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Feasibility of the Conventional Laparoscopic Set-up in Trans Umbilical Cholecystectomy in Low Economic Country

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Background: Many different minimally invasive techniques for cholecystectomy were described in the literature to achieve better cosmetic results. Trans umbilical cholecystectomy (TUC) gained popularity but with associated challenging ergonomic and higher cost due to the need of specialized access platform and instruments (SAPI). This has led to limiting their widespread especially in low economic countries. We aimed here to study the feasibility and safety of using the conventional laparoscopic set-up in performing trans umbilical cholecystectomy (TUC) in our tertiary care university hospital.

Patients and methods: We conducted a prospective cohort study, from January 2016 to June 2018, eligible patients with symptomatic gall stones (100 cases) were divided into two groups: group A, TUC with conventional instruments (TUC-CI) versus group B, TUC with specialized instruments (TUC-SI). Exclusion criteria were acute cholecystitis, biliary pancreatitis, choledocholithiasis, BMI ≥ 35, previous upper abdominal surgeries, pregnancy, and ASA score higher than 2. Demographic data, perioperative complications, conversion rate, hospital stay, and procedure cost were recorded and statistically compared between the groups.

Results: There was sample homogeneity between both groups regarding age, sex, and BMI. No significant difference (P -Value ≥0.05) between both groups regarding the mean operative time (48± 23.50, 45.5 ± 19.11), hospital stay (0.4 ± 1.06 vs 0.32 ± 0.84) respectively, postoperative complications, and conversion rate to CLC. No major intraoperative complications or conversion to open surgery were needed in both groups. The cost of TUC-SI was significantly higher due to the cost of SAPI.

Conclusions: Trans umbilical single incision laparoscopic cholecystectomy is feasible with the same set-up used in conventional laparoscopic cholecystectomy in selected patients without any additional cost of specialized access platform & instruments. CLC is still our primary procedure.

Key words: SILS. Single Incision Laparoscopic Surgery. Trans- umbilical Cholecystectomy. Single Incision Laparoscopic Cholecystectomy. NOTES. Natural Orifice Transluminal Endoscopic Surgery. Conventional laparoscopic cholecystectomy. Mini laparoscopic Cholecystectomy.

Introduction

Conventional laparoscopic cholecystectomy (CLC) remains the gold standard worldwide as the surgical treatment of gallstones disease although the technical innovation and evolution in laparoscopic surgery.

Many other different techniques were described in the literature with heterogeneous data lacking a firm evidence base like mini-laparoscopic cholecystectomy (MLC), natural orifice translumenal endoscopic surgery (NOTES), trans umbilical single incision laparoscopic cholecystectomy (TU-SILC), and robotic surgery.[1]

TU-SILC gained interest and diffusion since first description in 1997,[2] as the umbilicus is considered embryological natural orifice with easier accessibility.[3] TU-SILC showed better cosmetic results and higher patient satisfaction compared to CLC in some studies,[4-6] but associated with challenging ergonomics and higher cost which limit its utilization especially in low economics countries.

Different authors described feasibility and safety of TU-SILC without using SAP to minimize the cost of the procedure.[7-15]

We aimed here to address the feasibility of using the conventional laparoscopic set-up used with CLC in performing trans umbilical single incision laparoscopic cholecystectomy in our tertiary care university hospital as alternative to specialized access platform and instruments to reduce the procedure cost.

Materials and methods

This study was conducted in accordance with The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement.[16] The population, intervention, comparator, outcomes, and study design (PICOS) approach were used to identify the inclusion criteria **(Table 1).**

Population

One Hundred adults with symptomatic gall stones disease were included and divided into two groups: group A, TUC with conventional instruments (TUC-CI) and group B, TUC with specialized instruments

(TUC-SI). Exclusion criteria were acute cholecystitis, biliary pancreatitis, choledocholithiasis, BMI ≥ 35, previous abdominal surgeries, and ASA score higher than 2.

