ACUTE OBSTRUCTIVE JAUNDICE MANAGEMENT IN EMERGENCY: MANAGEMENT, CLINICAL AND PATIENT'S SAFETY CONSIDERATIONS REGARDING THE USE OF THE SHORT OBSERVATION UNIT

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ABSTRACT

Introduction*: Obstructive jaundice is a frequent cause of access to the Emergency Department (ED) and requires rapid hospitalization in order to perform an endoscopic retrograde cholangiopancreatography (ERCP). To reduce overcrowding, Brief Observation Units (BOU) were set up in EDs throughout Italy where patients receive treatment for 48-72 hours, significantly decreasing hospitalizations. The objective of this study is to evaluate the cost-effectiveness of a new model for managing obstructive acute jaundice in BOUs and provide indications regarding the possibility of systematic implementation thereof within EDs.*

Materials and methods*: From 1 January 2019 to 31 December 2019, we evaluated 213 patients (100 M/113F, mean age 65±16.8 years) who presented at the ED with acute obstructive jaundice and were subsequently admitted to the BOU. Each patient underwent blood tests, an ECG, and an ultrasound or CT scan to confirm the diagnosis. In addition, each patient presented with ERCP indications. We analyzed the introduction of the BOU from a clinical, economic and discharge time perspective and made some recommendations regarding the organizational opportunities.*

Results*: Clinical management in BOUs has produced excellent results, but it is not cost-effective. It does, however, produce excellent performance in terms of discharge times.*

Conclusion*: This study shows both good clinical performance in the procedures carried out in the BOU and the opportunity to avoid patient hospitalization, thus optimizing the use of available hospital beds. From an economic perspective, BOUs prove more costly and receive lower reimbursements from the Diagnosis Related Groups (DRG) system. However, despite its inefficacy in terms of costs, it may be used with certain objective advantages, especially in view of the need to liberate as many hospital beds as possible and avoid unnecessary hospitalizations during the current pandemic. Furthermore, BOUs may also improve clinical results and patient safety. Management of obstructive jaundice in BOUs may be seen as an alternative care setting to the traditional methods of admission, although with economic limitations.*

Keywords: *healthcare management, patient safety, SARS-CoV-2, clinical risk management, emergency room.*

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Introduction

Acute obstructive jaundice is one of the most frequent causes of access to Emergency Departments (EDs), necessitating prompt treatment. Obstructive jaundice is a clinical syndrome caused by reduced bile flow at any point within the biliary tree. This condition appears clinically in the form of biliary colic, expression of the presence of gallstones in the biliary tract, or of jaundice with no pain, often associated with neoplastic occlusion, starting from the pancreas, biliary tract or, more rarely, the duodenal ampulla and lymph nodes[(1)].

Patients with jaundice may arrive at the ED complaining of dyspesia, pain in the epigastric region or right hypochondrium, or they may remain asymptomatic[(2)]. Diagnostic tests used in the ED include laboratory tests such as blood cell count, he-

patic function and cholestatic indices, and hepatobiliary ultrasound, which enables the identification of intra or extra-hepatic duct dilatation due to focal, parenchymal or gallstone-related disease[3]. Computed axial tomography is superior in identifying pancreatic disease. The therapeutic choice, be it surgical or medical, is determined by the site and nature of the biliary obstruction, the patient's clinical conditions, and the degree and rapidity of jaundice onset[4].

Endoscopic retrograde cholangiopancreatography (ERCP) represents the imaging method of choice both in terms of diagnostic and treatment potential (gallstone extraction, stent placement) in the presence of obstructive pathology of the common bile duct. On completing the ERCP procedure, an observation period of 48-72 hours is indicated, during which the patient is monitored to detect potential complications and to measure the decrease of the cholestatic index. The observation period is normally completed in a medical or surgical ward and, although the abrupt onset of this condition is what led the patient to the emergency department, the procedure continues under ordinary hospitalization[5].

In the context of the ED, acute cholangitis is the most important and serious pathology to diagnose and treat immediately. Emergency sphincterotomy is the procedure of choice for the treatment of acute pancreatitis and cholangitis caused by bile stones. Park et al. studied the role of emergency ERCPs for the treatment of cholangitis in 2016. Approximately 330 patients aged 75 and older with a diagnosis of cholangitis were enrolled. The authors studied the impact of the timing of emergency ERCPs on patient prognoses and lengths of stay, finding that performing ERCPs reduced mortality and lengths of hospital stays[6].

In clinical practice it is well known that the clinical parameters and laboratory exams of patients with obstructive jaundice clearly improve after cleaning the biliary tract. Rapid ED diagnosis and procedure execution are the crucial factors. Nevertheless, the improvement of diagnostic management of these patients in the ED means a high number of patients to treat. Notably, overcrowding in EDs throughout Italy has become a socioeconomic problem.

In 2015, Di Somma et al conducted a study on this phenomenon and showed that in the last 15 years the levels of clinical activity in EDs throughout Italy have increased, resulting in a greater demand for more effective organization and management of common pathologies. To that end, a new ED unit called the Brief Observation Unit[7] was set up.

