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Retrospective Analysis of Quality Indicators of Transduodenal Endobiliar Interventions without Anaesthesia

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Abstract.

The objective of the research was to assess the advantages and disadvantages of transduodenal endobiliar surgeries without general anesthesia. The analysis of 1,678 hospital records of patients who underwent transduodenal endobiliar surgery was made including the average duration of surgery, its effectiveness and the incidence of adverse cardiorespiratory events. The number of terminated procedures and subjective evaluation of the procedure by the patient and endoscopist were taken into account.

Results. There has been a growth of minimally invasive operations since 2008. The analysis indicated that endoscopists refused to perform high-risk surgery in patients with high comorbidity. Choledocholitoextraction without general anesthesia was possible only in 50-75% of cases. One of the disadvantages of the procedure was psychological efforts made by physicians. The incidence of cardiorespiratory events was 1-2%, and surgery was terminated in 12 to 32% of cases. Postoperative mortality was 0.18%, the total mortality rate was 1.8%.

Conclusions. Endobiliar interventions without general anesthesia showed significant limitations and disadvantages. Intraoperative complications of cardiorespiratory system when performing endoscopic surgery without general anaesthesia were obsereved only in 2% of patients, however, this small number was achieved by careful selection of low-risk patients excluding those at risk of age-related complications and those having risky comorbidities. The absence of anaesthesia significantly reduces patient safety.

Keywords: endoscopic surgery; anesthesiological management

Problem statement and analysis of the recent research

The use of endoscopic access to the biliary tree allowed us to increase the effectiveness of treatment of benign and malignant obstructions of the biliary tract. Since the early 2000s endoscopic interventions have become routine significantly expanding the possibilities of biliary and pancreatic surgery [1, 2]. Diagnostic capabilities of endoscopic retrograde cholangiopancreatography (ERCP) are known to exceed in sensitivity and specificity other methods of visualization such as ultrasonography, computed tomography, and magnetic resonance imaging reaching 98-99% [3, 4]. Endoscopic interventions are also of special value due to the combination of both diagnostic and therapeutic manipulations in ERCP. The possibilities to diagnose biliary obstruction caused by cancer or stones in the bile ducts quickly and effectively and remove the blockage of the bile ducts immediately led to modernization of biliary surgery towards the minimally invasive surgery, stage-by-stage approach and differentiation depending on the clinical case. Biliary endoscopy has evolved from an endoscopy of the upper gastrointestinal tract and adopted both instrumental and technological provision and methods of anaesthesia. Prior to the widespread use of biliary surgery only topical oropharyngeal anesthesia including a 10% solution of lidocaine on the background of standard premedication with the opiate analgesic, anticholinergic drug and antihistamine was used. It allowed the doctors to complete the surgery successfully in most cases. However, in some cases the procedure was terminated prematurely at the patient's insistence due to a longer duration of the procedure, painfulness and discomfort. Unwanted cardiorespiratory events were noted in some patients. They included angina attacks, hypertensive crisis, arrhythmia, hemodynamic instability, asphyxia, laryngospasm, bronchospasm and others. In addition, performing risky endoscopic manipulation without general

aneasthesia increased psychological and physical strain among endoscopists. It was difficult for them to combine the performance of endoscopic intervention and control of the patient's general condition and his/her vital signs.

The objective of the research was to assess the advantages and disadvantages of transduodenal endobiliar interventions without general anesthesia using a retrospective analysis of the indicators of the effectiveness and quality of the surgical operations performed in Ivano-Frankivsk regional clinical hospital over the period 2003-2007.

Materials and methods

A retrospective analysis of statistical reports of the department over the period 2003-2012 including 1,678 hospital records of patients who underwent transduodenal endobiliar surgery in Ivano-Frankivsk regional clinical hospital over the period 2003-2007 was made.

The analysis was made generating statistical reports of hospital computer network "Medsoft" and creating a relational database with the use of spreadsheet software Microsoft Excel 2007. Every database entry included the spreadsheet lines with parametric and nonparametric indicators selected from the hospital records of the patient. In particular, the duration of surgery, its effectiveness or ineffectiveness according to the dynamics of the development of jaundice and treatment effects were evaluated. The presence or absence of unwanted cardiorespiratory events was assessed. They included hypertensive crisis, angina attacks, hemodynamic instability, arrhythmia, laryngospasm, bronchospasm and others. The total number of terminated procedures for some technical reasons or due to the patient's condition was taken into account. The cases of the patient's refusal to continue the surgery, psychological and emotional traumas, cases of pain syndrome and discomfort, subjective evaluation of the procedure by the patient were assessed quantitative. In some patients their vital signs were assessed including blood pressure (BP), heart rate (HR), respiration rate (RR) and arterial oxygen saturation (SaO_2).

The verification of the subjective evaluation of the procedure of endoscopic intervention was made interviewing 212 patients via phone. The survey included patient's self-assessment of pain syndrome, psychological discomfort and effects of surgery in the postoperative period on a 10-point scale.

