Surg Endosc (2013) 27:957–963
DOI 10.1007/s00464-012-2540-9

Kumar versus Olsen cannulation technique for intraoperative cholangiography: a randomized trial

K. Tim Buddingh · Ben M. Bosma · Brenda Samaniego-Cameron · Henk O. ten Cate Hoedemaker · H. Sijbrand Hofker · Gooitzen M. van Dam · Rutger J. Ploeg · Vincent B. Nieuwenhuijs

Received: 30 May 2012 / Accepted: 9 August 2012 / Published online: 10 October 2012

Abstract
Background There is resistance to routine intraoperative cholangiography (IOC) during cholecystectomy because it prolongs surgery and may be experienced as cumbersome. An alternative instrument may help to reduce these drawbacks and lower the threshold for IOC. This trial compared the Kumar cannulation technique to the more commonly used Olsen clamp for IOC (KOALA trial; Dutch Trial Register NTR2582).
Methods Patients undergoing elective laparoscopic cholecystectomy were randomized between IOC using the Kumar clamp and the Olsen clamp. Primary end points were the time that the IOC procedure took and its perceived ease as measured on a visual analog scale from 0 (impossible) to 10 (effortless). To detect a difference of 33 % in IOC time, a total sample size of 40 patients was required.
Results Fifty-nine patients were randomized. Nine were excluded because of conversion to open cholecystectomy before the IOC procedure. Twenty-eight patients underwent IOC with the Kumar clamp and 22 with the Olsen clamp. The success rate was 23 (82.1 %) of 28 for the Kumar clamp and 19 (86.4 %) of 22 for the Olsen clamp ($p > 0.999$). The mean IOC time was 10 min 27 s ± 6 min 17 s using the Kumar clamp and 11 min 34 s ± 7 min 27 s using the Olsen clamp ($p = 0.537$). Surgeons graded the ease of the Kumar clamp as 6.8 ± 2.7 and the Olsen clamp as 6.8 ± 2.1 ($p = 0.977$).
Conclusions IOC using the Kumar clamp was neither faster nor easier than using the Olsen clamp. Both clamps facilitated IOC in just over 10 min. Individual surgeon preference should dictate which clamp is used.

Keywords CBD (common bile duct) · Cholecystectomy · Complications

Surgical removal of the gallbladder is one of the most commonly performed operations on the digestive tract. A major complication of cholecystectomy, and especially laparoscopic cholecystectomy, is bile duct injury, which occurs in approximately 0.5 % of cases. There is general consensus that the main factor that leads to bile duct injury during laparoscopic cholecystectomy is misperception of the biliary anatomy [1]. Several techniques have been tested for intraoperative visualization of the bile ducts, but the widely accepted gold standard remains intraoperative cholangiography (IOC) [2].

Whether IOC is performed routinely, selectively, or not at all varies widely between and within countries. High rates of IOC use are reported in Australia and the United States [3, 4]. In a recent survey by our group, however, we found that IOC is hardly performed at all by the majority of the surgeons in the Netherlands [5]. It seems that despite the frequently reported beneficial effects of IOC, there is resistance to its routine application during laparoscopic cholecystectomy. Important reasons for this objection to the procedure are the fact that IOC lengthens the operation time and that bile duct cannulation may be experienced as a cumbersome procedure.

K. T. Buddingh · B. M. Bosma · B. Samaniego-Cameron · H. O. ten Cate Hoedemaker · H. S. Hofker · G. M. van Dam · R. J. Ploeg · V. B. Nieuwenhuijs
Department of Surgery, University Medical Center Groningen, Groningen, The Netherlands
e-mail: k.t.buddingh@chir.umcg.nl

V. B. Nieuwenhuijs (✉)
Department of Surgery, Isala Klinieken, Postbus 10500, 8000 GM Zwolle, The Netherlands
e-mail: v.b.nieuwenhuijs@isala.nl

The most commonly used technique for IOC is cystic duct cannulation. An incision is made in the cystic duct through which a catheter is advanced. The catheter is then fixed with a clamp. A frequently used instrument for this is the Olsen clamp (Cook Medical, Limerick, Ireland).

