

# Single center retrospective analysis of early vs. delayed treatment in acute calculous cholecystitis: application of a clinical pathway and an economic analysis

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## ABSTRACT

**BACKGROUND:** Treatment option and timing for surgery in case of acute calculous cholecystitis (ACC) is still a matter of discussion. Tokyo Guidelines (TG13) offers some rules but they don't reflect entirely the information of Evidence Based Medicine (EBM). This study aimed to draw some consideration from our practice in the application of the guidelines and put forward the clinical, economic and organizational effect of it.

**METHODS:** The study is a single center retrospective study based on administrative database formed by gathering information from clinical registry. Data were collected between January 1<sup>st</sup>, 2008 and April 30<sup>th</sup>, 2013. A cutoff point was established on May 15<sup>th</sup>, 2010 when we moved from a single surgeon method to a shared EBM method to treat ACC. The economic aspect was developed considering health service reimburse and hospital costs.

**RESULTS:** Five hundred and two patients were selected, 203 patients before the organizational change (Group 0) and 299 after (Group 1). In Group 0, 24.63% of the patients were treated with early laparoscopic cholecystectomy (ELC) and 39.4% received surgery delayed in second admission (DLC). After the change, 57.5% of the patients were treated with ELC while 13% were treated with DLC. Median length of stay (LOS) was significantly lower after the change (9.5 vs. 7.3,  $p < 0.0001$ ), and no difference in terms of complication was noticed.

**CONCLUSION:** Application of evidence based medicine in clinical practice resulted in better results. Economically, the clinical change resulted in a proper use of resources with a positive gap between the costs and refund to the hospital.

**Keywords:** Acute cholecystitis; clinical pathway; economic analysis; early laparoscopic cholecystectomy; evidence based medicine; timing.

## INTRODUCTION

The treatment of acute calculous cholecystitis (ACC), especially regarding the timing of intervention, is still debated in the scientific community despite the presence of several studies, meta-analysis and guidelines suggesting early cholecystectomy. During the "prelaparoscopic era", several studies had

demonstrated that the better treatment for ACC was early cholecystectomy, whenever possible within 7 days from the onset of symptoms, in order to reduce rehospitalization for the high rate of recurrence.<sup>[1-3]</sup> However, when laparoscopic cholecystectomy became the golden standard in elective settings, surgeons developed some concerns on its applicability in the acute scenario. The technical difficulties in recognizing anatomical structures due to acute inflammation, the potential hazard of severe complications, like common bile duct lesions, and the related high conversion rate led the surgeons to introduce delayed laparoscopic cholecystectomy, namely initial conservative antibiotic therapy until resolution of acute inflammation followed by elective interval surgery after 8–12 weeks, when it was supposed to have the opportunity to approach a "simple gallbladder with calculous".<sup>[4-7]</sup> During the following years, from reports, case series, RCT and several meta-analysis and our experience,<sup>[8-12]</sup> early laparoscopic cho-

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lecystectomy (ELC) and delayed laparoscopic cholecystectomy (DLC) have resulted significantly not different in terms of conversion rate to open cholecystectomy or in terms of common bile duct lesions. In the meantime, same studies have shown that the ELC group has a significant decrease in total hospital stay, being a more cost effective approach. In 2007, the first international guidelines for the treatment of ACC were published, called Tokyo Guidelines (TG),<sup>[13]</sup> in order to uniform the management of this common pathology among the world surgical community. However, data available at this time still show that up to 80% of the patients with ACC have not received definitive surgical treatment during the first hospital admission<sup>[14-18]</sup> although early treatment has been proved to be better. On the basis of this debate, we performed a retrospective analysis of the patients admitted to our institution with non-complicated ACC during the last six years, and we also had the opportunity to match two different modalities, DLC vs ELC, for the treatment of ACC. During this period, the organization of the emergency surgery service of our hospital and even the clinical approach to ACC changed. In the first period, the approach to ACC was apparent, more cautious, based on the decision of a single surgeon, consisting of an initial conservative treatment, followed by a delayed laparoscopic cholecystectomy in a later hospital admission (DLC). In the second period of time, the approach was based on evidence and in agreement with the guidelines, and explicitly, laparoscopic cholecystectomy was performed as soon as possible during the first hospital admission (ELC). In both groups, decision for surgery was based according to the clinical status and comorbidity, and patients requiring emergency operation, due to peritonitis, were operated immediately.