In addition to the objective analysis a subjective method of focus group which is a group interview of several specialists (in our case the group of endoscopists) was used. During the interview, they were asked about the advantages and disadvantages of performing endoscopic interventions without general anaesthesia. The survey included 3 endoscopists with 5-25 years of medical experience.

The obtained digital data were processed using descriptive statistics with determination of the average values and their squared deviation. The evaluation of the type of distribution was made using computer programs with the determination of the measure of central tendency between the mean, median and mode, bias (symmetry) and ascent (kurtosis). The normality of the variable's distribution was assessed using the Kolmogorov-Smirnov test.

Results and discussion

The dynamics of changes in surgical tactics in case of obstructive jaundice for 10 years is presented in Tables 1 and 2. We have revealed a significant increase in the number of minimally invasive surgeries since early 2008. Similar tendency was observed both when treating choledocholithiasis and managing patients with malignant bile duct obstructions.

Table 1

Proportion of patients who underwent different types of surgery in choledocholithiasis (%)

Variants of surgical tactics	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012
Endoscopic lithoextraction	15.4	12.3	21.2	15.3	17.6	28.4	25.3	26.9	31.1	29.3
Two-stage minimally invasive interventions*	31.9	32.8	35.2	31.5	30.3	37.1	52.8	58.5	47.1	51.4
The total number of minimally invasive interventions	47.3	45.1	56.4	46.8	47.9	65.5	78.1	85.4	78.2	80.7
Laparotomy lithoextraction	12.4	14.3	11.7	18.2	31.6	27.3	11.4	5.3	12.6	6.8
Combination of several surgical tactics **	40.3	40.6	31.9	35	20.5	7.2	10.5	9.3	9.2	12.5
Total number of open surgeries	52.7	54.9	43.6	53.2	52.1	34.5	21.9	14.6	21.8	19.3

Notes: * Endoscopic choledocholithoextraction followed by laparoscopic cholecystectomy

** ERCP followed by laparotomy

Table 2

Proportion of patients who underwent different types of surgery in malignant bile duct obstructions (%)

Variants of surgical tactics	**2003**	**2004**	**2005**	**2006**	**2007**	**2008**	**2009**	**2010**	**2011**	**2012**
Endobiliary stenting	32.5	45.4	37.8	43.5	53.3	75.3	86.3	89.5	93	91.8
Palliative surgery (open surgery)	67.5	54.6	62.2	56.5	46.7	24.7	13.7	10.5	5	3.1
Curative resection (pancreaticoduodenal resection)	0	0	0	0	0	0	0	0	2	5.1

In 2008, general anaesthesia was recommended to use when performing endoscopic surgeries. Thus, statistical data indicated simultaneous and interrelated progress in the techniques of anaesthetic management and surgical technologies in the field of biliary surgery. The analysis of the results of endoscopic surgeries performed without general anaesthesia over the period 2003-2007 revealed the following picture.

During the study period 1,678 patients were treated. The number of patients varied slightly from year to year (Table 3).

Table 3

Dynamics and structure of endobiliar surgery performed without general anaesthesia

Type of surgery/Year	2003	2004	2005	2006	2007
ERCP	22(7.9%)	33(8.1%)	24(7.8%)	23(6.5%)	25(7.7%)
ERCP + papillotomy	36(12.9%)	39(8.1%)	35(11.3%)	44(12.4%)	38(11.7%)
ERCP + choledocho-lithoextraction	64(22.9%)	92(22.5%)	86(27.8%)	81(22.8%)	86(26.5%)
ERCP + EBS*	125(44.6%)	194(47.5%)	126(40.8%)	158(44.4%)	142(43.7%)
Repeated EBS	33(11.8%)	50(12.3%)	38(12.3%)	50(14.0%)	34(10.5%)
Total number of surgeries	280	408	309	356	325

Note: * Endobiliary stenting

Female patients constituted 69.7% and male patients constituted 30.3%. The distribution by age and sex is presented in Table 4.

Table 4

Age and gender distribution of patients

Age	**18-29**		**30-49**		**50-69**		**70-89**	
Gender	**abs**	**%**	**abs**	**%**	**abs**	**%**	**abs**	**%**
Males	60	44.8	72	23.4	300	28.5	76	41.3
Females	74	55.2	236	76.6	752	71.5	108	58.7
Total number of patients	134	8.0*	308	9.6*	1052	17.1*	184	1.6*

Note: * of the total number (1678)

Female predominance among the patients with biliary pathology is generally accepted. At the same time, the structure of biliary pathology in the relatively small number of senile patients differs from that described in accepted publications [4]. A rational explanation of this fact is the endoscopists' refusal to perform endoscopic procedures without using general anaesthesia in high-risk patients with high comorbidity.

During the study period all the patients received topical anesthesia including a 10% lidocaine aerosol. Intramuscular injections of omnopon, atropine and diphenylhydramine were used for premedication that was performed 30-40 minutes before the intervention. Before the operation a peripheral venous access was established that was used in 10-20% only.

The procedure was carried out with the patient lying on his left back. The endoscope was inserted into the oropharynx. The duodenoscope with the side-viewing optics having a diameter of 12.6 mm or, if necessary, the gastroscope with straight-forward-optics having a diameter of 8.0 mm were used. Endoscopy equipment II-III generation

manufactured by Olympus (Japan) was included into the study. The radiological control was carried out using serigraph Philips (Germany).