An alternative to standard IOC via cystic duct cannulation is cholangiography using the Kumar Pre-View clamp (Nashville Surgical Instruments, Springfield, USA), referred to here as the Kumar clamp. The instrument consists of a clamp placed over the base of the gallbladder and an attached needle that extends into the gallbladder to puncture the Hartmann pouch. Radiopaque contrast material is then injected through the needle. The Kumar clamp may decrease the time necessary for cholangiography and increase the ease with which it is performed.

To our knowledge, there are no studies that compare the efficacy of these two cannulation techniques. The aim of this study, therefore, was to perform a randomized trial to assess whether IOC using the Kumar clamp is faster and easier to perform than IOC using the standard Olsen catheter.

Methods

Study design and primary outcomes

The primary end points were twofold: first, time necessary for IOC (defined as the time between start of the cholangiography procedure to the time that the IOC had been interpreted), and second, the ease of the cholangiography procedure, recorded on a visual analog scale by the surgeon just after performing the operation. These two primary end points, rather than a single end point, were chosen because we thought that a substantial reduction in either one would result in a lower threshold to perform IOC. Statistical analysis on multiple end points has been previously described in the literature [6].

Secondary end points were as follows: to assess the success rate of IOC (defined as the proportion of patients in whom radiopaque contrast was seen at least in the common bile duct); to determine the number of biliary tree segments depicted on the cholangiogram (cystic duct; common bile duct; and right, left and posterior hepatic ducts); to ascertain the total exposure to X-ray radiation (mGy/m^2); to track the number of bile duct injuries; and to track the number of overall complications.

Sample size calculation

A sample size calculation was performed on the time needed for IOC (first primary end point); no reference numbers were available for the ease of IOC (second primary end point). Estimated time needed for standard IOC (Olsen clamp) is quoted in the literature at 15 ± 8 min [7], 10 min [8], and 27 min [9]. In a retrospective analysis of all cholecystectomies performed at our center between 2007 and 2008, we found an added time of 18 min for procedures in which an IOC was performed (unpublished data). On the basis of these data, we assumed that the standard IOC technique (Olsen catheter) time is 18 ± 8 min. To detect a difference of 33 % with the Kumar clamp (thus assumed to be 12 ± 5 min) with a power of 0.80 and an alpha of 0.05, group sizes would be needed of 20 patients in each arm, totalling 40 (OpenEpi, version 2.3; http://www.openepi.com/). Because these numbers are estimates, and in order to allow for unexpected exclusions, this study continued until a total of 50 laparoscopic cholecystectomies was reached, as defined in the study protocol.

Ethics and registration

The study was approved by the local ethics board, study number METc 2009/339, and the Dutch Central Committee on Research involving Human Subjects (CCMO), study number NL30638.042.09. All patients provided written informed consent. The trial was registered in the Dutch Trial Register, study number NTR 2582, before inclusion. Results are presented in accordance with 2001 the CONSORT guidelines.

Setting and follow-up

The study was conducted at a university hospital. The inclusion started on November 1, 2010, and the last patient was included on November 21, 2011. Follow-up was at least 6 weeks for all patients.

Patients

Patients were eligible for participation if they were aged 18 years or older and scheduled to undergo elective laparoscopic cholecystectomy with IOC. IOC is performed routinely at our center except in patients who are pregnant or allergic to radiopaque contrast agent. Patients in whom the operation date was planned to be within 72 h were considered to acute or semiacute and were not included in this study. Patients were excluded if they did not provide informed consent or if they had already participated in a different randomized trial.

Instruments and training

The Kumar Pre-View cholangiography clamp (Nashville Surgical Instruments) was ordered via Apgar, Brøndby,