Reports from the international literature available tend to agree that BOUs may be seen as an alternative care setting to the traditional methods of admission, ensuring optimal clinical care for healthcare utilizers while reducing the burden on available resources[8, 9, 10].

The potential for actively treating a conspicuous number of patients presenting at the ED in the BOU should, in theory, have an impact on reducing the hospitalization rate. Given the specific objective of introducing the BOU, i.e., to promote dehospitalization, to reduce hospital bed occupation and to improve the organization of services, this model of annual reimbursement for activities within the BOU leads to a corresponding decrease in costs for all institutions that includes a dedicated quota to acute admissions in their budget, as described in the annual deliberation regarding the regional division of healthcare funds[11,12,13].

Consequently, beginning on 1 March 2008, BOUs were introduced in Lazio Emergency Departments, including in the ED at the Agostino Gemelli University Hospital Foundation on 18 July 2011. This BOU, equipped with 12 beds and a dedicated medical team, has helped assist some categories of patients who are in a non-hospitalization regime. This represents a success in view of the reduction of acute care beds in regional hospitals. In fact, in Lazio, as in all of Italy, there has been a progressive reduction in hospital beds, dropping from approximately 296,000 in 2000 to 230,000 in 2012 - a 22% reduction. This decreased further to 224,000 at the beginning of 2014. The reimbursement fee of 275 euros is fixed for every patient, which includes all aspects of their care calculated based on an average length of stay of 0-3 days[14,15,16, 17]).

From mid-2014, in conjunction with emergency endoscopy personnel, a new organizational method was experimented, which involves the use of the BOU for the complete management of patients with acute obstructive jaundice to perform ERCPs. These patients are sent to the digestive endoscopy unit for immediate testing and subsequently complete the observation period (generally 48-72 hours) in the BOU. This strategy may reduce procedure access time whilst maintaining the same level of care, with less inconvenience for the patient.

Furthermore, controlling hospitalizations and discharges in this way facilitates increased availability of hospital beds for other patients, thus improving healthcare efficiency. The development of this management and organizational model, precisely

because of its ultimate purpose of reducing inappropriate or unnecessary hospitalizations, requires clearly defined guidelines and strategies with the aim of selecting specific patients that will benefit from this care path. The objective of this article is to evaluate the financial sustainability of the model and its economic and clinical advantages in addition to considering the potential of the BOU system to provide greater patient safety, including within the context of the current pandemic.

Materials and methods

This is a retrospective, single-center study conducted in Policlinico Universitario "A. Gemelli", IRCCS, in Rome. From 1 January 2019 to 31 December 2019, we evaluated 213 patients (100 M/113F, mean age 65±16.8 years) admitted to the BOU. The inclusion criteria were men and women (>18 years of age) diagnosed with acute obstructive jaundice, formulated on the basis of the objective structured clinical examination of the patient, signs of cholestasis (elevation of the values of direct bilirubin, gamma-GT and alkaline phosphatase) and ultrasound or CT scan. Patients, in relation to their clinical and general conditions, all presented with emergency ERCP indications having undergone ECG and chest X-rays for anesthetic evaluation. Exclusion criteria were patients < 18 years of age and pregnancy.

Clinical and demographic data was collected from the computerized clinical record forms in use in all hospital EDs within the Lazio Regional Health Service (GIPSE®). Only patients with a hemodynamically stable condition were admitted to the BOU and were thus discharged within 36 hours at the most. The objective was to analyze economic performance as regards the management of medical procedures, particularly ERCPs, in the BOU, specifically focusing on the costs for each type of ERCP, from diagnostic to sphincterotomy to stent application. BOU costs were calculated as follows: pre-ERCP diagnostic procedures including the blood test, ECG, x-ray and abdomen ultrasound; medical and nursing staff hourly wages and the time spent with the patient in euros; costs of all medicines used, and anesthetist and endoscopist fees. The financial data used was taken from the specific tariff nomenclature for the DRG and procedures in use on a regional basis. As regards the tariffs, costs were calculated on the basis of the tariff indicated at the DRG level for the specific procedure. Ordinarily, a specific DRG would be produced for hospitalized patients, whereas in the BOU, an all-inclusive rate was calculated per observation day. The data was then processed for comparison and subsequent observations. The study concluded by analyzing patient discharge numbers from the BOU. All data was collected in a database using STATA 14 software. Tables have been used to summarize the main results.

Results

From a clinical point of view, 213 patients were managed in the BOU: 200 patients were discharged post-procedure (92.6% of cases), while 13 patients necessitated hospitalization (7.4% of cases). From an economic point of view, the average costs for normal admissions with ERCPs were calculated and have been displayed in Table 1.