Besides the analysis of data in order to evaluate the effect of the organizational change in the clinical outcomes of the patients, an economic analysis was also performed in order to assess the advantages of the clinical change on health economy.

## MATERIALS AND METHODS

This is a single-centre, retrospective analysis of patients admitted to our hospital for ACC from January 1<sup>st</sup>, 2008 and March 30<sup>th</sup>, 2013. Patients were treated according to common clinical practice: fasting, iv fluid and iv antibiotic therapy; whenever indicated, and investigations (endoscopic ultrasound or cholangio-MRI according to availability) for concomitant common bile duct lithiasis were done before surgical intervention. In case of bile duct stones, the clearance of the biliary tree was performed by ERCP before surgery. The first surgical attempt is always laparoscopic unless there are contraindications. Empiric antibiotic therapy was started as soon as possible; blood and/or bile cultures were obtained for complex cases; antibiotics were routinely continued for seven days and shifted to specific drugs after obtaining culture results. Data were collected from discharge

records including all patients older than 18 years of age, with an emergency non-planned hospital admission. In order to select only patients with ACC, we included patients with a code of ACC and with an Italian DRG code of biliary tree disease, and we excluded patients with concomitant pancreatitis (ICD9CM code 577.x) or cholangitis (576.x). Surgical data were obtained from surgical registry; all diagnostic procedures were recorded from the administrative database and the results were collected from specific registries and time intervals were calculated from hospital admission. For each patient, Charlson's comorbidity index was calculated based on the presence of concomitant disease in the index.<sup>[19]</sup> Data regarding thirty days and one year mortality, and later re-admissions for a gallstones-related disease (ICD9CM codes 574.x 575.x 576.x 577.x) were collected from provincial health service database, and readmissions for delayed cholecystectomy were included into this sum. For those readmissions, same variables were calculated. Total hospital stay was calculated as the sum of each hospital stay length during the period of the study. Economic analysis was performed comparing the hospitalization cost with the payments refunded to the hospital by the regional health care system according to the Diagnostic Related Group (DRG) mechanism. Hospitalization costs were calculated with the mean cost of hospitalization per day at our hospital, based on the direct costs provided by the administrative and financial department (they include costs related to hospitalization, ancillary services and nursing care): for each patient, the costs were calculated multiplying mean hospitalization cost per day with the cumulative length of stay during the observed period and for each patient, the refund by Health Care System was calculated as the sum of each refund during the same period of time. Economic gaps were calculated as the difference of direct costs and refunds from the health care system. From the entire study group, we obtained two subgroups with the cut-off 31<sup>st</sup>, May, 2010 when our approach to ACC was changed.

All statistical analyses were performed with IBM SPSS 20. Continuous variables were shown as mean ( $\pm$ standard deviation) or median (interquartile range) and were compared with Student's t test and Mann-Whitney, as appropriate. Statistical significance was defined as  $p < 0.05$ . Based on the Italian laws, informed consent is not due for retrospective studies. The ethical committee was informed regarding the study protocol. The present study was performed in accordance to the Declaration of Helsinki.

## RESULTS

With the above mentioned method, from January 1<sup>st</sup>, 2008 to April 30<sup>th</sup>, 2013, five hundred and two patients were selected; two hundred and three patients before the organizational change (Group 0) and two hundred and ninety-nine after (Group 1). Demographic and clinical features were homogeneous between the two groups (Table 1). In Group

**Table 1.** Results are shown as median; Group 0 and Group 1 are patients treated respectively before and after the organizational change

