World J. Surg. 25, 1325–1330, 2001
DOI: 10.1007/s00268-001-0118-0

WORLD
Journal of
SURGERY
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Internationale de Chirurgie

Incidence, Risk Factors, and Prevention of Biliary Tract Injuries during Laparoscopic Cholecystectomy in Switzerland

Lukas Krähenbühl, M.D.,[1,2,3] Guido Sclabas, M.D.,[1] Moritz N. Wente, M.D.,[1] Markus Schäfer, M.D.,[1,2,3] Rolf Schlumpf, M.D.,[3] Markus W. Büchler, M.D.[1]

[1]Department of Visceral Transplantation Surgery, University of Bern, Inselspital, CH-3010 Bern, Switzerland
[2]University of Zürich, Rämistrasse 100, CH-8091 Zürich, Switzerland
[3]Aarberg Hospital, CH-3270 Aarberg, Switzerland

Published Online: August 24, 2001

Abstract. Bile duct injury (BDI) during laparoscopic cholecystectomy (LC) which may result in patient disability or death are reported to occur more frequently when compared to open surgery. The aim of this nationwide prospective study beyond the laparoscopic learning curve was to analyze the incidence, risk factors, and management of major BDI. During a 3-year period (1995–1997) 130 items of all LC data were collected on a central computer system from 84 surgical institutions in Switzerland by the Swiss Association of Laparoscopic and Thoracoscopic Surgery and evaluated for major BDIs. Simple biliary leakage was excluded from analysis. There were 12,111 patients with a mean age of 55 years (3–98 years) enrolled in the study. The overall BDI incidence was 0.3%, 0.18% for symptomatic gallstones, and 0.36% for acute cholecystitis. In cases of severe chronic cholecystitis with shrunken gallbladder, the incidence was as high as 3%. Morbidity and mortality rates were significantly increased in BDIs. BDI was recognized intraoperatively in 80.6%, in 64% of cases by help of intraoperative cholangiography. Immediate surgical repair was performed laparoscopically (suture or T-drainage) in 21%; in 79%, open repair (34% simple suture, 66% Roux-en-Y reconstruction) was needed. The BDI incidence did not decrease during the last 7 years. In 47%, BDIs were caused by experienced laparoscopic surgeons, perhaps because they tend to operate on more difficult patients. In conclusion, the incidence of major BDIs remains constant in Switzerland at a level of 0.3%, which is still higher when compared to open surgery. However, most cases are now detected intraoperatively and immediately repaired which ensures a good long-term outcome. For preventing such injuries, exact anatomical knowledge with its variants and a meticulous surgical dissecting technique especially in case of acute inflammation or shrunken gallbladder are mandatory.

Since its introduction in 1987, laparoscopic cholecystectomy (LC) has rapidly replaced open cholecystectomy (OC) for treating symptomatic gallstones [1–4] and acute cholecystitis [5–8]. This surgical revolution was initiated by the overwhelming benefits of the minimal invasive approach, patients demand for this new technology, and a strong economic interest of the involved industry. However, no randomized series comparing LC to OC have been published at that time, and all the presumed advantages of LC were based only on case series [9, 10].

It is estimated that the incidence of major and minor complications after LC are the same as that for OC [11, 12]. Among them, bile duct injuries (BDI) represent a major complication of hepatobiliary surgery. BDI markedly increased during the clinical introduction of LC, which may result in patient disability, or death as well as financial disaster [13, 14]. The reported incidence ranged between 0% and 3% [1, 15–18], which is 10-fold higher than the published range from 0% to 0.2% for OC [19–21]. The learning curve of the surgical community and the increased number of patients undergoing operations for "symptomatic" gallstones were main factors causing the high BDI rate. Recently published series have shown that the BDI rate after the learning curve has decreased to a range between 0.2% and 0.6%, which still remains higher when compared to OC [12, 13, 16, 20, 22, 23].

The aim of this prospective study was to evaluate the clinical relevance of BDI after LC in Switzerland. To this end, the data of all LCs performed by members of the Swiss Association of Laparoscopic and Thoracoscopic Surgery (SALTS) between 1995 and 1997 were analyzed and compared to two previously published series [12, 18].

