

### Executive summary

Every year about 13 000 patients have their gallbladder removed because of gallstone disease (cholecystectomy) in Sweden and 30 to 40 will suffer a surgically inflicted injury to the bile ducts. An X-ray investigation of the bile ducts (intraoperative cholangiography (IOC)) is done routinely in all patients. This report compares routine use with use in selected patients.

### Conclusions

- ▶ The risk of bile duct injury is possibly reduced if intraoperative cholangiography is used routinely compared with doing it only when the surgeon finds it necessary. The type of injuries that are avoided may require extensive surgery to correct, may cause long-standing suffering with reduced quality of life and, may in worst case cause the death of the patient.
- ▶ When IOC is used routinely the total dose of radiation to the patient group is larger than if it is done in selected patients. It is assumed that approximately 40% of all patients in Sweden could be eligible for a selective investigation. The added dose of irradiation given when IOC is used routinely is estimated to induce one extra case of cancer among the 26 000 patients who undergo surgery during a 2-year period.
- ▶ In a health economic model analysis, the base-case scenario using IOC routinely is estimated to avoid a bile duct injury in seven patients per year in Sweden compared with selective use. The yearly cost for routinely used IOC is estimated to be 14.5 million Swedish crowns (SEK) (1.41 million EUR (1 EUR =10.3 SEK)) higher than if used selectively. This is balanced by a reduction of cost of approximately 6 million SEK (580 000 EUR) per year because of the bile duct injuries that are avoided.



- ▶ When an injury due to surgery is prevented, undue suffering for the patient is avoided. In the base case scenario, the cost per saved quality adjusted life year is approximately 300 000 SEK (29 100 EUR) if IOC is used routinely instead of selectively.

SBU has evaluated benefits, risks, costs and ethical consequences of using IOC routinely compared to selective use.

There is no data on outcomes and risks of using selective IOC in a Swedish setting. Thus, several assumptions, some uncertain, based on data in the literature have been made in the model analysis. This is reflected in the sensitivity analysis.

### Background

The project was suggested by the Swedish Surgical Society with aim to create a scientific basis for a national clinical guideline for gallstone surgery.

Bile duct injuries caused in gallstone surgery varies from small lesions in the bile duct wall to complete transections of a bile duct. Small injuries can usually be repaired with minor procedures while larger injuries may require extensive surgery and reoperations. For the latter there is a risk of late strictures requiring

further surgery. Patients may also die from complications to the injuries.

In Sweden a surgically inflicted bile duct injury occurs in 0.3% of all cholecystectomies. This equals 30–40 injuries per year whereof about one third are serious. Data suggests that bile duct injuries are more common and more serious internationally than in Sweden. The anatomy of the bile ducts varies and only about 60% of western people have a typical anatomy. An IOC during cholecystectomy aims to visualise the bile duct anatomy before the gallbladder is removed. In Sweden an IOC is performed or attempted in 94% of all cholecystectomies. The alternative, which is more common internationally, is to do the investigation when the surgeon finds it necessary during the operation.

In Sweden about 40% of all cholecystectomies are done because of complications to gallstone disease, mostly cholecystitis. Theoretically could an IOC be warranted in all these cases.

### **Aim**

To evaluate benefit, risks, costs and ethical consequences of using IOC routinely instead of selectively at cholecystectomy.

### **Method**

The report is a systematic review of the literature with evidence evaluation according to GRADE combined with a health economic model analysis.

### **Results**

In the metaanalysis of data from the literature, the rate of bile duct injuries was 0.53% in patient groups where IOC was done in selectively (or not at all) compared with 0.36% in the groups where IOC was used routinely. The ingoing studies are heterogeneous, but some include a very large number of patients. In total, the metaanalysis includes more than 2 million patients undergoing a cholecystectomy and of those, 9 000 suffered a surgically induced bile duct injury.

When IOC is used routinely the total dose of radiation given to the patient group as a whole is larger (additional 16 Sievert) than if IOC is done selectively. The added dose is estimated to induce one extra cancer case at a later stage in the 26 000 patients who are undergoing a cholecystectomy in Sweden during a 2-year period.

In the health economic model's base case assuming an increased risk for bile duct injury of 43% when IOC is done selectively, it is estimated that seven injuries will be avoided per year in Sweden where IOC

is done routinely. Thirty-three quality adjusted life years (QALYs) are saved at a net cost of 8.5 million SEK (825 000 EUR). The cost for each saved QALY is approximately 300 000 SEK (29 100 EUR). In a life time perspective, the cost per saved QALY will be less.

In the sensitivity analysis the cost per saved QALY when using IOC routinely varies from cost-saving to 700 000 SEK (68 000 EUR). The assumptions which affects the model outcome most are the risk of injury when IOC is used selectively, the impact of an injury on the patient's quality of life over time and the proportion of patients that undergo an IOC in a setting with a selective strategy.

### **Knowledge gaps**

We lack data on outcome and risks for bile duct injuries if IOC is done selectively in a Swedish setting.

### **Ethics**

An ethical aspect is the balance between gaining benefit and risking a decrease in health from a procedure. A bile duct injury may greatly affect a patient's quality of life and may be deadly. These risks will be reduced if bile duct injuries can be avoided. On the contrary, the added dose of radiation from routinely used IOC may infer a risk of extra cancer cases in the long run.

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