Group	0	1	p
Patients (n)	203	299	
Age (mean)	62.80	61.61	0.8
Male gender (%)	58.60	54.50	0.25
Charlson's index	3.00	3.00	0.75
Cumulative LOS	9.58	7.32	<0.0001
Cumulative costs	4137.00	3162.00	<0.0001
Cumulative reimburse	3432.00	3200.00	0.09
Length of surgery	85.77	89.46	0.15
Conversion, n (%)	11 (8.7)	38 (18.5)	0.014
Post-op LOS	3	3	0.42
Investigation for choledocholithiasis, n (%)	59 (29.1)	104 (34.8)	0.17
Admission in surgical ward, n (%)	94 (46.3)	166 (55.5)	0.043
In hospital mortality, n (%)	0 (0)	4 (1.34)	0.09
Mortality 30 days, n (%)	0 (0)	1 (0.3)	0.12
Mortality 1 year, n (%)	7 (3.4)	7 (2.4)	0.11
Later hospital admissions, n (%)	102 (50.2)	54 (18.1)	0.001
N° hospital admissions (mean)	1.63	1.23	<0.0001

0, mean age was 62.8 years, male gender constituted 58%, and median Charlson comorbidity index of 3. The general surgery ward collected 46.3% of the admissions, but 24.63% received an indexed surgery with a median delay from the admission of 37.83 (15–124) hours: conversion rate to open cholecystectomy was 8.7% and median postoperative length of stay (LOS) was 3 (2.44–4.31) days. The delayed group formed 39.4% of the patients; however, 15% of these experienced readmission to the emergency department due to relapse of ACC. During the study period, we observed mean of 1.63 hospital admissions related to a biliary tree disease, with a median cumulative hospital stay of 9.58 (6.19–14.99) days. Finally, 35.96% of the patients were treated only conservatively and never operated. In Group 1, mean age was 61.6 years, male gender constituted 54% and a median Charlson comorbidity index of 3. 55.5% of the patients were admitted to the general surgery ward, and 57.5% were operated during the same hospitalization period, with a median delay of 59.98 (25.11–111.84) hours. Conversion rate to open cholecystectomy was 18.5% with a median postoperative LOS of 3 (2–4.45) days. 13.04% of the patients were treated conservatively and operated in a later admission, and 29.43% of the patients were never operated on. During the study, there was a mean of 1.23 hospital admissions, related to a biliary tree disease, with a median cumulative hospital stay of 7.32 (4.79–12.98) days. No differences in terms of complications and no biliary duct injuries were reported in both groups. Mortality was noticed only in Group 1, but the

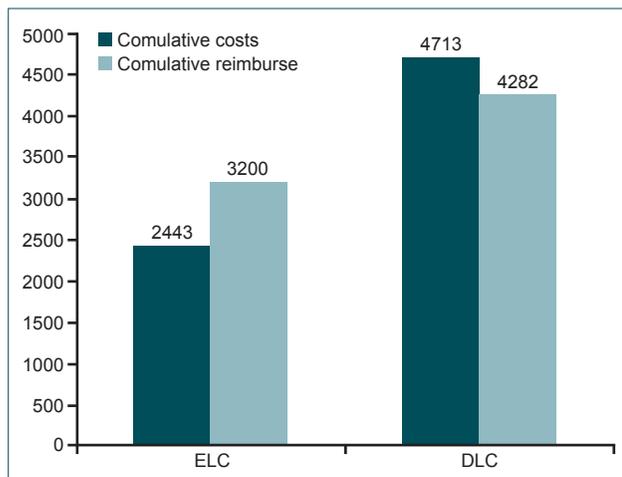
difference with Group 0 didn't reach statistical significance. It cannot be concluded that mortality is an effect related to the new treatment approach because mortality in one of the operated patients was due to comorbidities, lung failure in a lung transplanted patient, and the other three patients were not operated and died because of septic shock, pulmonary embolism, and acute myocardial infarction. All results are shown in detail in Table 2.