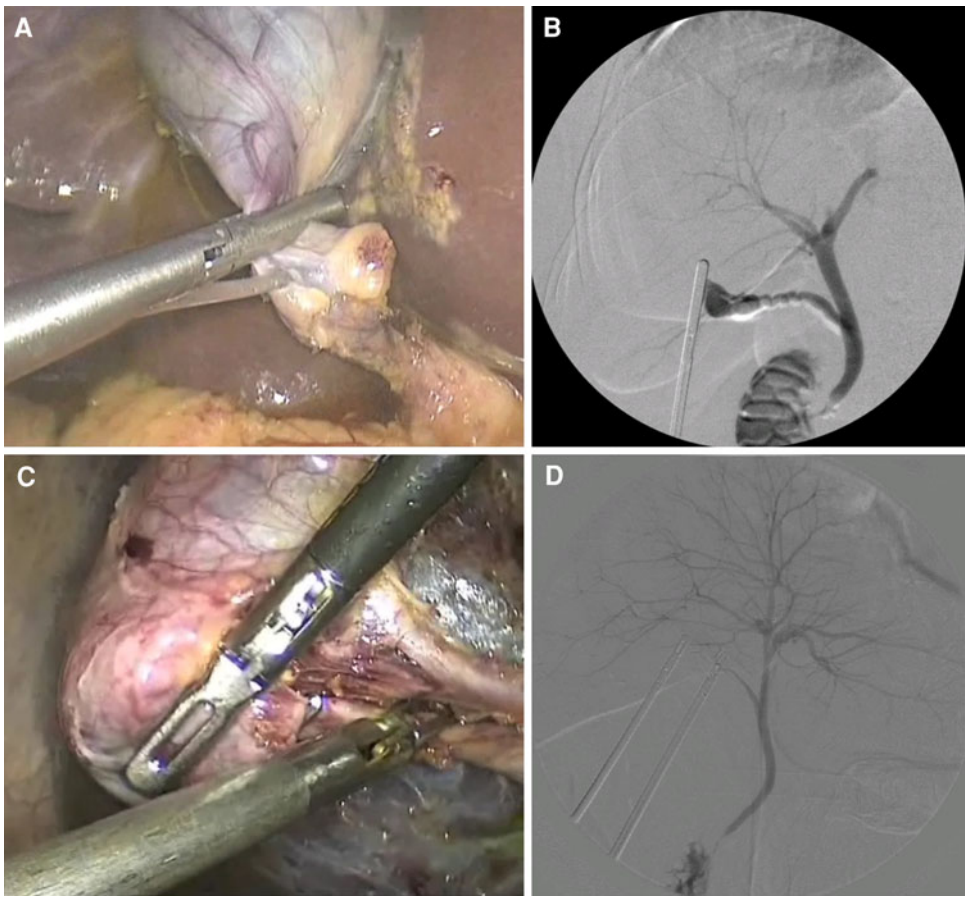

Fig. 1 The Kumar clamp with needle tip extending into the Hartmann pouch (**A**) and the corresponding cholangiogram (**B**). The Olsen clamp holds the catheter in the cystic duct (**C**) and the corresponding cholangiogram (**D**) in place

Denmark. It was used in conjunction with the Kumar Pre-View cholangiography catheter (19-gauge needle, 76 cm long, 16 gauge; Nashville Surgical Instruments; hereafter referred to as Kumar catheters).

The Olsen clamp was ordered via Cook Medical, as were the catheters (C-NFEP3.0-18-43-P-NS-OECS; referred to here Olsen catheters). The caliber, 4F or 5F, was chosen according to the surgeon's preference.

All participating surgeons received instructions on use of the Kumar clamp and practiced on a simulation model of the gallbladder. Most surgeons were familiar with the Olsen clamp and had used it before. If they were not familiar with the Olsen clamp, they received similar instructions on its use. Furthermore, instructions and videos were available on the hospital network on use of both of the clamps.

Randomization and blinding

Patients were randomized just after induction of anesthesia by opening an opaque unmarked envelope. The patients were blinded to the intervention until the day of discharge from the hospital. The surgeon and the investigator performing the time measurements were not blinded.

Procedure and time measurement

Laparoscopic cholecystectomy was performed using four laparoscopic ports. In the Kumar group, surgeons were free to use the Kumar clamp as a standard instrument from the start of the operation. However, the majority chose not to, introducing the Kumar clamp only for the IOC procedure. The critical view of safety was achieved in all patients and recorded on photo and video images. The following time points were recorded by an investigator not involved in the surgery: first incision, start of the cholangiography procedure (defined as opening the Kumar clamp or opening the scissors for IOC using the Olsen clamp), achievement of biliary access (defined as injection of saline with no leakage), the time the cholangiogram had been interpreted, and the time of removal of the scope from the abdomen.

Statistical analysis

Statistical analysis was performed by SPSS Statistics software for Windows, version 17.0 (SPSS, Chicago, IL, USA). Analysis was performed on an intention-to-treat basis. Pearson's chi-square test was used to compare proportions.