Intervention & surgical technique

Trans umbilical single incision laparoscopic cholecystectomy was attempted in 100 patients. We operated in French position, for which the surgeon standing between the patient's legs, and the assistant to the left side of the patient.

Group A (TUC-CI)

A 2.5-3.0 cm slightly curved transverse incision around the umbilicus is deepened down to the fascia and the flap is undermined for about 1 cm to create natural fascial access platform to allow direct insertion of three reusable trocars: one 10 mm trocars for 30-degree scope, two working10/5 mm trocars using conventional straight instruments, through three separate fascial punctures with preservation of fascial bridge between trocars as shown in **(Figure 1).**

Group B (TUC- SI)

The umbilicus was everted with placement of two stay sutures on either side of the intended incision line and a 1.5 cm vertical incision was made between the two stay sutures with 2 cm vertical fascial incision is made directly through the umbilicus, then SILS port (Covidien, Mansfield, MA, USA) was introduced using at least one articulated endograsper/ endodissector instrument as shown in **(Figure 1)**.

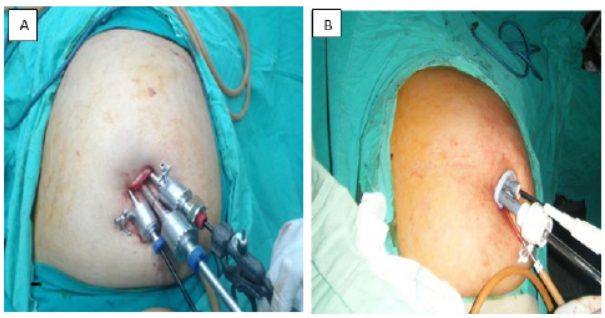

Fig 1: A: TUC-CI group showing the usage of conventional straight instruments through three separate fascial punctures with preservation of fascial bridge between trocars. B: TUC-SI group showing the usage of a SILS port (Covidien, Mansfield, MA, USA) with articulating instrument.

We insufflated the abdomen by open Hasson technique and operated using 30-degree scope in all cases. Then we placed the patients in reverse Trendelenburg position with the table tilted downward to the patient's left. The first step was to suspend the gall bladder fundus to abdominal wall using transabdominal 2/0 polypropylene suture as retractor as shown in **(Figure 2).** Then we used combined sharp and blunt dissection to achieve critical view of safety (CVS) technique in all cases before clipping the cystic artery and duct. Extraction of gall bladder was from umbilicus with closure of the fascia with 0 polypropylene/PDS sutures, and dermis of umbilicus with subcuticular Monocryl with 3/0.

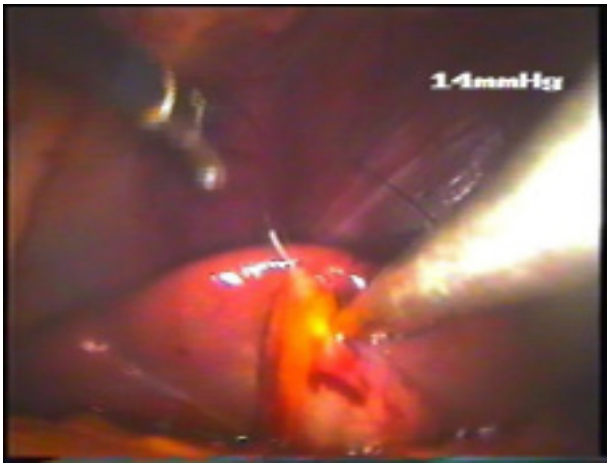

Fig 2: Retraction of GB fundus with transabdominal polypropylene suture.

Comparators

We compared two groups: trans umbilical cholecystectomy (TUC) with conventional instruments (CI) versus TUC with special instruments (SI), with 50 patients in each group (CI versus SI), respectively.