### Economic Analysis

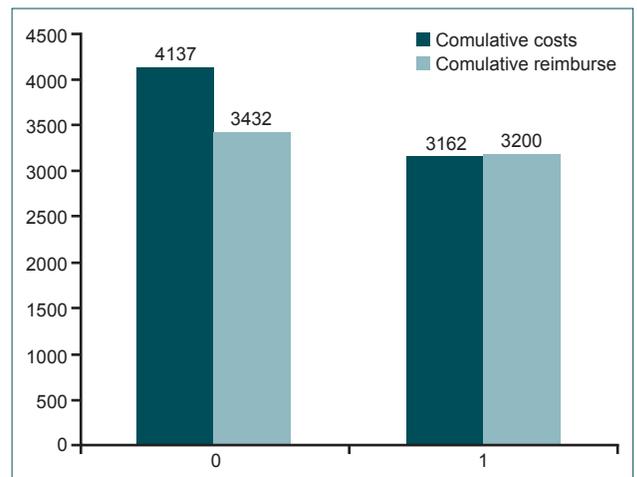
Sorting the data collected for the different treatment received, the ELC approach resulted in a median hospitalization cost of 2443 (1650–3831) € and a median refund, by the health care system, of 3200 (3200–3217) €, with a positive gap of +757 € for each patient gained by the hospital and the DLC approach resulted in a median cost of 4713 (3543–6841) € and a median reimburse, by health care system of 4282 (3784–4468) € with a negative gap of –431€ for each patient (Fig. 1). The same data were analyzed comparing the two different groups before and after the organizational change. Group 0 had a median hospitalization cost for each patient of 4137 (26697–6464) € with a median reimburse to the hospital by the regional health care system of 3432 (2190–4282) €, resulting in a loss of –705 € for each patient and in Group 1, the median cost of hospitalization for each patient was 3162 (2072–5589) € with a median reimburse to the hospital of 3200 (3197–3829) €, resulting in a “gain” of +39 € for each patient (Fig. 2).

**Table 2.** results are shown as median; Group 0 and Group 1 are patients treated respectively before and after the organizational change

	0				1				P
	ELC	DLC	No surgery	Tot	ELC	DLC	No surgery	Tot	
N (%)	50 (24.63)	80 (39.41)	73 (35.96)	203 (100.00)	172 (57.53)	39 (13.04)	88 (29.43)	299 (100.00)	
Age (mean)	55.72	60.19	70.53	62.80	55.88	62.17	72.57	61.61	0.7
Male gender (%)	58	56.2	61.60	58.60	50.6	64.1	58.1	54.50	0.25
Charlson	2	3	5.00	3.00	2	3	5	3.00	0.75
Cumulative LOS	6.45	10.69	12.77	9.58	5.61	11.27	10.81	7.32	<0.0001
Cumulative costs	2786	4618.1	5516.64	4138.56	2423.52	4868.64	4669.92	3162.24	<0.0001
Cumulative reimburse	3098	4250	1632.00	3432.00	3200	4410	1555	3200.00	0.09
Length of surgery	82.44	88.11	-	85.77	85.71	110.29	-	89.46	0.15
Delay of surgery (hours)	37.83				59.98				0.08
Time intervalsf or delayed		126.99				104.13			0.21
Conversion, n (%)	2 (4.2)	9 (11.4)	-	11 (8.7)	31 (18.6)	7 (18.4)	-	38 (18.5)	0.014
Post-op LOS	3	2.77	-	3	3	3.46	-	3	0.42
Investigation for choledocholithiasis, n (%)	10 (20)	22 (27.5)	27 (33)	59 (29.1)	55 (32)	13 (33.3)	36 (40.9)	104 (34.8)	0.17
Admission in surgical ward, n (%)	41 (82)	30 (37.5)	23 (31.5)	94 (46.3)	140 (81.4)	10 (25.6)	16 (18.2)	166 (55.5)	0.043
In hospital mortality, n (%)	0 (0)	0 (0)	0 (0)	0 (0)	1 (0.6)	0 (0)	3 (3.4)	4 (1.34)	0.09
30 days mortality, n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1.2)	1 (0.3)	0.12
1 year mortality, n (%)	0 (0)	0 (0)	7 (9.6)	7 (3.4)	3 (1.8)	0 (0)	4 (4.7)	7 (2.4)	0.11
Later hospital admission, n (%)	2 (4)	80 (100)	20 (27.4)	102 (50.2)	2 (1.2)	39 (100)	13 (14.8)	54 (18.1)	0.001
N° hospital admission (mean)	1.08	2.11	1.47	1.63	1.01	2.15	1.24	1.23	<0.0001



