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## Editorial

## Biliary surgery 2.0<sup>☆</sup>

### Cirugía biliar 2.0



The single-stage treatment of choledocholithiasis by minimally invasive surgery has appeared in most international clinical guidelines of the last decade as a recommended treatment option for bile duct lithiasis with gallbladder *in situ*.<sup>1-4</sup> Other options are two-stage treatments, meaning ERCP followed by laparoscopic cholecystectomy and intraoperative ERCP. When two-stage treatment is chosen, it is recommended to perform cholecystectomy shortly after ERCP, with time limits ranging from 72 h to 2 weeks. However, this is not always complied with due to the overload of patients in the surgical services and the lack of coordination that sometimes exists with the gastroenterology services and endoscopy units.

This equality in the recommendation of one or the other treatment is based on the similar efficacy and morbidity of these therapeutic alternatives demonstrated by successive studies in recent decades.<sup>5-7</sup> These same studies have demonstrated (some more than 20 years ago) a decrease in hospital stay (and therefore in cost) for single-stage treatment,<sup>8</sup> either by laparoscopic cholecystectomy with intraoperative ERCP or laparoscopic bile duct exploration (LC-LBDE).

However, these guidelines do not reflect the reality of several recently published meta-analyses, some of which appeared after the publication of the mentioned studies. In addition to confirming the reduction in costs with single-stage treatment, they begin to demonstrate a decrease in morbidity and a higher success rate with laparoscopic bile duct exploration (LBDE).<sup>9-12</sup>

At most hospitals, the implantation of laparoscopy as the approach of choice for cholecystectomy was the perfect setting for ERCP to gain ground as a treatment for choledocholithiasis, even in patients with gallbladder *in situ*. LBDE posed a technical challenge that very few surgeons were willing to accept. This, together with the primitive characteristics of the existing instruments, encouraged the surgical services themselves to refer their patients to the gastroenterology services for ERCP in an attempt at simplifying treatment.

We must admit that, at the beginning of laparoscopy, performing a choledochotomy and extraction of the lithiasis with its subsequent primary or decompression choledochorrhaphy added complexity and surgical time to a relatively simple cholecystectomy procedure. Given the characteristics of the existing instruments, this complexity was even greater if a transcystic examination was attempted.

On the other hand, it is necessary to remember that ERCP is not an innocuous technique. It is associated with pancreatitis in 3.5% of cases, 3% of which have fatal outcomes.<sup>13</sup> Other possible complications are perforation and bleeding. Additionally, it causes destruction of the sphincter of Oddi, which could be associated with bile duct reflux, with consequences that require further study but may include the formation of new choledocholithiasis, recurrent cholangitis, and the development of cholangiocarcinoma.

The latest published meta-analysis reports similar global morbidity rates with the two techniques, mainly biliary fistula in one-stage treatment versus a higher rate of pancreatitis in the two-stage treatment.<sup>14</sup> This type of morbidity distribution seems evident since each is inherent to each technique, and the association of biliary fistula with ERCP seems unlikely. We should consider whether, with equal frequency, acute pancreatitis (with its wide spectrum from mild to very severe) has a greater morbidity than postoperative fistulae, which are normally well tolerated thanks to surgical drainage. However, as usual, the severity of pancreatitis or bile leaks were not mentioned in this study. In this regard, whenever the morbidity rates of both techniques are compared, the frequency and severity should be analyzed using the different existing scales, as well as the Clavien-Dindo scale or CCI.<sup>15-17</sup>

In 2018, a comprehensive study by Ricci<sup>18</sup> compared the four possible alternative treatments for lithiasis of the bile duct with gallbladder *in situ*, once again confirming that two-stage surgery presented the highest risk of acute pancreatitis secondary to ERCP, while LC-LBDE was the worst option in terms of biliary fistula. In this study, due to the high incidence

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of biliary fistula in LBDE, the best option was cholecystectomy with intraoperative ERCP. However, we know that this option is not very widespread due to the coordination that is required between the surgical and endoscopy teams. By scrutinizing the studies of this meta-analysis, we found that the transcystic route had been used in only 36% of CL-LBDE cases. This figure is similar to our review of the literature (32%),<sup>19</sup> and corresponds with what we could call the beginnings of laparoscopic exploration of the bile duct, or biliary surgery 1.0, prior to the incorporation of advanced techniques and the evolution of instruments. The technological advances in recent years have allowed bile duct surgery to also become simplified and an increasingly less invasive procedure. The first advance in LBDE was the discontinued use of the Kehr tube for choledochorrhaphy in favor of antegrade stents,<sup>20</sup> which were later found to be associated with a high rate of pancreatitis<sup>21</sup> and fell into disuse to give way to primary closure of the choledochotomy. We also know that primary closure is associated with a significant incidence of biliary fistula.<sup>22</sup> Thus, the efforts of surgical teams in recent years have focused on trying to increase transcystic approach rates, as it is associated with the practical disappearance of bile leakage.

The advent of techniques derived from endourology, such as laser lithotripsy and the LABEL technique, the use of metal guides, dilators and introducers, and especially the availability of 3-mm choledochoscopes (often disposable) have led to increased transcystic approach rates, from the previous 30% to the current 80-90%, which would have been unimaginable years ago.<sup>22</sup> This has made it possible to reduce the morbidity associated with biliary fistula as a consequence of the closure of the choledochotomy and increase the success of the procedure to almost 100% when done by experienced teams. Therefore, it seems evident that if biliary fistula is the main drawback of CL-LBDE compared to ERCP-CL, the increased use of the transcystic route will translate into fewer complications, demonstrating a clear advantage over two-stage treatments.

However, we know that any technique needs to be reproducible for its use to become extended, and the transcystic approach could be shunned if training is not standardized. To avoid the repeated disinterest of surgeons in this technique, as was the case with choledochotomy, we believe that detailed teaching and simulated models should be implemented before the real situation is faced in patients. This will help shorten surgical times and increase success rates, avoiding frustration and abandonment of the technique. The PARA model (pending publication) that we use in our courses is based on the standardization and dissection methodology of the different surgical steps for modular learning, which are repeated until the acquisition of competence.

The transcystic approach is destined for success if technological advances and teaching methodologies, previously only enjoyed by ERCP, are applied.<sup>23</sup> As its frequency of use increases, clinical trials will most likely confirm what they are now beginning to suggest: definitive superiority in efficacy and morbidity over two-stage treatment. We are convinced that we are facing a true giant leap, which should be reflected in the clinical guidelines in coming years.

Therefore, we define 'Biliary Surgery 2.0' as the framework in which, through a set of techniques assisted by instruments and advanced materials, it is possible to increase the success rate of the transcystic approach to more than 80%, with a low incidence of failure due to impacted calculi and biliary fistula. This also entails promoting training in these techniques through practice and simulated models, with the ultimate goal of increasing the number of patients with bile duct lithiasis and gallbladder *in situ* who are successfully treated without complications.

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