Patients and Methods

Since 1989, the SALTS has prospectively collected data from patients undergoing LC at 84 surgical institutions, which accounts for more than 60% of all LCs in Switzerland. More than 130 items, including personal data, indication for surgery, surgical technique, morbidity, mortality, and short-term follow-up, were recorded on a computerized data-sheet [12, 24].

BDIs were classified as minor or major according to the Strasberg classification of laparoscopic injuries of the biliary tract [23]. Minor BDIs are biliary leaks and biliomas caused by failed occlusion of the cystic duct or injuries to aberrant biliary ducts at the liver bed. Major BDIs are always lesions of the hepatic or the common bile duct, such as occlusion or transection. Every patient

Correspondence to: M.W. Büchler, M.D., e-mail: markus.buechler@insel.ch

Table 1. Characterization of patients (n = 12.111).

	LC total	CCL	AC	BDI
Patients (n)	12,111	9338	2207	36
	100.0%	77.1%	18.2%	0.3%
Mean age (range) in years	54.7 (3–98)	53.3 (3–98)	58.6 (16–98)	
Surgical procedure				
Elective	88.6%	96.8%	54.6%	86.1%
Emergency	11.4%	3.2%	45.4%*	13.9%
Therapy				
CE with IOC	37.3%	37.7%	35.6%	54.3%*
CE without IOC	62.7%	62.3%	64.4%	45.7%
Conversion rate	7.3%	3.6%	19.5%*	63.9%*

LC: laparoscopic cholecystectomy; CCL: chronic cholecystitis/cholecystolithiasis; AC: acute cholecystitis; BDI: bile duct injury; CE: cholecystectomy; IOC: intraoperative cholangiography.
*$p < 0.05$ AC/BDI vs. LC total.

Table 2. Overall complication rate.

	LC total	CCL	AC	BDI
Intraoperative	10.4%	7.8%	19.3%	100.0%
Postoperative				
Local	4.7%	6.9%	6.8%	41.7%*
Systemic	3.7%	2.9%	6.8%	16.7%*
Mortality	18 (0.15%)	7 (0.07%)	11 (0.50%)	0

LC: laparoscopic cholecystectomy; CCL: chronic cholecystitis/cholecystolithiasis; AC: acute cholecystitis; BDI: bile duct injury.
*$p < 0.05$ BDI vs. LC total.

Table 3. Bile duct injuries (n = 36 patients).

	Patients (n)	%
Localization		
Common bile duct	28	77.8%
Hepatic bile duct	8	22.2%
Diagnosis		
Intraoperative	29	80.6%
Postoperative	7	19.4%
Disease		
CCL	17/9338	0.18%
AC	8/2207	0.36%
Shrunken gallbladder	11/370	2.97%*
Total	36/12,111	0.30%

CCL: chronic cholecystitis/cholecystolithiasis; AC: acute cholecystitis.
*$p < 0.05$ vs. total.

with a reported BDI in the SALTS data-base was identified, but only patients with major injuries were further investigated. Simple biliary leaks and biliomas were excluded because they can be managed conservatively in more than 95% of cases by percutaneous drainage or endoscopic stenting.

In Switzerland, the patients are operated on in a supine position with the surgeon standing between the patient's legs. A four trocar technique was used with the camera-port inserted at the umbilicus. Dissection of the gallbladder is either performed by using hook or scissors with monopolar current. Both, the cystic duct and the cystic artery are divided between clips. Intraoperative cholangiography (IOC) is not routinely performed (only 40%). The gallbladder was removed at the umbilical port hole either by enlarging the incision up to 2 cm or by using an Endobag (Ethicon, Johnson & Johnson, Spreitenbach, Switzerland) in cases of inflammation or perforation. For elective LC, a closed suction drain was rarely inserted, whereas for acute cholecystitis it was routinely used.

The results are expressed as mean ± standard deviation and range values, respectively. Data were compared by chi square test with Yates correction. A p value < 0.05 was considered to be significant.

Results

Characterization of Patients and Operative Complication Rates

There were 12,111 patients (69% female) who underwent LC predominantly for symptomatic cholelithiasis (CCL) in 77.1%, acute cholecystitis (AC) in 18.2%, and some less frequent indications (biliary pancreatitis, polyps). The overall mean age at the time of operation was 54.7 years (range 3–98 years). Emergency surgical procedures were more often performed in AC ($p < 0.05$ versus total LC and CCL), whereas 86.1% of BDIs occurred during elective cases. The rate of IOC was significantly higher in BDIs in which 64% of all injuries could be diagnosed intraoperatively with help of this radiographic test. Significant differences compared to total LC were found in the conversion rates of AC (19.5% vs. 7.3%; $p < 0.05$) and BDI (63.9% versus 7.3%; $p < 0.05$). The demographic baseline data are shown in Table 1.