Table 1 Baseline characteristics

Characteristic	Kumar ($n = 28$)	Olsen ($n = 22$)	p
Age (years), mean ± SD	53 ± 13	48 ± 15	0.407
Female gender	17 (60.7 %)	11 (50.0 %)	0.568
ASA score, median (IQR)	2 (2–2)	2 (2–3)	0.239
BMI, mean ± SD	30.1 ± 7.3	30.5 ± 7.0	0.860
Indication			
Cholecystolithiasis	17 (60.7 %)	15 (68.2 %)	
Choledocholithiasis	4 (14.3 %)	3 (13.6 %)	
Previous cholecystitis	1 (3.6 %)	3 (13.6 %)	
Biliary pancreatitis	4 (14.3 %)	0	
Other	2 (7.1 %)	1 (4.5 %)	
Surgeon experience[a]			0.289
Trainee year 1–3	7 (26.9 %)	3 (14.3 %)	
Trainee year 4–6	8 (30.8 %)	9 (42.8 %)	
Fellow in GI surgery	3 (11.5 %)	2 (9.5 %)	
GI surgeon	8 (30.8 %)	7 (33.3 %)	
Number of previous cholecystectomies[a]			0.462
<10	2 (7.7 %)	1 (4.8 %)	
10–50	12 (46.2 %)	5 (23.8 %)	
50–100	2 (7.7 %)	3 (14.3 %)	
>100	10 (38.5 %)	12 (57.1 %)	
Number of previous IOC[a]			0.849
<10	11 (42.3 %)	8 (38.1 %)	
10–25	8 (30.8 %)	7 (33.3 %)	
26–50	1 (3.8 %)	1 (4.8 %)	
>50	6 (23.1 %)	5 (23.8 %)	

ASA American Society of Anesthesiology, *IQR* interquartile range, *BMI* body mass index, *GI* gastrointestinal, *IOC* intraoperative cholangiography

[a] Three missing values

Table 2 Outcome

Characteristic	Kumar ($n = 28$)	Olsen ($n = 22$)	p
Success rate	23 (82.1 %)	19 (86.4 %)	>0.999
Cannulation time, mean ± SD	4 min 14 s ± 3 min 17 s	5 min 33 s ± 5 min 39 s	0.349
Total IOC time, mean ± SD	10 min 27 s ± 6 min 17 s	11 min 34 s ± 7 min 27 s	0.537
Total surgery time, mean ± SD	75 min ± 29 min	83 min ± 37 min	0.461
Ease on VAS scale, mean ± SD	6.8 ± 2.7	6.8 ± 2.1	0.977
No segments depicted, median (IQR)	5 (5–5)	5 (4–5)	0.115
Radiation received (Gy/m^2)	0.41 ± 0.28	0.48 ± 0.40	0.542
Bile duct injuries	0	0	–
CBD stones	1/23 (4.3 %)	1/19 (5.3 %)	>0.999
Complications	0	1/22 (4.5 %)	0.440

IOC intraoperative cholangiography, *VAS* visual analog scale, *CBD* common bile duct

Fisher's exact test was used when one of the cells had a count of less than 5. The independent Student's t test was used to compare continuous normally distributed variables.

Results

Patients

The recruitment of the patients is shown in Fig. 1. Out of 84 patients who met the inclusion criteria, 59 were enrolled and subsequently randomized. Nine patients were excluded because of conversion to open cholecystectomy before the IOC procedure took place. Twenty-eight patients underwent IOC using the Kumar clamp and 22 using the Olsen clamp.

The baseline characteristics of the patient population is listed in Table 1. There were no significant differences between the two groups at baseline. In two patients allocated to the Kumar group, however, a perioperative decision was made to use the Olsen clamp instead. In one case, it was because a lesion was present in the cystic duct, and