**Figure 1.** Economic gap between surgical approaches; data are shown as median.



**Figure 2.** Economic gap between groups; data are shown as median.

## DISCUSSION

From the analysis of the results, some considerations could be drawn. In Group 0, only a small part of the patients received ELC during their first hospitalization, which resulted in a selection of “healthier” patients to be operated until the supposed “golden” 72 hours. This fact could justify the relatively low conversion rate (8%) obtained compared to that reported in the literature (25%),<sup>[11]</sup> but this approach led to a need for a second already planned hospitalization for the large amount of remaining patients; about 15% of these patients required a second emergent hospitalization. Overall, in Group 0, we observed a mean of 1.63 hospital admission during that period of time. The change that occurred at our hospital resulted in several advantages. The percentage of the patients treated with ELC was more than redoubled, excluding patients never operated during each period of time, we obtained 81% in the second period starting from the 38% in the first one. This amount of cases resulted in an increased delay to surgery (59 hours), very near to the proposed limit of 72 h and an increased conversion rate (18%) that is, in any case, lower than that reported in the literature;<sup>[11]</sup> however, we did not notice an increased complication rate. Evident advantages were the significant reduction of the median length of hospitalization and the significant reduction of the number of hospitalization ( $p < 0.0001$  in both cases) for each patient.

Furthermore, the ELC approach (Group 0 plus Group 1) resulted even in an economic benefit for the health care system and for the hospital management. Our data confirmed the economic advantage, about 1200€ saved, of reported in the literature in different settings.<sup>[20,21]</sup> Cholecystectomy performed at the first admission allowed our Hospital to reduce all the efforts that each hospital presentation usually requires. Consequently, we had the opportunity to confirm this economic advantage also when comparing the impact of our organizational set-up change (Group 0 vs. Group 1): before the change, the gap between cost and refunding was

negative for the hospital, with a loss of -431€ for each patient; whereas, after the change, the gap became positive, plus 39€ for each patient. Clinical approach to ACC is an issue of great debate among the scientific community, and despite the presence of strong evidence supporting ELC approach; the real situation is that a variable percentage of patients do not receive the right treatment. From this point of view also, TG13 is, in our opinion, quite controversial. TG13 has the big value to offer a base to guide clinician in this setting; however, they fail, in contrast to RCT and meta-analysis results, to suggest early surgery for a big rate of patients with ACC. They recommend early surgery for mild cholecystitis, early drainage for the severe and conservative management with delayed cholecystectomy, or surgery in experienced centres for the moderate ones;<sup>[13]</sup> however, this different approach to ACC, based on the proposed classification, is in contrast with the data in the literature and do not show an improvement in the outcome<sup>[22]</sup> as noticed by Campanile.<sup>[23]</sup> In contrast to TG 13 and according to the favourable results of ELC in the literature, we selected patients for ELC on the basis of predicted mortality rate less than 10% calculated with the P-Possum score after organizational change. Furthermore, the indication to surgery was determined as surgery “as soon as possible”, without the strict limit of 72 hours. Indeed, in a meta-analysis recognizing the superiority of early surgery, the time limit is variable from 48 h to seven days<sup>[12]</sup> and recent evidence has not shown clinical advantage with this strict temporal limit.<sup>[24–26]</sup>

One question rises looking at the gap between clinical and economic advantages of index cholecystectomy for AAC and the “reluctance” to apply ELC: why? One reason could be still related to the surgeon fair for an anecdotal belief of higher common bile duct injury and higher conversion rate in the acute setting. However, this aspect, in our opinion, is decreasing by the time because surgeons are more and more confident with laparoscopy, and RCT results are easily avail-

able. The second reason that we focused on refers to the cultural perception of acute care surgery. The organization hospital plans diffusely show to have focused on elective and emergent cases such as oncology, trauma, solid organ transplantation, stroke, cardiac ischemia and so on.<sup>[21]</sup> However, there is a large part of patients not included in these categories that suffer acute diseases, like ACC. Very often; the hospital organization fails to prearrange dedicated resources able to allow an EBM acute care surgery. Our report could be interesting also for some consideration on human resources and organization consequence of clinical change, in which the introduction of an evidence based approach to acute cholecystitis replaces a single-physician based approach. Similar experience and results have been reported by Sheffield and colleagues with the introduction of a clinical pathway including all hospital staff, from the Emergency Department to the surgical theater.<sup>[27]</sup> In our case, at this moment, the change of clinical approach involved only the general surgery staff. The shift to proper management, even without the application of a well-defined clinical pathway and only restricted to one of the many “players” generates an improvement in the whole system. An institutional clinical pathway based on EBM offers, at the opposite, a valid instrumentation to overcome individual variability and an effective plan for the Hospital Administration in order to make ready for that clinical scenario.