During the surgery the patient's position was changed from the left lateral to prone. It allowed us to optimize endoscope position to access the bile papilla and improve the visualization of anatomic structures displayed on the screen of serigraph. The initial stage of surgical operation including the moment of endoscope insertion and fixation of the bile papilla lasted in average 6.5 ± 3.0 min. During the initial stage the moments of endoscope insertion and initial irritating of the oropharynx were the most uncomfortable for the patient. Individual susceptibility of some patients to the gag reflex and panic attack at the beginning of the procedure resulted in termination of the procedure in 8 patients. According to all surveyed endoscopists one of the disadvantages of the procedure without using general anaesthesia was the need for significant psychological efforts made by physicians to establish contact with the patient and convince the latter of the need for continuing the manipulation.

The stage including the cannulation of the bile papilla and performance of ERCP lasted in average 12 ± 5 min. The patients felt painful sensations when contrast was injected into the biliary tree or pancreatic duct under increased pressure. An additional source of pain was the moment of diathermal coagulation in case of papillotomy. Pain syndrome present during this stage limited the possibility to complete papillotomy that, in turn, did not allow the endoscopists to perform lithoextraction.

In case of a mismatch between the size of the calculus and the distal portion of the common bile duct there is a need in the use of balloon dilator and/or mechanical lithotripsy when performing lithoextraction. Both procedures last 10-40 min and may cause painful sensation. Therefore, according to all surveyed endoscopists the performance of the procedures mentioned above without using general anaesthesia is possible only in some cases (50-75%) as indicated in the data of the protocols of performed surgical interventions.

Endobiliary stenting in jaundice of tumoral origin has a palliative character and therefore often requires repeated endoscopic interventions. The patients who underwent endobiliary stenting without general anaesthesia are known to refuse to undergo repeated endoscopic interventions more often and insist on alternative palliative interventions – biliodigestive anastomosis.

The total duration of one endoscopic intervention was 27 ± 8 min. The endoscopist often decided to terminate the procedure not due to the successful completion of the operation but due to his doubts about the safety of the endoscopic procedure, the patient's anxiety, or when the patient refused to continue the intervention. It explains a relatively large number of repeated endoscopic interventions using topical anaesthesia in choledocholithiasis (12.4%) and obstructive jaundice of tumoral origin (10.2%).

The mortality rate among patients during performing endoscopic interventions was 0.18% (3 patients). The total mortality was 1.8% (30 patients). The most common cause of death was hepatorenal syndrome. The minor causes of death included pancreonecrosis, acute suppurative cholangitis, and cardiovascular insufficiency.

The structure of the cardiorespiratory complications during performing endoscopic procedure is presented in Table 5.

Table 5

Cardiorespiratory complications in patients who underwent endobiliar surgery without general anaesthesia

Complications	N patients	
	abs	%
Laryngospasm	18	1.1
Bronchospasm	12	0.7
Hypertensive crisis	8	0.5
Angina attack	4	0.2
Hemodynamic instability	15	0.9
Arrhythmias	33	2.0
Patient's refusal to continue surgical procedure	216	12.9
Termination of the procedure for some technical reasons*	537	32.0

Note: * Termination of the procedure by an endoscopist due to impossibility to complete it safely

During the study period the vital functions were monitored speculatively without being protocolled. According to the records of the patients' medical histories in most cases only BP was measured before and after the procedure. Pulse oximetry and cardiac monitoring were practically not used. The vital signs were often controlled by the nurse and

endoscopist. Only in some cases (5%) an anaesthesiologist was involved in anaesthetizing patients during endoscopic procedure. However, after endoscopic surgery 28 patients (1.7%) had to be transferred to the intensive care unit. The analysis of the patient's self-assessment of pain syndrome and discomfort during performing the procedure revealed that 22% of respondents identified their feelings as unbearable (9-10 points), 54% of respondents identified their feelings as pain and discomfort of moderate or severe intensity (5-8 points) and only 14% of respondents identified their feelings as light and of moderate intensity (5 points). Most respondents would not agree to undergo repeated endoscopic surgery without general anaesthesia and would not recommend it to their relatives and friends.

Conclusions

1. The performance of endobiliar surgery without using general anaesthesia but with topical anaesthesia and premedication is a historical stage of the development of biliary surgery which has significant limitations and disadvantages.

2. There was a low incidence of occurring intraoperative cardiorespiratory complications (5%) when performing endoscopic surgeries without general anaesthesia, however, this small number was achieved by careful selection of low-risk patients excluding those at risk of age-related complications and those having risky comorbidities.

3. The absence of anaesthesia and monitoring of the vital functions when performing biliary surgeries significantly reduces patient safety and should be recognized as a significant disadvantage of this tactic.

4. Biliary surgeries without using general anaesthesia are accompanied by the patient's psychological and emotional discomfort and pain syndrome and significant psychological and physical efforts made by endoscopists.

Prospects for further research include a thorough comparative analysis of endoscopic biliary interventions using different types of anaesthesia.

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