Outcomes

Demographic data, perioperative complications, conversion rate, hospital stay, and cost were recorded and statistically compared between the groups.

Study Design

Prospective cohort study. All procedures performed in this study were in accordance with the ethical standards of the Institutional and/or National Research Committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. The approval of the Ethics Committee of our hospital was obtained before the start of the study. Informed Consent was obtained from all individual participants included in this study.

The collected data was revised, coded, tabulated and introduced to a PC using IBM SPSS (Statistical Package for Social Science, IBM Corp, Armonk, NY) for Windows, Version 21. Description of quantitative variable was done as mean and standard deviation (SD), and qualitative data as frequency. Chi-square test was used to compare the groups as regard qualitative variable. Student T-test was used to compare two groups as regard quantitative variable

in parametric data. ANOVA test was used to compare categorical variables and means. The results will be considered significant (S) with P<0.05, highly significant (HS) with P<0.01 and Non-significant (NS) with P≥0.05.

Results

Demographic characteristics of patients

Table 2 summarizes the characteristics of the 100 patients in both groups. There was no significant difference between both groups; Female represent most of the cases (76%, 68%), the mean age ± SD (45.4 ± 8.5, 46.7 ± 8.3), BMI (30.1 ± 3.7, 28.8 ± 4.2) in group A and B respectively.

Perioperative data

Table 3 shows that there was no significant difference between the groups regarding the perioperative data.

Operative time was slightly higher in group A 48± 23.50 vs 45.5 ± 19.11 with no major intraoperative complications in both groups. No conversion to open cholecystectomy was required but we had to convert to conventional laparoscopic cholecystectomy in 5 cases (10%) in group A and in 4 cases (8%) in group B either due to failure to gain good exposure for safe dissection, or to control intraoperative bleeding.

All the cases were operated as day case surgery, been discharged for home six hours postoperatively if doing well. Hospital stay was 0.4 ± 1.06 day in group A vs 0.32 ± 0.84 day in group B.

Postoperative complications

Table 4 shows no significant difference regarding postoperative complications between the groups, while **(Table 5)** shows the type of interventions in both groups.

Three cases of bile leakage in our study; two in group A and one in group B. There was no major bile duct injury. The first case in group A was one of the cases were converted to CLC and drain was left in situ, managed by ERCP stenting due to cystic duct clip slippage. The other case was managed by laparoscopic washout for liver bed accessory duct. The case in group B was one of the cases that were converted to CLC, and intraoperative drain was left in situ which continued draining postoperatively and managed by ERCP stenting due to liver bed accessory duct.

One case of liver bed hematoma in group A was managed conservatively with watchful wait and antibiotics. The port site infection rate was 6% and 4% in both groups respectively and all were managed by antibiotics. One case in group B presented on day 10 with incarcerated umbilical hernia and was managed by surgical repair.

Procedure cost

Cost of TU- SILC in group A (TUC -CI) was significantly lower than group B (TUC-SI) due to the cost of SAPI used.

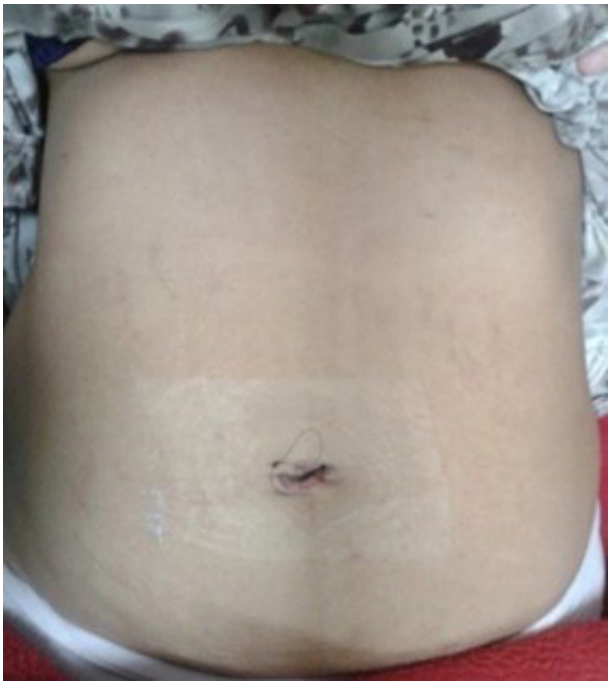

Fig 3: Postoperative abdominal picture after TUC.

