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Utility of routine drainage after elective laparoscopic cholecystectomy. A prospective randomized study

Utilidad del drenaje rutinario después de colecistectomía laparoscópica electiva. Estudio prospectivo aleatorizado

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Palabras clave:
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ABSTRACT

Introduction: the use of prophylactic drains after elective laparoscopic cholecystectomy is a common practice; however, its utility is still controversial. **Objectives:** to determine whether the use of routine drains after laparoscopic cholecystectomy can modify postoperative morbidity, hospital stay, the need for rescue analgesia, or the requirement for antiemetics. **Material and methods:** a randomized study evaluated patients undergoing elective laparoscopic cholecystectomy at the General Hospital of Mexico over 36 months (December 2016 to December 2019). Two groups were formed: group A with prophylactic Penrose drain and group B without drainage. **Results:** 400 patients were included in the randomization process, of which 209 belonged to group A and 191 to group B. No significant differences were found in the incidence of complications (1.9% vs. 0.5%, p = 0.24), rescue analgesia (54.9% vs. 48.3%, p = 0.19), or the requirement for antiemetics (36.8% vs. 34.1%, p = 0.29). The average hospital stay (31.1 vs 27.3 hours, p = 0.001) and prolonged hospital stay (11.9% vs 3.6%, p = 0.0001) were significantly higher in group A. The behavior of patients excluded from the randomization process due to the use of drainage at the surgeon's discretion for difficult cholecystectomy was analyzed, forming a third group (group C) with 63 patients. This group showed a higher incidence of complications compared to groups A and B (12.6% vs 1.25%, p = 0.0001) and greater severity of complications (p < 0.0001). **Conclusions:** the routine use of drains associated with cholecystectomy is not justified. Its utility lies in selective use under the surgeon's discretion.

RESUMEN

Introducción: *el uso de drenajes posterior a una colecistectomía laparoscópica electiva es una práctica común, sin embargo, su utilidad aún es controvertida.* ***Objetivos:*** *determinar si el uso de drenajes rutinarios después de una colecistectomía laparoscópica puede modificar la morbilidad postquirúrgica, estancia hospitalaria, necesidad de analgesia de rescate o requerimiento de antieméticos.* ***Material y métodos:*** *estudio aleatorizado que evaluó a pacientes sometidos a colecistectomía laparoscópica electiva en el Hospital General de México en un periodo de 36 meses (diciembre de 2016 a diciembre de 2019). Se conformó un grupo A con drenaje tipo Penrose y un grupo B sin drenaje.* ***Resultados:*** *se incluyeron 400 pacientes en el proceso de aleatorización, de los cuales, 209 pertenecieron al grupo A y 191 al grupo B. No se encontraron diferencias significativas en la incidencia de complicaciones (1.9% vs 0.5%, p = 0.24), analgesia de rescate (54.9 vs 48.3%, p = 0.19) o requerimiento de antieméticos (36.8% vs 34.1%, p = 0.29). El promedio de estancia hospitalaria (31.1 vs 27.3 horas, p = 0.001) y la estancia hospitalaria prolongada (11.9 vs 3.6%, p = 0.0001) fueron significativamente mayores en el grupo A. Se analizó el comportamiento de los pacientes excluidos del proceso de aleatorización debido al uso de drenaje a conveniencia por colecistectomía difícil conformando un tercer grupo (grupo C) con 63 pacientes, encontrando una mayor incidencia de complicaciones respecto a los grupos A y B (12.6 vs 1.25%, p = 0.0001) y una mayor severidad de éstas (p < 0.0001).* ***Conclusiones:*** *el uso rutinario de drenajes asociados a colecistectomía no está justificado. Su utilidad se encuentra en un uso selectivo bajo el criterio del cirujano.*

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INTRODUCTION

Drains are used after cholecystectomy as a protective measure for a condition that does not exist but could exist. Their hypothetical usefulness is reducing complications by providing an exit route for hematic, biliary, or purulent collections and facilitating early diagnosis.

