Data Analysis:

All analyses were performed using R Statistical Software (v4.1.3; R Core Team 2022),

The Sociodemographic, Indications, Outcomes, and Complications data were represented as frequency and percentage for categorical variables, while mean and standard deviation were used to represent the continuous variables.

2 multivariate logistic regression models were performed to determine the association between

1. the probability of occurrence of post-ERCP pancreatitis (PEP) and other variables [age group, pan-cannulation, pan-stenting]
2. The probability of Post ERCP Complications occurrence and two risk factors [Pre-ERCP, Pan-cannulation]

The variable selection process for the multivariate regression models depended on the p-value of the chi-square test with a 0.05 cutoff.

The results were reported as OR, and the p-value of 0.05 was considered significant with 95% CI.

Results:

A total number of 1909 patients who performed ERCP procedure between 2017, and 2022 was selected to participate in the study, among them 28.9% were ≤ 40 years, 36.1% and 35% were between 41-64 years, and ≥ 65 years respectively, while the mean (SD) for Age was 54.1 (20.3).

The Gender distribution was 45.2%, and 54.8% between males and females respectively, and most of the participants were mainly from the West Bank (94%) while the other 6% were from Gaza Strip.

The distribution of the participants per the admission year between 2017 and 2022 was 0.8%, 13.4%, 22.2%, 19.5%, 20.0%, and 24.1% respectively.

**Table 1: Demographics**

|  |  |  |
| --- | --- | --- |
| **Patient Characteristics n (%)** | | |
| **Age group** | ≤ 40 years | 551 (28.9%) |
|  | 41-64 years | 689 (36.1%) |
|  | ≥ 65 years | 669 (35%) |
| **Mean age (SD)** |  | 54.1 (20.3) |
| **Gender** | Male | 863 (45.2%) |
|  | Female | 1046 (54.8%) |
| **Referral site** | West Bank | 1793 (93.9%) |
|  | Gaza Strip | 116 (6.1%) |
| **Year** | 2017 | 15 (0.8%) |
|  | 2018 | 256 (13.4%) |
|  | 2019 | 423 (22.2%) |
|  | 2020 | 372 (19.5%) |
|  | 2021 | 382 (20.0%) |
|  | 2022 | 461 (24.1%) |
| **Total** |  | **1909 (100%)** |

The indications of our patients were mainly Obstructive jaundice with known stones (35.3%), Stent removal/exchange (20.3%), Obstructive jaundice with known malignancy (13.0%), and Obstructive jaundice with unknown biliary stricture suspected for malignancy (7.5%), while the other 14% of indication types were distributed between [Dilated CBD on image without jaundice, Post-operative complications, Acute cholangitis, Pancreatic disease other than malignancy, Other types of Obstructive jaundice, and Peri-ampullary lesion]

**Table 2: Indications**

|  |  |
| --- | --- |
| **Procedure Indications n (%)** | |
| **Obstructive jaundice with known stones** | 673 (35.3%) |
| **Stent removal/ exchange** | 388 (20.3%) |
| **Obstructive jaundice with known malignancy** | 248 (13.0%) |
| **Obstructive jaundice: unknown biliary stricture suspected of malignancy** | 144 (7.5%) |
| **Dilated CBD on image without jaundice** | 119 (6.2%) |
| **Post-operative complications** | 100 (5.2%) |
| **Acute cholangitis** | 90 (4.7%) |
| **Pancreatic disease other than malignancy** | 76 (4.0%) |
| **Obstructive jaundice: Others** | 53 (2.8%) |
| **Peri-ampullary lesion** | 18 (0.9%) |
| **Total** | 1909 (100%) |

the procedure outcomes were mainly Stones/Sludge (36.6%), Stent removal (16.2%), Strictures (10.7%), Stent exchange (8.1%), Stent insertion (6.1%), and the Normal ERCP represented only 5.0%.

at the same time, the 17.3% of the procedure outcomes was distributed between [Failure of cannulation, Leaking, Peri-ampullary diverticulum with biliary stones, Ampullary mass/ lesion,,,, etc.] **(Table 3)**