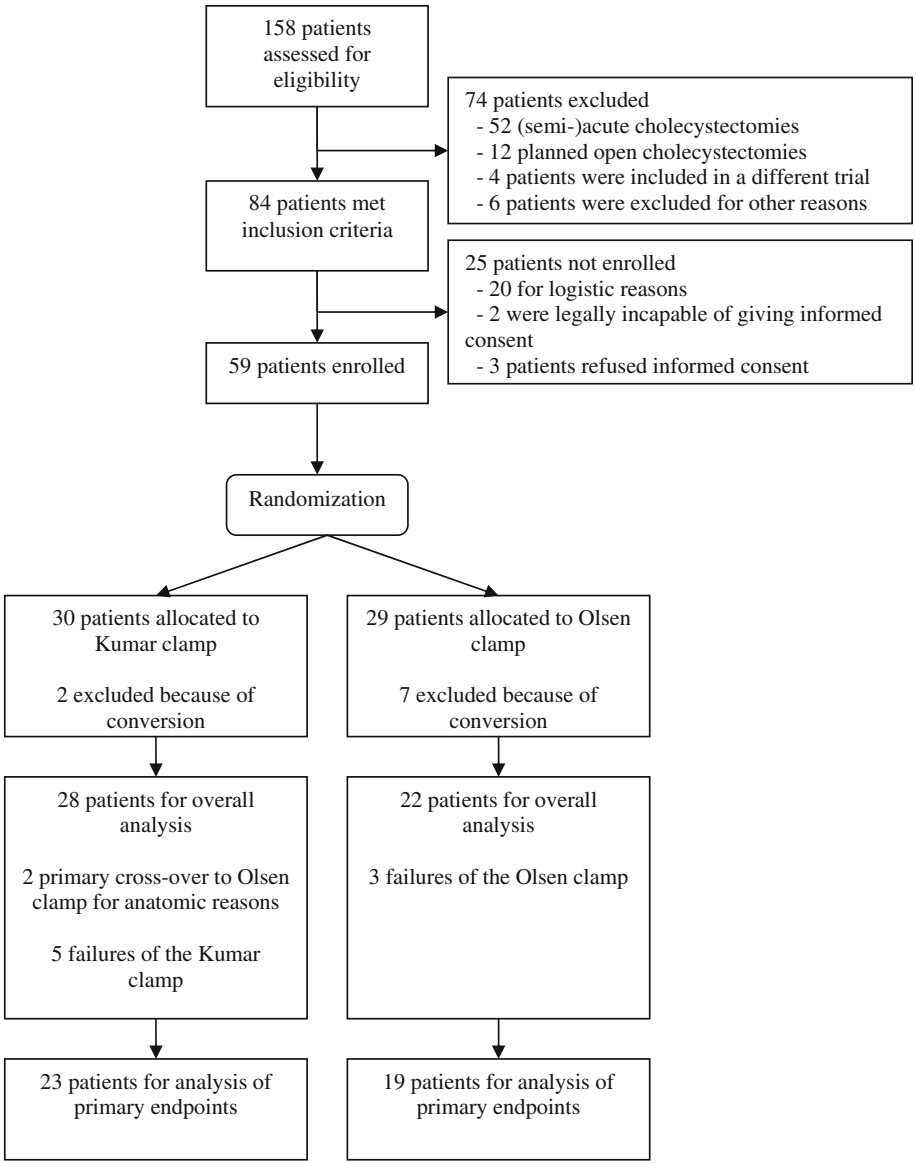

Fig. 2 Study inclusion flow chart

in the other, it was because of a frail Hartmann pouch. These crossover patients were analyzed in the Kumar group (on an intention-to-treat basis).

Primary outcome

The outcomes of the cholecystectomies are shown in Table 2. The success rates of both clamps were similar: 82.1 % for the Kumar clamp and 86.4 % for the Olsen clamp ($p > 0.999$). IOC using the Kumar clamp was not faster than using the Olsen clamp: 10 min 27 s ± 6 min 17 s, compared to 11 min 34 s ± 7 min 27 s ($p = 0.537$), as shown in Fig. 2A. When only the time that it took to achieve biliary access was taken into account, there was no significant difference.

On average, surgeons judged IOC using both clamps as being equally easy: 6.8 ± 2.7 for the Kumar clamp and 6.8 ± 2.1 for the Olsen clamp ($p = 0.977$) (Fig. 3).

Secondary outcome

There were no differences in the success rate, the number of depicted segments of the biliary tree, the amount of radiation received, the number of bile duct injuries or the number of complications between the Kumar and Olsen groups (Table 2). The only complication that occurred was a case of acute urinary retention in the Olsen clamp group. Two patients with choledocholithiasis were treated successfully by postoperative endoscopic retrograde cholangiopancreatography.