On the other hand, it has been described that there is a risk of complications inherent to their presence, such as infection, pain, bleeding, and hernias in the site through which they are externalized; they can also favor the formation of adhesions, intestinal lesions or fragment and require interventional maneuvers for their removal.[1-5] These complications are described with a very low frequency, and the cause-and-effect relationship with the presence of drainage can be complicated to demonstrate.

The reality is that, despite being routine practice for some surgeons, the evidence regarding its risks and benefits could be more consistent and sometimes contradictory.[6] *Table 1* summarizes the results of randomized studies that have evaluated the routine use of drains associated with laparoscopic cholecystectomy.

MATERIAL AND METHODS

In 36 months from December 2016 to December 2019, patients undergoing laparoscopic cholecystectomy (LC) at the Hepatopancreatobiliary Surgery Clinic (HPB) of the General Hospital of Mexico were analyzed using an accidental non-probabilistic sampling. Patients over 18 years of age who underwent scheduled LC with the diagnoses of symptomatic gallbladder stones, gallbladder polyps, or with a history of complications associated with stones (choledocholithiasis and acute pancreatitis of biliary origin) were included. A computer randomization system decided the placement of ½ inch caliber Penrose drain. The surgeon knew the result of the randomization once the gallbladder had been removed and any hemostasis maneuvers had been completed. Patients with drainage constituted Group A or the experimental group, and patients without drainage constituted Group B or the control group.

Patients with conversion to open surgery, development of transoperative complications, and the need to place a drain for convenience were excluded; that is when the surgeon considered its use necessary and placed it outside the randomization process. The determinants for the use of convenience drains were established as evident biliary leakage, suspicion of biliary tract involvement, and a friable cystic duct.

The use of antiemetics (metoclopramide 10 mg IV) was selective and was only administered in subjects with nausea or vomiting. In all cases, intravenous paracetamol 500 mg was used for pain control, and metamizole was escalated to rescue analgesia when the intensity exceeded 3 points on the visual analog scale (VAS). Both antiemetics and rescue analgesics were administered in response to patient demand or when found necessary in systematic assessments every four hours. The incidence and severity of complications were recorded using the Clavien-Dindo (CD) classification.

A prolonged hospital stay was defined as spending more than one night. All patients were evaluated in the outpatient clinic seven days after discharge, where a record sheet was completed.

During the protocol's development and outside the objectives set at the beginning, it was considered relevant to record and analyze the behavior of the patients with exclusion criteria due to the placement of drains at convenience and to form a third group (group C), whose evolution was contrasted with that of groups A and B.

Descriptive statistics consisted of means and percentages. Analytical statistics were performed using the Student's t-test for continuous quantitative variables with normal distribution and the Mann-Whitney U test for those with non-normal distribution. Qualitative variables were analyzed using 2×2 contingency tables, where statistical significance was determined by χ^2 when all frequencies were greater than five and by Fisher's exact test for frequencies less than 5.

Table 1: Utility of the use of routine drainage associated with cholecystectomy in randomized studies.

Author (year)	Sample	Type of Surgery	Post-surgical morbidity	Pain	IHS	Nausea or vomiting	Subhepatic collections	Other
Nursal (2003)[7]	69	Elective and urgent	Similar	Similar	NA	More severe without drainage	NA	Reduced amount of subdiaphragmatic gas post-surgery
Uchiyama (2007)[8]	120	Elective	Similar	More severe with drainage	Similar	NA	NA	–
Tzovaras (2009)[9]	565	Elective	Similar	More severe with drainage	Similar	NA	NA	–
Georgiou (2011)[10]	116	Elective	Similar	More severe with drainage	Longer with drainage	Similar	Similar	Longer surgical time with drains (6.9 min)
El-Labban (2012)[11]	160	Elective	Similar	Similar	Longer with drainage	Similar	Similar	–
Picchio (2012)[12]	106	Elective	NA	Similar	NA	NA	Similar	–
Shamim (2013)[13]	155	Elective	NA	NA	Longer with drainage	NA	Longer with drainage at 24 hours. Similar at 72-hours	–
Park (2015)[14]	159	Urgent	Similar	NA	Longer with drainage	NA	Similar	–
Kim 2015[15]	193	Urgent	Similar	More severe with drainage	Similar	NA	NA	–
Qiu 2018[16]	212	Urgent	Similar	Similar	Longer with drainage	NA	NA	Less incapacity without drainage

IHS = In-hospital stay. NA = not available.