Table 2 gives the overall complication rate. The intraoperative complication rate of the total LC group was 10.4%. AC was associated with an increased (not significant) intraoperative complication rate of 19.3%, whereas CCL revealed less intraoperative complications (7.8%). Postoperative complications were summarized as either local (e.g., bile duct stones, ileus, trocar hematoma, wound infection) or systemic (e.g., pulmonary embolism, cardiac decompensation, urinary tract infection) complications. Postoperative local (41.7% vs. 4.7%; $p < 0.05$) and systemic (16.7% vs. 3.7%; $p < 0.05$) complications were significantly increased in BDIs compared to total LC and both subgroups. There was no death from BDIs, whereas the mortality rate for total LC was 0.15%.

BDIs and Their Management

Three of four BDIs were localized in the common bile duct, the remaining 22.2% were lesions of the right hepatic duct. In 29 patients, BDIs were recognized intraoperatively (80.6%) followed by an immediate surgical repair. The total BDI incidence was 0.3%, 0.18% in CCL and 0.36% in AC, respectively (not significant). However, a significant increase of BDI rate was noted in cases of severe chronic cholecystitis with shrunken gallbladder (2.97% vs. 0.3%; $p < 0.05$) (Table 3).

As seen in Table 4, longer surgical procedures (> 120 minutes) occured more frequently (66.7% vs. 15.4%; $p < 0.05$) in BDIs compared to total LC, because immediate surgical repair was achieved in 80% of cases. Laparoscopic experience of the surgeon was the same in all groups and did not prevent the patient from BDI. It is noted that in 47% of BDIs, experienced laparoscopic surgeons (> 100 LCs) performed the surgical procedure.

Table 5 summarizes the surgical management of biliary lesions during or after LC. Intraoperative management was achieved laparoscopically in 21% either by simple suturing or T-tube inser-

Table 4. Risk factors for bile duct injuries.

	LC total	CCL	AC	BDI
Patients (*n*)	12,111	9338	2207	36
Operation time (min)				
< 60	27.8%	31.5%	13.4%	2.8%
60–120	56.8%	55.6%	61.7%	30.5%
> 120	15.4%	12.9%	24.9%	66.7%*
Laparoscopic experience[a]				
< 50	29.7%	31.5%	25.3%	27.8%
51–100	19.3%	18.4%	22.3%	25.0%
> 100	51.0%	50.1%	52.4%	47.2%

LC: laparoscopic cholecystectomy; CCL: chronic cholecystitis/cholecystolithiasis; AC: acute cholecystitis; BDI: bile duct injury.

[a]Experience of the surgeon in numbers of laparoscopic operations performed.

*$p < 0.05$ BDI vs. LC total.

Table 5. Management of bile duct injuries ($n = 36$ patients).

	Patients (*n*)	%
Intraoperative recognition	29	80.6%
Laparoscopic repair	6/29	20.7%
Open repair	23/29	79.3%
Primary closure + T-tube	8/23	34.8%
Roux-en-Y reconstruction	15/23	65.2%
Postoperative recognition	7	19.4%
ERCP+ stent	5/7	71.4%
Percutaneous drainage	1/7	14.3%
Roux-en-Y reconstruction	1/7	14.3%

ERCP: endoscopic retrograde cholangiopancreatography.

Table 6. Learning curve of bile duct injuries in Switzerland.

	BDI total	BDI intraoperative recognition	BDI postoperative recognition	Mortality in BDI group
Schlumpf et al. (1994) *n* = 3722 (1989–1992)	0.8%	19.4%	80.6%	0.0%**
Z'graggen et al. (1998) *n* = 10,174 (1992–1995)	0.3%*	43.8%*	56.2%*	9.4%
Present data *n* = 12,111 (1995–1997)	0.3%*	80.6%*	19.4%*,**	0.0%**

BDI: bile duct injuries.