Table 1: PICOS criteria for the study

Parameter	Criteria
Population	100 Patients with Symptomatic Gall Stones, Exclusion criteria were acute cholecystitis, biliary pancreatitis, choledocholithiasis, BMI ≥ 35, previous upper abdominal surgeries, pregnancy and ASA score higher than 2
Intervention	Trans- Umbilical Laparoscopic Cholecystectomy (TUC)
Comparator	TUC with conventional instruments (TUC-CI), versus TUC with special instruments (TUC-SI)
Outcomes	Demographics data, Perioperative Complications, Conversion Rate, Hospital Stay were recorded and statistically compared
Study design	Prospective Comparative Cohort, comparing two groups TUC-CI vs TUC-SI

Table 2: Patient demographics

Parameter	TUC-CI	TUC-SI	P value
Total Patient Number	50	50	N/A
Age (Mean ± SD)	45.4 ± 8.5	46.7 ± 8.3	NS
Sex (F/M), Female (%)	12/38 (76 %)	16/34 (68%)	NS
Pre-operative BMI	30.1 ± 3.7	28.8 ± 4.2	NS

Table 3: Perioperative data

	TUC-CI	TUC-SI	P Value
Operative Time (Minutes)*	48± 23.50	45.5 ± 19.11	NS
Conversion to CLC**	5 (10%)	4 (8%)	NS
Hospital Stay (Days)*	0.4 ± 1.06	0.32 ± 0.84	NS
30-Day Reintervention	2 (4 %)	2 (4%)	NS

** Number & Percentage. * Mean ± Sd. NS: non-significant.

Table 4: Postoperative complications

	TUC-CI	TUC-SI	P Value
Biliary Leakage**	2 (4%)	1 (2 %)	NS
Hemoperitoneum**	1 (2 %)	0 (0%)	NS
Port site infection**	3 (6%)	2 (4%)	NS
30-day Port site hernia**	0	1 (2%)	NS

** Number & Percentage. NS: non-significant.

Table 5: 30 Day reintervention types

	TUC-CI	TUC-SI
Bile leakage case 1	ERCP (Cystic duct clip slippage)	ERCP (Liver bed accessory duct)
Bile leakage case 2	Laparoscopic washout	
Liver bed Hematoma	Antibiotics	
Port site infection	Antibiotics	Antibiotics
Port site hernia		Surgical repair due to incarceration

Discussion

Recent systematic review and meta-analysis showed that TU SILC is feasible, safe in selected patients, with equal length of stay and quality of life compared to CLC but with higher cost due to longer operative time and usage of SAPI with inconsistent data regarding better cosmesis, and lower postoperative pain.[17]

Since the introduction of TU SILC, different newly developed SAPI were innovated to facilitate its ergonomics which contribute to the higher cost of the procedure.[18] European Association of Endoscopic Surgery (EAES) recommended that one could consider associated costs for the selection of access devices, taking into account that specific reusable metal devices are available nowadays in single-incision endoscopic surgery.[19]

To keep the balance between the current ongoing surgical innovation and advances in the surgical technology and our limited financial resources as in low economic country, we conducted this study in our university hospital to answer one question; Can we perform TU- SILC safely with the same laparoscopic set up we used to perform the conventional laparoscopic cholecystectomy?