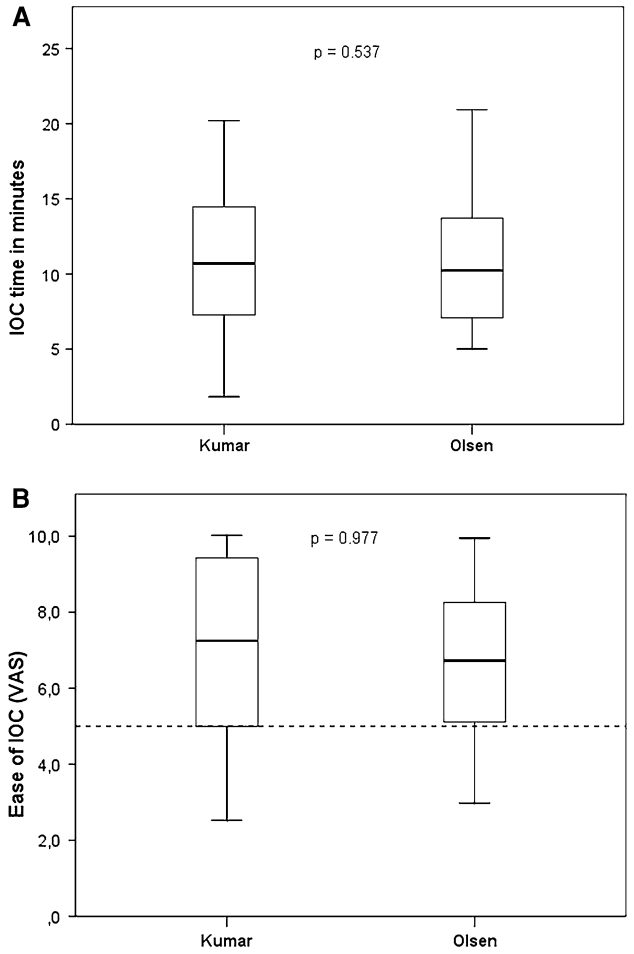

Fig. 3 Primary end points: **A** cholangiography time and **B** ease of cholangiography procedure (*dotted line* indicates the score that surgeons were instructed to view as average ease of IOC). *IOC* intraoperative cholangiography, *VAS* visual analog score

Further analyses

When a per-protocol analysis was performed, the time for IOC using the Kumar clamp was 9 min 48 s, versus 12 min 5 s using the Olsen clamp ($p = 0.205$). In terms of ease of IOC, a per-protocol analysis yielded a score of 7.2 ± 2.5 for the Kumar clamp versus 6.5 ± 2.3 for the Olsen clamp ($p = 0.321$). Results were similar when only the first half or only the second half of the patient data were analyzed separately (data not shown).

Discussion

To our knowledge, this is the first randomized, controlled trial to compare the Kumar clamp to the more standard cystic duct cannulation method—in this case, the Olsen clamp. We found that both clamps were similar in time necessary for IOC and in perceived ease by the surgeon. Nor were differences found in secondary end points such as complications and total amount of radiation.

The Kumar clamp has been in production since 1992, but only two series of laparoscopic cholecystectomies with IOC have been reported using the Kumar clamp [10, 11]. The first was described by Kumar in 1992 [11]. In a series of 50 cases, IOC was performed using this clamp; 98 % were successful, and no complications occurred.

In the second series described by Holzman et al. in 1994 [10], of the 60 cases in which the Kumar clamp was used, 83 % were successful. The time to insert the Kumar clamp and introduce the sclerotherapy needle was reported to be approximately 2 min, and the time for completing the entire cholangiogram was 10 min. These results are similar ours here.

A possible additional advantage of the Kumar clamp is that, in contrast to the Olsen clamp, it allows visualization of the biliary tract before any tubular structures are incised or cannulated. Theoretically, where IOC using the Olsen clamp would downgrade a complete transection of the common bile duct (type D injury) to a common bile duct leak (type B), IOC using the Kumar clamp could prevent this injury altogether. The numbers in this trial were too small to assess, and no series of IOC with the Kumar clamp that are large enough to assess this possible benefit are known to us.

One limitation of this study is that there was a discrepancy between the expected and observed time for IOC. The power analysis for this study was performed using an estimate of 18 min for IOC using the Olsen clamp. Considering that the actual time was closer to 12 min, this study may be somewhat underpowered to detect small differences in time. However, from our results, it seems likely that use of the Kumar clamp will not result in a clinically significant reduction of the time spent on IOC.