*$p < 0.05$ Z'graggen et al vs. Schlumpf et al.

**$p < 0.05$ present data vs. Z'graggen et al.

tion and in 79% by open repair. One third of the open repairs were primary closures of the bile duct and T-tube insertion, the remaining two thirds by Roux-en-Y bilioenteric anastomosis. Partial liver resection or even liver transplantation was not required in this series. Postoperatively identified BDIs were mainly minor with biliary leakage due to a lateral tear of the biliary system and could be conservatively managed in 71.4% either by endoscopic papillotomy and stenting or percutaneous drainage (14.3%). Only one patient needed open reoperation with Roux-en-Y reconstruction.

The learning curve and incidence of BDI over a 10-year period in Switzerland is shown in 6. The rate of BDIs decreased significantly (0.8% to 0.3%; $p < 0.05$) after a learning phase in the first years and has now reached a plateau at a level of 0.3%. When comparing the present data with the previously published two series, with increased surgical experience, BDIs were more frequently recognized intraoperatively and immediately repaired (43.8% versus 19.4%; $p < 0.05$ respectively; 80.6% versus 43.8%; $p < 0.05$). During the present series, BDI was not associated with mortality, which was very high during the second study period (9.4%).

Discussion

The aim of the present series was to investigate the incidence and management of major biliary complications during LC beyond the learning curve in Switzerland. Therefore, the data of all LCs performed by members of the SALTS between 1995 and 1997 were analyzed and compared to two previously reported series [12, 18].

According to Strasberg et al., BDIs are *minor* (e.g., biliomas or bile leaks due to failure of occlusion of the cystic duct or injuries to smaller ducts at the liver bed) or major (e.g., occlusion or transection of the common bile duct) [23]. The main interest of this series was concentrated on *major* BDIs (Strasberg type D and E lesions) which may cause considerable disability with increased morbidity and mortality rates [12, 13, 16, 23]. From our data analysis, we were not able to classify each injury according to Strasberg et al. [23], since this classification was not used during standard data collection by the SALTS.

Early reports on LC showed a high incidence of BDI compared to OC [16–18, 25]. This may partially be explained by the inclusion of biliary leaks into the patient group with major BDIs. If simple bile leaks are included in the present data, overall BDI incidence would be as high as 1%. Another important reason explaining the high incidence of BDI is strongly associated with the learning curve of the surgical community. This also exists in open surgery. In OC, 85% of BDIs was caused by surgeons who had performed < 100 OCs [19]. For LC, the Southern Surgeons Club [1] documented a 2.2% incidence of BDI for the first 13 cases performed by every surgeon, whereas for the subsequent patients, the incidence decreased to 0.1%. Nevertheless, the introduction of LC created the phenomenon of the learning curve, which in fact, only represents the collective and synchronized gain of experience with a new surgical technique. Therefore, a temporary increase of well-known biliary complications could have been expected.

6 shows the learning curve for Switzerland. During the initial 3-year period (1989–1992), the BDI incidence increased up to 0.8%, whereby more than 60% of all injuries were caused by surgeons who performed less than 15 LCs [18]. In the following period from 1992 to 1995, the BDI incidence decreased to 0.3%. The effect of the learning curve was still considerable, because more than 60% of BDIs were caused by surgeons who performed less than 50 LCs [12]. During this second period, the mortality rate for BDIs was significantly increased to 9.4% compared to the total LC group (0.2%). This was related to the limited intraoperative recognition of BDIs (only 44%), and the consecutively delayed surgical repair. Our data are comparable to previous reports that revealed significantly increased morbidity and mortality rates for late recognition and repair of BDIs [13, 16, 26–28]. However, the present series demonstrate for the first time that the incidence of BDIs remains unchanged for several years at a level of 0.3%. Being beyond the collective learning curve, about half of all BDIs are now caused by experienced laparoscopic surgeons, perhaps

because they tend to operate on more difficult patients. Therefore, it can be concluded that factors other than the learning curve may influence the BDI rate during LC.

For OC it is well documented that anatomical variations of the biliary tract, such as an aberrant right hepatic duct, may play an important role in causing BDI [29]. This cannot be documented by the present data, since anatomical variations were not collected by the data-sheet. However, various technical steps are important to prevent BDI during LC [23]. In particular, a meticulous dissection technique is mandatory in order to identify Calots triangle, including the gallbladder, cystic duct, hepatic duct, and common bile duct junctions. Safe dissection is hampered in cases of acute inflammatory tissue reactions and a shortened cystic duct [13, 23, 30].