RESULTS

Out of an initial sample of 499 patients who met the inclusion criteria, two patients (0.4%) were excluded due to noted transoperative complications (in both cases, biliary tract affections), two (0.4%) due to conversion to open surgery, 32 (6.4%) due to inconsistent data in the collection sheets, and 63 (12.6%) due to the placement of drains at convenience (constituting group C). The final sample was 400 patients; 209 comprised group A and 191 group B.

General analysis

The mean age of the patients in groups A and B (n = 400) was 43.1 years (range 18 to 83), 79.5% (n = 318) were women and 20.5% (n = 82) were men. The incidence of complications was 1.25% (n = 5), and all of them were considered mild as they were classified as type I DC. No patient was reintervened, and there were no deaths. The mean hospital stay was 29.3 hours, and 8% of the patients had a prolonged hospital stay (n = 32).

The variables needed for rescue analgesia and the requirement of antiemetics were reliably collected in 378 and 377 patients, respectively, so this analysis was performed with samples of smaller magnitude: 51.8% (196 of 378 patients) required rescue analgesia, and 35.5% (134 of 377 patients) required antiemetics.

Group analysis

The average length of hospital stay and the incidence of prolonged stay were significantly higher in group A than in group B. The other variables analyzed showed no significant differences between groups. The complications that occurred were bleeding from a port, biliary leak, and vomiting (considered a complication when it generated a prolonged hospital stay), classified as mild complications in all cases (CD type I). The results are shown in *Table 2*.

The causes that conditioned a prolonged hospital stay were nausea, abdominal pain, drainage appearance, and undetermined reasons when the cause was not collected. The results are shown in *Figure 1*.

Serobiliary, serohematic, and high serous output only appear as causes of prolonged stay in group A since, in the absence of drainage in group B, eventual hematic or biliary leaks were not noticed.

Group C analysis

Group C consisted of 63 patients. When the causes for the placement of drains at convenience were analyzed, only two cases (3.2%) did the decision adhere to the elimination criteria established during the planning phase

Table 2: Results of group A vs group B.

	Group A N = 209 n (%)	Group B N = 191 n (%)	p
Age (years)*	43.7 [18-83]	42.8 [19-81]	0.56
Female gender	159 (76.1)	159 (83.3)	0.076
Complications	4 (1.9)	1 (0.5)	0.24
Hospital stay (hours)*	31.1 [19-127]	27.3 [18-56]	**0.001**
Prolonged hospital stay	25 (11.9)	7 (3.6)	**0.0001**
Rescue analgesia	111/202 (54.9)	85/176 (48.3)	0.19
Antiemetic requirement	75/204 (36.8)	59/173 (34.1)	0.59

* Values expressed as mean [range].