Our data have several limitations. First of all, this is a retrospective study and data were extracted from an administrative dataset, with lack of some clinical information although clinical registry information was collected, and consequently, the number of patients studied was relatively restricted. Despite these quite important restrictions, our data contain some positive aspects that we would like to emphasize. It is a single-center experience with a cheering number of patient/year. Moreover, more than 90% of the surgical staff contributed to the applicability of the clinical management change, to the extent that we noticed. This fact could encourage surgical teams for EBM-based change in clinical practice.

In conclusion, despite all the limitations of the study, we can confirm that the proper treatment for ACC is laparoscopic cholecystectomy at the index hospitalization with a benefit for the patient and a clear advantage in terms of health policy and with a more careful use of economic resources. In order to obtain a further increase in patients treated properly with a more evident reduction in total length of stay and an additional reduction in costs, we advocate the introduction of similar institutional clinical pathways according to the EBM.

Conflict of interest: None declared.

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## ORİJİNAL ÇALIŞMA - ÖZET

### Akut taşlı kolesistitin erken ve geç dönem tedavisinin tek merkezli geriye dönük analizi: Klinik yöntem uygulaması ve bir ekonomi analizi

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**AMAÇ:** Akut taşlı kolesistitte (ATK) tedavi seçeneği ve cerrahinin zamanlaması hâlâ tartışma konusudur. Tokyo Kılavuzları (TG13) bazı kurallar teklif etmesine rağmen kanıt dayalı tıptan (KDT) edinilen bilgileri tam olarak yansıtmamaktadır. Çalışma kılavuzları uygulamamıza ilişkin bazı hususlara ve bunun klinik, ekonomik ve organizasyona ilişkin etkilerine dikkat çekmeyi amaçlamaktadır.

**GEREÇ VE YÖNTEM:** Bu çalışma idari veri tabanı ile birlikte klinik kayıtlardan gelen bilgilerin birleştiği tek merkezli bir çalışmadır. 1 Ocak 2008 tarihinden 30 Nisan 2008'e kadar veriler toplandı. ATK'yi tedavi için tek cerrahlı yöntemden paylaşımli KDT yöntemine geçtiğimiz 15 Mayıs 2010'u referans noktası olarak aldık. Sağlık hizmetlerinin geri ödemesi ve hastane maliyetlerini göz önüne alarak çalışmanın ekonomiyile ilgili yönü geliştirildi.

**BULGULAR:** İki yüz üçü organizasyonda değişikliğe gitmeden önce (Grup 0) ve 299'u sonra (Grup 1) olmak üzere toplam 502 hasta seçildi. Grup 0'da hastaların %24.63'ü erken dönemde laparoskopik kolesistektomi (ELK) ile tedavi edilirken %39.4'üne ikinci kez gelişlerinde geç dönemde (GLK) cerrahi uygulandı. Değişliğe gittikten sonra hastaların %57.5'i ELK ve %13'ü GLK ile tedavi edilmiştir. Değişiklikten sonra hastanede ortalama kalış süresi anlamlı derecede daha kısa (9.5 ve 7.3 gün,  $p < 0.0001$ ) olup komplikasyonlar açısından herhangi bir fark izlenmedi.

**TARTIŞMA:** Klinik pratiğe kanıt dayalı tıp uygulaması daha iyi sonuçlar alınmasına neden olmuştur. Ekonomik açıdan klinik değişiklik maliyetlerle hastaneye geri ödeme arasında olumlu bir farklılıkla birlikte kaynakların doğru kullanılmasına yol açmıştır.

**Anahtar sözcükler:** Akut kolesistit; ekonomik analiz; erken dönem laparoskopik kolesistektomi; kanıt dayalı tıp; klinik yöntem; zamanlama.

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