1 shows that 18% of LCs were performed for AC, which was considered to be a relative contraindication for a laparoscopic approach during the early period between 1989 to 1995. The incidence of BDI therefore increased (not significantly) from 0.18% to 0.36% in cases of acute inflammation, probably because dissection of Calots triangle was more difficult. It is important to note that in cases of a shrunken gallbladder with severe chronic inflammation, the BDI rate significantly increased up to 3% because of the presence of a short cystic duct and difficult dissection [13, 23, 30]. However, from the present data, it can only partially be concluded that with increasing experience, laparoscopic surgeons extended their indication for LC to more difficult cases, and to patients with inflammation and technically demanding dissecting maneuvers, which may partially explain the constant BDI incidence rate of 0.3% from 1992 to 1997. In cases of a shrunken gallbladder with difficult dissection and the documented increased BDI rate, it should now be questioned if such patients, who are mostly elderly patients, should not routinely undergo open surgery.

The role of IOC in preventing BDI is still under debate. Some studies report an increased incidence of BDI after IOC [31], whereas others show that IOC is useful for identifying anatomical variants and BDI during LC [32, 33]. From the present data, where 37% of patients had IOC with a success rate greater than 92%, it cannot be concluded that IOC prevents BDI, although 81% of all biliary injuries were detected intraoperatively (with 64% of cases by IOC). Thus, IOC may be useful in detecting stones in the common bile duct or in demonstrating a suspected BDI. However, IOC is normally used early during LC when dissection of the common bile duct has not yet been performed.

The best long-term results of bile duct lesions can be achieved if BDIs are recognized intraoperatively and immediately repaired [14, 28]. Depending on the type of lesion, an immediate repair can be performed laparoscopically by sutures or simple T-tube insertion or by conversion to open surgery. If BDIs are recognized postoperatively, they can be managed by percutaneous drainage of biliomas, endoscopic stenting, or open surgery (Roux-en-Y reconstruction). Late repair is associated with a poor long-term outcome (stenosis, stricture) and financial disaster [14, 23, 29]. This series documents the learning curve of recognizing BDI intraoperatively. During the early collecting period from 1989 to 1995, BDIs were detected intraoperatively between 19% and 44%, respectively, and were recognized in 81% during the present series, with a 0% mortality rate. Immediate laparoscopic repair was achieved in 20% of cases, whereas 80% were converted to open surgery. Furthermore, the immediately open-repaired patients did not show an increased hospital stay (10 days) compared to the converted cases due to AC (9.7 days). However, long-term results are lacking, and it cannot be concluded that a biliary stricture or stenosis with subsequent reoperation can be prevented. Late recognition of BDI in the present data was mostly associated with biliary leakage and lateral tear of the biliary system, which could be managed conservatively in 86% of cases by endoscopic stenting (72%) or percutaneous drainage (14%).

Conclusions

The incidence of major BDIs in Switzerland remains constant at a level of 0.3% which is still higher than that for open surgery. This may be explained by the fact that experienced laparoscopic surgeons tend to operate on more difficult cases (acute inflammation, shrunken gallbladder) with an increased risk for biliary lesions during dissection. However, most of the cases are now detected intraoperatively and immediately repaired either laparoscopically or by conversion to open surgery. If a biliary injury is suspected during dissection, the surgeon should perform an intraoperative cholangiography and not hesitate to convert to open surgery. More important in preventing such injuries by using the knowledge of normal anatomy with its many variants is a meticulous surgical dissecting technique, especially in cases of acute inflammation or a shrunken gallbladder.