EXAM	AMOUNT	EXAM	AMOUNT	EXAM	AMOUNT
BLOOD TESTS	38.82	BLOOD TESTS	38.82	BLOOD TESTS	38.82
ECG	11.62	ECG	11.62	ECG	11.62
CHEST X-RAY	15.49	CHEST X-RAY	15.49	CHEST X-RAY	15.49
ABDOMEN ULTRA-SOUND	60.43	ABDOMEN ULTRA-SOUND	60.43	ABDOMEN ULTRA-SOUND	60.43
ERCP	526.28	ERCP + SPHINC-TEROTOMY	1086.24	ERCP + SPHICN-TEROTOMY AND PROSTHESIS	1457.06
TOTAL	**652.64**	**TOTAL**	**1212.60**	**TOTAL**	**1583.42**

Table 1: Costs calculated based on ordinary admission (euro).

Then, the costs for the same procedures were calculated when carried out in the BOU: €1124 for an ERCP, €1555 for an ERCP with sphincterotomy and €1928 for an ERCP with stent placement. In addition, an estimate was made for the costs incurred by the hospital organization for procedures performed in the BOU. The overall results were calculated on the basis of the number of cases and have been displayed in Table 2.

	Average cost per procedure in BOU (euro)	Average difference per procedure in BOU (euro)	N° of cases in the study	Total difference on cases handled in the BOU (euro)
ERCP	1124	+471.36	35	+16.497.60
ERCP with sphincterotomy	1555	+342.40	96	+32.870.40
ERCP with stent placement	1928	+344.58	82	+28.255.56

Table 2: Comparison of costs on cases in and out of the BOU.

Discussion

The new model for managing acute obstructive jaundice in the ED became the object of study due to the need for more effective management of one of the most frequent causes of patient admission to the emergency department. Many scientific studies show that an urgent ERCP with the extraction of biliary calculus must be carried out earlier (within 24 hours) rather than later (after 24 hours). Urgency is of even greater importance if cholangitis is suspected.

The management of patients with acute obstructive jaundice in the BOU of an emergency department facilitates patient treatment and discharge without hospitalization, a most satisfying result as it reduces the number of inappropriate hospitalizations - the main purpose of the BOU. However, proper selection of patients who will benefit from this care path is key.

In particular, each individual patient must be correctly classified, especially in prognostic terms, which requires dedicated personnel who understand the purpose and regulations of the BOU. To that end, it is important to define more precise guidelines based on experience and retrospective analyses in order to identify which diseases are most suitable for management in the BOU[18, 19, 20, 21].

The development of new care pathways, such as the model described by this study for patients with obstructive jaundice, contributes to the extension of assistance in the BOU to pathologies that currently do not benefit from it, thus increasing healthcare efficiency. In economic terms, this study analyzed the clinical and cost-revenue profile of managing obstructive jaundice in the hospital in question. In particular, we observed the role of ERCPs in the BOU. The execution of this procedure in the BOU does not appear financially advantageous due to the higher costs involved that are not sustained by the reimbursement received from the DRG system.

This represents a financial negative for the hospital, as it is faced with additional expenses and less income. However, this should not hinder the implementation of BOUs. The current SARS COV-2 pandemic has led to the necessity to find new methods of organizing medical and care resources in order to ensure maximum availability of such resources for patients who are not affected by the virus but who require care and treatment. This includes the need to ensure patient and staff safety[23], which appears to be one of the fundamental purposes of Law No. 24/2014 on the safety of care in Italy[24,25].

The introduction of BOUs facilitates the prevention of long hospital stays, contributes to the substantial increase in available hospital beds, and has the capacity to eliminate the risk of transmission among patients who are not infected but require long stays in an environment that already poses the risk of nosocomial infections[26,27]. Moreover, the speed of treatment that the BOU can ensure is a key factor, along with the fact that it can improve patient outcomes due to the rapid access to appropriate procedures for their specific health problems. This proactive approach will facilitate the reduction of risks caused by and linked to care and medical activities, resulting in a decrease in medical liability disputes; this decrease may in turn provide an overall financial saving[28,29].

In our opinion, the current healthcare situation obligates us to support EDs in order to prevent overcrowding, which compromises the quality of services rendered. The BOU has shown evidence of excellent medical management, but it is not supported by an equally effective economic profile. Our proposal, in light of this data, would be to increase the number of beds within the ED in order to reserve space for ERCPs in the BOU. This structural adjustment would enable a more effective management of staff and access to the various departments and procedures.

Conclusions

Although conducted on a limited number of patients and in a limited period of time, this study shows how the use of a BOU in an ED serves to provide a rapid and coherent response to patient healthcare needs and also facilitates rapid discharge, liberating hospital beds to be used for other patients in need of different types of treatment. The average economic profile is more costly than the usual method of admission due to the lower reimbursement offered by the DRG system. Nevertheless, reserving space in the ED specifically for a BOU presents a real opportunity in that it enables swifter treatment access and discharge times, which in turn, reduces the risks of overcrowding in hospitals. We believe that this research is particularly important and can be applied to the current pandemic situation where, to ensure the health and safety of patients and hospital staff, crowding must be reduced as much as possible to prevent exceeding capacity and/or contracting nosocomial infections. For these reasons, we believe that integrating beds dedicated to the BOU in a con-

sistent and organized way in the ED may represent a real opportunity to improve general hospital management, which is even more important in times of pandemic.

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