A debate: Is major bile duct injury preventable?

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In the history of general surgery perhaps there in no other single surgical procedure that has created such an impact as laparoscopic cholecystectomy. Reasons are well known and are all evidence based. [1] With it came a string of complications inherent to laparoscopic surgery. Of all, major bile duct injury is the most serious and the most dreaded complication of laparoscopic cholecystectomy.

Many factors are considered contributory to the occurrence of BDI. Patient factors such as obesity, congenital abnormalities of the extra hepatic biliary and vascular tree and pathological changes such acute inflammation and fibrosis is common to the open approach as well. Other factors such as case load,[2] learning curve,[3,4] individual skills in adopting to two dimensional depth perception,[4,5] optical illusion,[5] changing indications for laparoscopic cholecystectomy [6] and the rate of conversion to open surgery [7,8,29] are either unique or specific to laparoscopic surgery. During last two decades, many stake holders such as surgical colleges and societies, universities, hospitals, instrument manufacturers and enthusiastic individual surgeons in many parts of the globe have taken multitude of steps to minimize the occurrence of BDI. Advanced surgical simulators with facilities for objective self assessment of laparoscopic dexterity skills, live animal and frozen human cadaver dissections, live workshops by experts, training programmes and mentoring systems, close supervision of laparoscopic procedures, centralized data bases for reporting the procedures and complications are often cited contributions . However inspite of the steps mentioned, the global incidence of bile duct injuries appear to be approximately four times higher than that of injuries following open cholecystectomy and this fact has remained stable in large surveys over 15 years. [9, 10,11,22])

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It is well accepted that the increased incidence of bile duct injuries occur during the surgeons early learning curve [12, 13, 20]. However, there is also evidence that one third of injuries would happen after the surgeon has performed more than 200 laparoscopic cholecystectomies [13]. Therefore one can conclude that it is more than simple inexperience that is responsible for the 'inadvertent' injury.

The question we debate in this article is still debated globally. The question is, whether bile duct injury should be regarded as a recognized complication or a preventable error. One study shows that 70% of surgeons regard bile duct injury as unavoidable[14]. When we consider the vide variations of the availability of measures described above in different regions of the world and problems of applying all such programmes in diverse socio cultural, economic and religious settings and issues of governance, accountability and the extent of impact of medico legal issues, it becomes clear that there is an urgent and a pressing need to revisit the issue of the major bile duct injury. Such a re-visit is important to our patients and also to us. Therefore the question we need to analyse critically is, what is the main cause for major bile duct injury and then to find a globally applicable solution.

Answer to this question is clearly identified in many studies. The answer is misidentification or misinterpretation of the biliary anatomy which may occur due to multitude of reasons during the performance of laparoscopic cholecystectomy [16,17]. Many preventive strategies have been suggested. Use of 30° scopes, cautious use of diathermy specially close to common hepatic duct, identification of the Rouviere's sulcus as a fixed extra biliary point during the dissection and conversion to open approach when there is a doubt are some of the suggested strategies [16,18,19].

In spite of these preventive strategies, why has the global incidence not changed? Is it because surgeons do not adhere to anatomical principles of dissection

and do not identify the structures beyond a reasonable doubt before irreversible actions such as using diathermy or division of a structure is undertaken? Or is it that if such identification becomes difficult as the dissection is progressing, we do not stop the procedure, revisit the decision and arrive at a judgment based solely on the safety of the patient and decide to convert? Should the bile duct injury be seen as a human error which may occur even in best of hands with optimal facilities and therefore consider as not totally preventable?

It is interesting to note the divergent views of experts on this point. Way and colleagues in an article published in Annals of Surgery in 2003 after an objective assessment of human factors and cognitive psychology came to the conclusion that not all bile duct injuries are excusable. Writing the editorial in the same journal Lillemoe argues in support of the view that all cases of bile duct injury that occur during laparoscopic cholecystectomy is not unavoidable and but at least some cases be considered as a simple human error [34]. These are difficult questions but the time is ripe for the profession to address these questions objectively to find a sustainable solution.

In addressing this thorny question, it is important for surgeons to appreciate the present day realities of patient care services and that we are in an era where the eminence based complacency is replaced by evidence based clinical excellence. It is also important to realize that irrespective of the statistics of population studies, control trials, anecdotal reports and perceptions of the individual surgeons on bile duct injuries, majority of patients will not consider major bile duct injury as an acceptable outcome following surgery for a benign disorder. Judging by the figures of settlements and the outcomes of many trials in the west during the last decade, it is becoming increasingly apparent that the global judicial systems are not prepared to accept such outcomes except under exceptional circumstances. [15, 26]

Although much has been written about the adherence to anatomical principles and unavoidable human errors I am of the opinion that it is the mindset of the surgeon and his inherent inability to revisit the decision and arrive at a judgment based solely on the safety of the patient that plays a pivotal part in the occurrence of the injury. Making the decision to stop and convert prior to undesirable outcome is based on two crucial human factors.

a. Risk taking behavior of the individual [21]
b. Inherent resistance to conversion

In the galaxy of literature related to the bile duct injuries and from the references presented in the article, one can re extract two evidence based statements to substantiate the said argument. These two facts are

a. the studies on 'learning curve effect' have shown that the risk of bile duct injuries are not only number dependent but also that the number is operator dependent [7]
b. the major bile duct injuries have occurred in the hands of experienced operators [13,14]

What is the present scenario in Sri Lanka? Only few studies are available on the subject of iatrogenic bile duct injuries [23,24,35]. However the reality is, during a period of 9 years a single tertiary referral centre had received a total of 67 bile duct injury referrals with 4 deaths [23,24,33]. Although must be considerable, no objective assessment is available at present on the physical and psychological impact on patients, their families and the emotional impact on surgeons. There is no dispute that the minimal access is the best way forward for our patients and the quality of care expected is continually changing to reach an ultimate goal of painless, safe, outcome based surgery. This goal is attainable. Therefore the time is ripe for surgeons to accept that major bile duct injuries are preventable.