We planned a prospective cohort study including eligible hundred patients with symptomatic gall stones disease. There was homogenous sampling between the groups regarding the age, sex, and BMI.

Our study showed comparable outcomes without any significant difference between the groups regarding the perioperative complications, hospital stay, and conversion rate to conventional laparoscopic surgery.

We succeeded in completing TU-SILC in 90% and

92% with operative time 48±23.50 and 45.5±19.11 in group A, and group B respectively. No conversion to open surgery was required, all conversion was to the CLC to gain better exposure view for safe dissection or adequate quick control of intraoperative bleeding.

We believe that operating in French position where the surgeon stand between the legs and the assistant to the left of the patients, plays a role in achieving better ergonomics as helping in better triangulation of the instruments towards the GB, and giving more space for both surgeon and assistant.

We operated as day case surgery; patients were discharged for home six hours postoperatively unless there were any concerns. Hospital stay was 0.4±1.06 day in group A vs 0.32±0.84 day in group B. CT abdomen and pelvis was the test of choice to evaluate for any postoperative eventual progression.

There were no significant differences regarding postoperative complications and 30-day reinterventions in both groups. Three cases of bile leakage in our study were managed as described earlier with no major bile duct injury. The port site infection rate was 6% and 4% in both groups respectively and all were managed by antibiotics.

One case in group B presented on day 10 with incarcerated umbilical hernia and was managed by surgical repair. No cases of port site hernia in group A were recorded in first 30 days, the fact of performing three separate fascial punctures with preservation of fascial bridge between trocars may contribute for this, on comparison to bigger fascial cut for placing the SILS port.

Few studies in the literature described the feasibility of TU-SILC using alternative techniques without using SAPI, most of them from low economic countries,[7-11] and China.[12-14] Most of them were retrospective case series, none of them compared with SAPI. One study by Zhao et al was randomized controlled study including 150 patients.

The results of the study by Sinha et al,[11] from India were very impressive as stated that they adapted TU-SILC with conventional laparoscopic set up as primary procedure since 2009 replacing CLC for all patients presented with gall stones disease including biliary pancreatitis and acute cholecystitis, and more interesting all procedures were done under spinal anesthesia.

Saidy et al,[15] described "marionette" technique by inserting two 5-mm trocars via separate fascial incisions via the same umbilical skin incision, in addition to another two silk stitches through the fundus and infundibulum. Operative time and cost were less with their technique compared with CLC.

Although the ongoing advances and innovation in the minimally invasive surgery, we believe that the conventional laparoscopic cholecystectomy will remain the primary management procedure worldwide for gall stones diseases, and all other approaches; NOTES, SILS, MLC, and robotic cholecystectomies will be limited mainly to academic and research purposes with very limited clinical applications.

EAES concluded in their last statement that considering the increased direct costs (Devices, instruments and operating time) of the SILS procedure and the prolonged learning curve, wider acceptance of the procedure should be supported only after demonstration of clear benefits.[19]

Our study was limited with small number and selection criteria as we excluded cases of acute cholecystitis, biliary pancreatitis, and high BMI. But this was the same as most of the published studies.[17]

The strength in our study is that we succeeded in answering our original question that we can perform TU-SILC by using same conventional laparoscopic set – up. According to the best of our knowledge, our study is one of the few in the literature evaluating the using conventional instrument in trans umbilical single incision laparoscopic cholecystectomy with prospective cohort study between the conventional and special access platform. Most of the other studies of TU SILC with conventional instruments were either compared to CLC or retrospective case series.

Conclusion

Trans umbilical single incision laparoscopic cholecystectomy is feasible with the same set-up used in conventional laparoscopic cholecystectomy in selected patients without any additional cost of specialized access platform & instruments. CLC is still our primary procedure.

Disclosures

Drs. Ahmed Elnabil-Mortada, Mohamed Elnagar, Amir Iskandar, and Sherif Albalkiny have no conflicts of interest or financial ties to disclose.

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