**Table 3: Outcomes**

|  |  |
| --- | --- |
| **Procedure Outcomes n (%)** | |
| **Stones/ sludge** | 699 (36.6%) |
| **Stent removal** | 309 (16.2%) |
| **Strictures** | 204 (10.7%) |
| **Stent exchange** | 155 (8.1%) |
| **Stent insertion** | 130 (6.1%) |
| **Normal ERCP** | 96 (5.0%) |
| **Failure of cannulation** | 74 (3.9%) |
| **Leak** | 55 (2.9%) |
| **Peri-ampullary diverticulum with biliary stones** | 34 (1.8%) |
| **Ampullary mass/ lesion** | 31 (1.6%) |
| **CBD dilation** | 27 (1.4) |
| **Peri-ampullary diverticulum** | 19 (1.0%) |
| **Retained stent** | 15 (0.8%) |
| **Failure to visualize/ altered anatomy** | 10 (0.5%) |
| **Stricture post-surgery** | 8 (0.4%) |
| **Hemobilia** | 6 (0.3%) |
| **Ampullary stenosis** | 5 (0.3%) |
| **Failure due to complications** | 5 (0.3%) |
| **Beaded appearance consistent with sclerosing cholangitis** | 4 (0.2%) |
| **Choledochal cyst** | 4 (0.2%) |
| **Pancreatic duct stricture** | 4 (0.2%) |
| **CBD polyp** | 3 (0.2%) |
| **Iatrogenic transection** | 3 (0.2%) |
| **Trans-biliary drainage** | 3 (0.2%) |
| **Intra-hepatic cyst** | 2 (0.1%) |
| **Stent in choledochoduodenostomy** | 2 (0.1%) |
| **Duodenal cyst** | 1 (0.1%) |
| **Leak with retained stones** | 1 (0.1%) |
| **Total** | **1909 (100%)** |

the post ERCP procedure complications represented only 5% of the whole cases, among them, Cardiopulmonary instability represented 2.1%, Early Bleeding (8.4%), Infection (21.1%), PEP (45.3%) while Perforation, Late Bleeding, Death and The Others Complications represented 7.4%, 1.1%, 11.6%, and 3.2% respectively.

The ERCP procedure was performed successfully in 96.6% of the patients, and the failure prevalence represented only 0.04%.

This failure of the ERCP procedure was distributed as 37.5% for Obstructing Tumor, 15.9% for Altered Anatomy, 35.2% for Failure of Cannulation, 6.5% for Failure Due to Cannulation, and 6.5% for Others.

In multivariate regression analysis of PEP, getting old [<=65 compared to <=40] was significantly associated with the decrease in the folds of the PEP by 65% [OR=0.35 (0.13-0.82, p=0.020)],

While the pan-cannulation showed a significant association with the PEP as the patients who didn’t perform pan-cannulation had shown a decrease in the folds by 77% compared to the patients who had performed pan-cannulation [OR=0.23 (0.12-0.44, p<0.001)], at the same time the pan-stenting procedure showed no significant association with the PEP in the multivariate level, however being significantly associated with the PEP on the univariate one.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| *Dependent: PEP* |  | *None [N=1814]* | *PEP [N=43]* | *OR (univariable)* | *OR (multivariable)* |
| *age.group* | <=40 | 520 (96.7) | 18 (3.3) | - | - |
|  | 41-64 | 655 (97.3) | 18 (2.7) | 0.79 (0.41-1.55, p=0.495) | 0.85 (0.43-1.68, p=0.637) |
|  | >=65 | 639 (98.9) | 7 (1.1) | 0.32 (0.12-0.73, p=0.010) | 0.35 (0.13-0.82, p=0.020) |
| *pancannulation* | Yes | 361 (94.0) | 23 (6.0) | - | - |
|  | No | 1453 (98.6) | 20 (1.4) | 0.22 (0.12-0.40, p<0.001) | 0.23 (0.12-0.44, p<0.001) |
| *pancstenting* | Yes | 77 (93.9) | 5 (6.1) | - | - |
|  | No | 1737 (97.9) | 38 (2.1) | 0.34 (0.14-1.00, p=0.026) | 0.96 (0.37-2.98, p=0.935) |

Considering the post ERCP complications, the Chi-square test showed no significant association regarding the age group nor the gender, at the same time, a significant association between the Pre-ERCP and Pancreatic cannulation was detected with p-value = (0.046 and 0.002) respictively.

A Logistic Regression model was performed to detect the relation between the pre-ERCP, pancannulation and the post-ERCP complications, the pan-cannulation variable have showed significant decrease in the odds by 46% in the group that didn’t perform pan-cannulation compared to the other group with [OR=0.54 (0.35-0.87, p=0.009)], while no significant association could be detected regarding the pre-ERCP variable.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Dependent: complications** |  | **-VE FOR COMPLICATIONS** | **+VE FOR COMPLICATIONS** | **OR (univariable)** | **OR (multivariable)** |
| **preercp** | Yes | 836 (96.2) | 33 (3.8) | - | - |
|  | No | 974 (94.1) | 61 (5.9) | 1.59 (1.04-2.47, p=0.037) | 1.39 (0.89-2.20, p=0.149) |
|  | Unknown | 4 (80.0) | 1 (20.0) | 6.33 (0.32-44.30, p=0.103) | 4.15 (0.21-30.06, p=0.215) |
| **pancannulation** | Yes | 361 (91.9) | 32 (8.1) | - | - |
|  | No | 1453 (95.8) | 63 (4.2) | 0.49 (0.32-0.77, p=0.001) | 0.54 (0.35-0.87, p=0.009) |