Résumé

Les lésions biliaires (LB) survenant pendant la cholécystectomie laparoscopique (CL) peuvent être responsables d'incapacité ou de décès: elles seraient plus fréquentes comparées à la chirurgie par voie traditionnelle. Le but de cette étude a été d'analyser l'incidence, les facteurs de risque et le traitement des lésions majeures de la voie biliaire principale survenant après la courbe d'apprentissage par une étude prospective nationale. Pendant une période de trois ans (1995–1997) 130 items provenant des données de toutes les CL effectuées par les 84 institutions chirurgicales appartenant à l'Association Suisse de la Chirurgie Laparoscopique et Thoracoscopique ont été analysés en vue d'isoler les LB. On a exclu de cette analyse les fuites biliaires simples. II y avait 12111 patients dont l'âge moyen était de 55 ans (3–98 ans). L'incidence globale de LB a été de 0,3%, 0,18% pour la lithiase symptomatique et 0,36% pour la cholécystite. En cas de cholécystite chronique sévère avec vésicule biliaire atrophique, l'incidence pouvait atteindre 3%. La morbidité et la mortalité ont été extrêmement élevées en cas de LB. On a reconnu 80,6% des LB en peropératoire, dans 64% des cas, grâce la cholangiographie peropératoire. Une réparation chirurgicale immédiate a été réalisée par voie laparoscopique (suture ou drain de Kehr) chez 21 % des patients, une réparation par voie ouverte chez 79% (34% suture simple, 66% par anse-en-Y). L'incidence des LB n'a pas diminué pendant les sept dernières années. Quarante-sept pourcent des LB ont été le fait de chirurgiens laparoscopiques expérimentés qui ont peut-être tendance à opérer les cas plus difficiles. En conclusion, l'incidence des LB majeures reste constante en Suisse (0,3%), toujours plus élevée que celle de la chirurgie ouverte. Cependant, la plupart des cas sont détectés en peropératoire et réparés immédiatement, ce qui assure une évolution à long terme satisfaisante. La prévention de telles lésions passe par la connaissance précise de l'anatomie avec ses

variantes et une technique de dissection méticuleuse surtout en cas d'inflammation aiguë ou de vésicule atrophique.

Resumen

Las lesiones del tracto biliar (LTB) que ocurren en el curso de la colecistectomia laparoscópica (CL) y que resultan en incapacidad o muerte, se informan con mayor frecuencia de la conocida con la colecistectomia abierta. El propósito de este estudio nacional prospectivo, sobrepasada la curva de aprendizaje laparoscópico, fue analizar la incidencia, los factores de riesgo y el manejo de LTB mayores. En un periodo de 3 años (1995–1997) se recolectó en un computador central la información sobre 130 aspectos de la totalidad de las CL provenientes de 84 instituciones quirúrgicas de Suiza a través de la Asociación Suiza de Cirugía Laparoscópica y Toracoscópica, a fin de identificar y evaluar LTB mayores. Los casos de drenaje biliar simple fueron excluidos del análisis. Se enroló un total de 12.111 pacientes, con edad promedio de 55 años (3–98 años). La tasa global de LTB fue 0.3%, 0.18% en cálculos sintomáticos y 0.36% en colecistitis aguda. En pacientes con severa colecistitis crónica y vesícula escleroatrófica, la tasa llegó hasta 3%. La morbilidad y mortalidad aparecieron significativamente incrementadas en la LTB. El 80.6% de las LTB fueron reconocidas intraoperatoriamente en 64% de los casos con la ayuda de colangiografía intraoperatoria. Se practicó reparación inmediata laparoscópica (sutura o drenaje por tubo-en-T) en 21%, en 79% se efectuó reparación abierta (34% sutura simple, 66% reconstrucción de Roux-en-Y). La incidencia de LTB no decreció en el curso de los últimos 7 años; 47% de las LTB fueron causadas por cirujanos laparoscópicos experimentados, y es posible que a ellos lleguen los casos más dificiles. En conclusión, la incidencia de LTB mayores permanece constante en Suiza a un nivel de 0.3%, que todavia es superior al de la cirugia abierta. Sin embargo, la mayoria de los casos ahora son detectados intraoperatoriamente y reparados de inmediato, lo cual asegura un buen resultado a largo plazo. En cuanto a la prevención de estas lesiones, sigue siendo mandatorio tanto el buen conocimiento anatómico del tracto biliar normal y de sus variantes, como una meticulosa técnica de disección, especialmente en caso de vesículas con inflamación aguda o escleroatróficas. Characterization of patients (n = 12.111). Bile duct injuries (n = 36 patients). Management of bile duct injuries (n = 36 patients).

Acknowledgments

The authors thank Mrs. Franziska Rieben for data collection and to all SALTS surgeons and institutions that contributed to this national study.

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