Another criticism of our study may be that surgeons may have been more familiar with the Olsen clamp to start with. We provided model training to all surgeons who performed cholecystectomies in this trial, but this may not have been sufficient to completely counter the experience bias. On post hoc analysis, there was no difference in IOC time when only the second half of cholecystectomies was analyzed, suggesting that further in the learning curve, little reduction in time is to be expected from the use of the Kumar clamp.

As bile duct injuries continue to plague (laparoscopic) cholecystectomies, the debate on the role of IOC continues. The Kumar clamp will probably not substantially lower the threshold for performing IOC. Further efforts are necessary to improve the safety of cholecystectomies. First of all, there is little doubt that global implementation of the "critical view of safety" surgical technique will increase

patient safety. Second, IOC needs to be addressed in the training program of surgical trainees. Third, novel techniques of assessing the biliary tree such as fluorescence cholangiography are being evaluated for safety and efficacy in clinical practice.

In conclusion, this randomized trial found no significant differences in speed or perceived ease of IOC using the Kumar clamp as compared to using the Olsen clamp. Individual surgeon preference should dictate which clamp is used.

Acknowledgments We are indebted to all the patients and surgeons who participated in this study.

Disclosures K. T. Buddingh, B. M. Bosma, B. Samaniego-Cameron, H. O ten Cate Hoedemaker, H. S. Hofker, G. M. van Dam, R. J. Ploeg, and V. B. Nieuwenhuijs have no conflicts of interest or financial ties to disclose. The instruments used in this trial were leased from Apgar A/S, Brøndby, Denmark. Neither restrictions nor prior insight were agreed upon regarding publication of the results.

References

1. Connor S, Garden OJ (2006) Bile duct injury in the era of laparoscopic cholecystectomy. Br J Surg 93(2):158–168
2. Buddingh KT, Nieuwenhuijs VB, van Buuren L, Hulscher JB, de Jong JS, van Dam GM (2011) Intraoperative assessment of biliary anatomy for prevention of bile duct injury: a review of current and future patient safety interventions. Surg Endosc 25(8): 2449–2461
3. Fletcher DR, Hobbs MS, Tan P, Valinsky LJ, Hockey RL, Pikora TJ, Knuiman MW, Sheiner HJ, Edis A (1999) Complications of cholecystectomy: risks of the laparoscopic approach and protective effects of operative cholangiography: a population-based study. Ann Surg 229(4):449–457
4. Flum DR, Dellinger EP, Cheadle A, Chan L, Koepsell T (2003) Intraoperative cholangiography and risk of common bile duct injury during cholecystectomy. JAMA 289(13):1639–1644
5. Buddingh KT, Hofker HS, ten Cate Hoedemaker HO, van Dam GM, Ploeg RJ, Nieuwenhuijs VB (2011) Safety measures during cholecystectomy: results of a nationwide survey. World J Surg 35(6):1235–1241
6. Xiong C (2005) Power and sample size for clinical trials when efficacy is required in multiple endpoints: application to an Alzheimer's treatment trial. Clin Trials 2(5):387–393
7. El Shallaly G, Seow C, Sharp C, Mughrabi A, Nassar AH (2005) Intraoperative cholangiography time in laparoscopic cholecystectomy: timing the radiographer. Surg Endosc 19(10): 1370–1372
8. Khaira HS, Ridings PC, Gompertz RH (1999) Routine laparoscopic cholangiography: a means of avoiding unnecessary endoscopic retrograde cholangiopancreatography. J Laparoendosc Adv Surg Tech A 9(1):17–22
9. Piacentini F, Perri S, Pietrangeli F, Nardi M Jr, Dalla Torre A, Nicita A, Lotti R, Castaldo P, Gabbrielli F, Castiglia D, Citone G (2003) Intraoperative cholangiography during laparoscopic cholecystectomy: selective or routine? G Chir 24(4):123–128
10. Holzman MD, Sharp K, Holcomb GW, Frexes-Steed M, Richards WO (1994) An alternative technique for laparoscopic cholangiography. Surg Endosc 8(8):927–930
11. Kumar SS (1992) Laparoscopic cholangiography: a new method and device. J Laparoendosc Surg 2(5):247–254