass.

Follow up	No.	%
<b>Stable</b>	<b>51</b>	<b>49.5</b>
<b>Stent replacement</b>	<b>37</b>	<b>35.9</b>
<b>Surgical intervention</b>	<b>15</b>	<b>14.6</b>

**Discussion:**

E.R.C.P. has evolved from a purely diagnostic to an almost exclusively therapeutic procedure. [4,5,6,7] Biliary stenting is used to treat biliary obstructions that is caused by variable causes which are either benign or malignant.

Among the malignant conditions, pancreatic head CA is the most common cause; and among the benign conditions, iatrogenic injury to the bile ducts is the most common. [8,9,10,11]. By comparison with Costamagna et, al. [9], we found that the indications for stenting in the benign and malignant conditions were nearly the same and the differences were found in particular cases: -

**Pancreatic head CA:** - our study shows lower percentage (25.2%) while the comparative study shows higher percentage (68.1%). In our study we have (26cases), 6 of them were managed by permanent uncovered S.E.M.S. ,Those cases presented with advanced disease(mass more than 7cm in size with C.B.D. infiltration and secondary metastasis to the liver);so they have short life expectancy, and palliation by uncovered S.E.M.S. was the best option, the other 20 cases were managed by temporary plastic stent ,of which (8cases) underwent surgical intervention later on after optimization of the general condition[8].

**Cholangiocarcinoma:** - our study shows higher percentage (17.4%) while it was (13%) in the comparative study. Here we have (18cases), plastic stents were used in (16cases) and uncovered S.E.M.S. were used in (2cases), those 2 patients were very old (80,83) years, presented with advanced disease with ampullary infiltration and secondary metastasis to the liver, with short life expectancy.

**Ampullary and periampullary tumors:** - The percentage was higher in our study (15.5%) while it was only (5.8%) in Costamagna et, al. study. In our study (16cases) were presented with these tumors ,2 of them were advanced cases with short life expectancy, so treated by uncovered S.E.M.S.; the other (14cases) were managed by plastic stent ,4 of them underwent later s of surgical intervention.

**Klatskins tumor:-** here the percentage is also higher(6.7%)in our study in comparison with Costamagna et, al. study(2.9%).In our study we have seven cases of Klatskin’s tumor, for each case 2 stents were used ,one was inserted in the right and the other one in the left I.H.B.D., these are permanent stents through which palliative biliary drainage can be achieved successfully and if the patient develops a new attack of jaundice (which indicates blockage of the stent) it can be removed endoscopically through E.R.C.P. and replaced by a new stent .

**CA. Gallbladder:** this indication the percentage in our study was lower (1.9%) in comparison with the other study (4.3%). Here we have (2cases), both were old age (more than 80 years old) and presented with tumor infiltrating the C.B.D both were managed by plastic stent. The cause of this discrepancy in the percentage can be explained by:

\*Differences in sample size, as in our study it was(103cases) while in the comparative study it was smaller(70cases).

\*The comparative study includes cases of liver cancers (primary and secondary) that were not included in our study.

## Conclusion

Our data shows that the most common indication of stents in E.R.C.P was for malignant biliary disorders, among which CA. Head pancreas was the most common indication followed by cholangio carcinoma, while among the benign indications post cholecystectomy bile leak was the most common indication. Regarding the follow up after stenting including (improvement in T.S.B. level, failure of stenting) and the complications of stent; all were included in other thesis that are performed in the E.R.C.P. Unit at Baghdad Teaching Hospital.

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