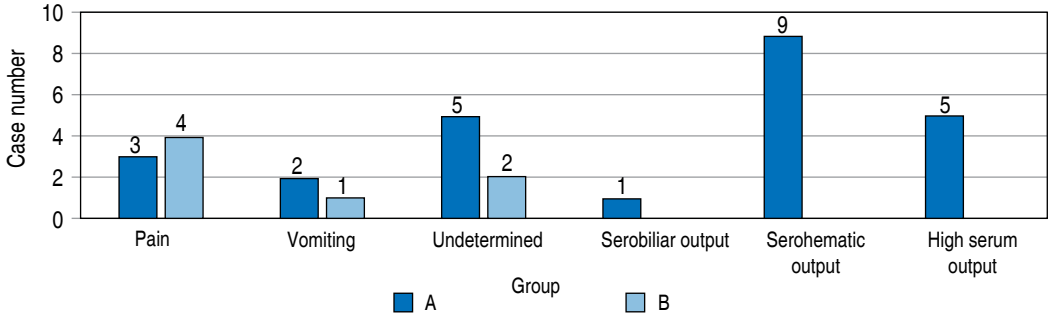

Figure 1: *Causes of prolonged hospital stay.*

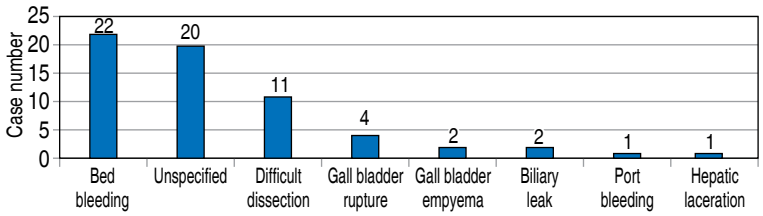

Figure 2: *Causes of drain placement at convenience (N = 63).*

(biliary leak), and in 41 cases (65%) the reasons were different from those pre-established. In 20 (31.8%), the surgeon did not specify the causes. The results are shown in *Figure 2*.

A higher incidence of post-surgical complications (12.6 vs 1.25%, p = 0.0001) and incidence of prolonged hospital stay (28.6 vs 7.25%, p ≤ 0.0001) were observed in this group for groups A and B. The results are shown in *Table 3*.

In the presence of complications in group C patients, Penrose drainage was considered beneficial diagnostically in all eight cases (100%) and therapeutically in six cases (75%) since it allowed conservative management by flushing out hematic and biliary collections without additional intervention. Bleeding was the most common complication (five patients); in two of them (40%), transfusion of blood products was required, and in two (40%), surgical reintervention for hemostasis (one case due to port bleeding and another due to bleeding from the surgical site). *Table 4* shows the behavior of these patients.

DISCUSSION

The routine use of drainage after laparoscopic cholecystectomy is a common practice, which is performed to reduce the incidence of postoperative complications or to facilitate early diagnosis. There are clinical trials that have evaluated the performance of the routine use of these drains with contradictory and inconsistent results, being performed in most cases with modest casuistry, which frequently prevents reaching significant and conclusive results, although with a constant tendency to dismiss their usefulness.[7-10]

As part of their nature, clinical trials are conducted under strict inclusion, exclusion, and elimination criteria to ensure that the effect of their variables can be reliably interpreted and the results can be reproducible. However, it should be kept in mind that excluding patients creates groups that will not be considered in the final analysis, so their behavior will not be known. These cases are part of routine clinical practice, and omitting their clinical course may result in considerable bias.[9] Previously, no study had analyzed the evolution of the excluded cases due to the placement of drains for convenience nor the factors that conditioned this behavior.

A Penrose drain may or may not be innocuous for the patients. One of the objectives established as a priority was to estimate the association of the Penrose with pain intensity since its effect as a foreign body or its capacity to evacuate the pneumoperitoneum (after the closure of surgical wounds, the Penrose maintains an escape route to the exterior) could have a favorable or unfavorable relationship with pain intensity.[12] Being a validated, standardized, and widely accepted instrument, we initially considered using the VAS scale as the unit of measurement; however, we concluded that implementing

it would be impractical since it allows us to estimate pain only at an exact moment in time. Determining that moment would be arbitrary and fallible. Thus, we opted for a dynamic system where analgesics were administered at the patient's request based on the World Health Organization (WHO) analgesic scale, and the results were collected as the need for rescue analgesia. We also sought to evaluate the relationship of Penrose with the incidence of nausea and vomiting, for which a similar system was used where antiemetics was used only on demand.[9-12]

Analysis of the results suggests no link between the presence of a Penrose drain and pain intensity. Nor is there any link between drains and the incidence of nausea or vomiting.

The main objective was to determine the relationship between the Penrose drain and postoperative morbidity, its effect on the incidence, and its possible therapeutic role in the face of complications. The conclusion

Table 3: Results of group A + B vs group C.

	Groups A + B N = 400 n (%)	Group C N = 63 n (%)	p
Age (years)* A	43.3 [18-83]	45.17 [18-91]	0.56
Female gender	318 (79.5)	45 (71.4)	0.076
Complications	5 (1.25)	8 (12.6)	**0.0001**
Severity of complications	CD I: 5 (1.25)	CD I: 3 (4.8) CD II: 2 (3.2) CD IIIb: 3 (4.8)	**< 0.0001**
Hospital stay (hours)*	29.3 [18-127]	40.12 [23-192]	0.06
Prolonged hospital stay	32 (8.0)	18 (28.6)	**< 0.0001**

CD = Clavien-Dindo classification.
* Values expressed as mean [range].