In simple terms the rationale for this argument is that there are many surgeons who have performed large numbers of laparoscopic cholecystectomies without a single duct injury **[**32**].** They all follow the basic time tested set of rules with patient safety as the foremost factor. The key is to strictly adhere to the anatomical rules of surgical dissection. At any stage if the dissection or identification of structures is proving difficult, then to stop the procedure, re-visit the decision to proceed solely on the patient safety and decide to convert. The often forgotten time tested golden principle in biliary surgery practiced by pioneering biliary surgeons over a century must never be forgotten in the laparoscopy era. This golden rule refers to the sequence of steps to follow, when one is confronted with a difficult open cholecystectomy. That is, first to attempt fundus first open cholecystctomy and if this is proving difficult then to proceed to subtotal cholecystectomy and if this too is not possible then, to perform a cholecystostomy, remove the stones and drain the gall bladder. *The core issue we must extract to apply to the laparoscopic era is that in situations when there is a safe alternative to every step in the decision making process the core*

issue must be the safety of the patient. When this principle is applied to laparoscopic cholecystectomy we must also remember that the indication for the procedure is a non cancerous condition.

The process of decision making during the performance of a difficult laparoscopic cholecystectomy is often compared with the scenario of an airline pilot attempting to land an aircraft in stormy weather and the discrepancies of the respective training programmes [25]. A leading article in BJS in 2011 had been critical of the said comparison [27]. Airline industry has a set of rigid protocols for pilots to adhere in such situations [16]. Serving in an era where evidence based clinical excellence is considered by patients and legal systems as the rule of the game, the need for such protocols have become more important for the safety of patients and surgeons.

As presented in this paper, conversion is considered as a way to avoid the probability of bile duct injuries in difficult cases. Wide variations exist in the conversion rates of published reports [28,29,33]. In the competitive world surgeons like any other professionals would like to improve their laparoscopic skills and as the experience accumulates, will naturally take on more challenging cases. Indications for laparoscopic cholecystectomy are evolving with conditions previously considered as contraindications no longer applicable. Studies have shown that most of the bile duct injuries have occurred before conversion [21]. Some surgeons have adopted a zero conversion policy with success and zero conversion is used as a policy in some units [7]. Therefore an argument can be made to use conversion rate as a tool to assess performance. In 2004, the Duch Health Care Inspectorate introduced a system to make all hospitals in the Netherlands to report the selected 'performance indicators of care' annually. The first version of the indicators included laparoscopic cholecystectomy conversion rate and percentage of open cholecystectomies as 'performance indicators' but these were eventually removed after extensive discussion with the surgeons [28]. This is because many surgeons considered conversion to an open procedure to be an important choice in the prevention of major injuries [29].

Taking into consideration the current global perceptions on iatrogenic bile duct injuries, we recommend the following steps to be performed during laparoscopic cholecystectomy to prevent major BDI.

1. Adequate exposure and visualization of the operative field
2. Opening the calot's triangle by lateral and inferior traction of the gall bladder neck.
3. Blunt dissection of the calot's triangle, avoiding overuse of electro-cautery.
4. Clear identification of the junction between the cystic duct and the gallbladder (Infundibulo-cystic duct junction), gaining circumferential control and demonstrating the said junction.
5. Avoidance of excessive cephalic push of the fundus of the gallbladder, a step which closes the calot's triangle and approximates the operating field closer to common hepatic duct.
6. Avoidance of excessive traction of the infundibulum of the gallbladder to prevent tenting of the bile duct.
7. Demonstration of the supero medial and infero lateral wall of the lower 1/3 of the gall bladder and confirm that the infundibulum on its superior and inferior aspects is in continuity with the duct which is identified as the cystic duct.
8. Avoidance of blind use of clips or cautery to control haemorrhage
9. Liberal conversion to open approach when anatomy becomes and remains unclear at any stage of dissection.
10. Taking undue care during the dissection of the lower medial part of the gallbladder close to the common hepatic duct, during the fundus first approach after conversion. Going too medial and bleeding at this point in an inflamed tissue may mark the beginning of a disaster.
11. If the anatomy is not clear, to perform a subtotal cholecystectomy by leaving the part of the Hartmann's pouch which is adherent to common hepatic duct and perform a sub total cholecystectomy.
12. If the anatomy is extremely unclear, perform cholecystostomy, remove stones and drain the gallbladder.

Summary

Major BDI following cholecystectomy is an iatrogenic mishap associated with significant morbidity and mortality, reduced quality of life and reduced long-term survival. [30, 31] The best treatment for major BDI is prevention.

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