Table 4: Penrose behavior in group C in patients who developed complications.

Morbidity	CD	Hospital stay (hours)	Resolution	Diagnostic usefulness	Therapeutic usefulness
1) Hemorrhage*	II	126	Conservative	Yes	Yes
2) Hemorrhage‡	IIIb	58	Reintervention	Yes	No
3) Biliary leakage§	I	96	Conservative	Yes	Yes
4) Biliary leakage (Strasberg A)	I	100	Conservative	Yes	Yes
5) Hemorrhage*	II	132	Conservative	Yes	Yes
6) Hemorrhage*	I	72	Conservative	Yes	Yes
7) Hemorrhage¶	IIIb	150	Reintervention	Yes	No
8) Biliary leakage (Strasberg D)	IIIb	192	ERCP	Yes	Yes

CD = Clavien-Dindo classification. ERCP = endoscopic retrograde cholangiopancreatography.
* The origin of the hemorrhage was not determined. ‡ Laparoscopic port hemorrhage. § The origin of the biliary leak was not determined.
¶ Vesicular bed bleeding.

is that, with post-surgical morbidity of 1.9% versus 0.5% for groups A and B, respectively ($p = 0.24$), the presence of the Penrose does not significantly impact its incidence. Interestingly, cases of biliary leakage and post-surgical hemorrhage (classified as CD I) were diagnosed in group A and absent in group B. This result can be understood only as the ability to notice an eventuality due to the clinically irrelevant drainage and not as a cause-effect relationship.

Although the routine use of drains did not represent a risk or a benefit in terms of morbidity, it was associated with a higher incidence of prolonged hospital stay (11.9 vs. 3.6% / $p = 0.0001$). This use was interpreted as the surgeons' response to an expense through the drain whose appearance generated concern and motivated them to prolong the hospital observation period.[12,13] Therefore, the routine use of drains after cholecystectomy is not justified since it does not benefit the patient and represents a risk of prolonged hospital stay.

Even though in the planning stage, we tried to establish objective exclusion criteria for convenience when deciding to place a drain, during the execution of the protocol, we found that it was impossible to make objective the conditions that merit the placement of these drains and that despite the attempt to standardize these conditions, in most cases it is a subjective decision of the surgeon, since of the 63 cases that were presented, only in two (3.2%) the reason for placing a drain followed the pre-established standards.

When contrasting the morbidity between groups A and B (subjected to randomization) with group C (drainage by convenience), we can affirm that the surgeon's subjective criterion for the decision to place a drain is correct since the analysis of group C shows significantly higher postoperative morbidity compared with groups A and B. Furthermore, morbidity in group C was significantly higher. However, it was also related to more severe complications ($p < 0.0001$), which confirms that the surgeon's criterion to detect a complex surgery that warrants the placement of a drain is an acceptable and correct practice.[12,15]

It would be interesting to determine the role played by using Penrose drainage as a therapeutic instrument in the presence of a complication. Unfortunately, the results obtained in this study do not allow this analysis. However, it should not be omitted that 75% of the complications encountered in group C ($n = 6$) were resolved conservatively, the role of the Penrose drain being fundamental to evacuating the hemoperitoneum or bilioperitoneum (depending on the case), avoiding the need for additional interventions. Thus, even though we do not have a control group or a statistical test that allows a categorical statement, we can say without a doubt that the Penrose drainage played a fundamental diagnostic and therapeutic role in managing the cases that developed complications.[16]

CONCLUSIONS

The results affirm that the routine use of a Penrose after elective laparoscopic cholecystectomy does not modify the incidence of post-surgical complications, the requirement of antiemetics, or the need for rescue analgesia. However, it represents a risk factor for a prolonged hospital stay, so we do not find grounds for its routine use. However, it is justified selectively at the surgeon's discretion when he/she notices a complex surgery, which, in the case of our patients, avoided reoperation in 75% of the cases.

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