

The Swedish Register of Gallstone Surgery and Endoscopic Retrograde Cholangiopancreatography (GallRiks) - A Valuable Platform for Clinical Research

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In surgery it is important to register intra as well as postoperative complications in order to monitor the outcome of the surgical treatment given. The purpose of the Swedish National Quality Registers is to ensure that the patients get the same high level of treatment regardless of where in the country the treatment is performed and also to detect sudden abrupt deteriorations of quality within different centers. Patient data within a quality registry will also eventually constitute a database that enable researchers, within their respective field, to analyze different treatment modalities and their respective pros and cons, thus hopefully improving both patient safety and quality of life. However, it is important that data within each registry is valid and that the registry is used to the same extent by all participating hospitals [1,2].

GallRiks, the Swedish Register of Gallstone Surgery and Endoscopic Retrograde Cholangiopancreatography (ERCP), supported by the Swedish National Board of Health and Welfare, was started in May 2005 [3]. The aim is to, on a regular basis, monitor gallstone surgery and ERCP and to hopefully improve outcome and patient satisfaction. Since the start there are now more than 130,000 procedures registered (cholecystectomies and ERCP). This huge database makes it possible to analyze even small but significant changes regarding complication rates between years as well as to analyze the outcome between different centers. It is also, due to the large number of procedures, possible to study the effects of new surgical and endoscopic techniques on the outcome. Furthermore, it may also be possible to address questions that have not yet been possible to previously address in randomized prospective controlled trials due to the large number of patients necessary to include in order to get enough statistical power.

However, research projects analyzing the GallRiks database have been able to answer some of the important questions regarding cholecystectomies as well as ERCP. Lundström et al. [4], in a study analyzing 10,927 cholecystectomies 2006-2007, found that there was no beneficial effect of prophylactic antibiotics in elective cholecystectomy on the postoperative infection rate. In the univariate analysis, paradoxically, the infection rate was increased in the group that received antibiotics. However, multivariate analysis, taking confounding factors into consideration, showed that this effect was due to selection bias, i.e. the patients where postoperative complications were anticipated got prophylactic antibiotics to a higher extent.

Another important question that has been addressed by analyzing GallRiks data is whether systemic intraoperative thromboembolic prophylaxis affects intra- or postoperative bleeding in laparoscopic cholecystectomy. Persson et al. [5] analyzed the data of 48,010 patients who had been operated with laparoscopic cholecystectomy and where 21,259 (44.3%) received thromboembolic prophylaxis. They found that a bleeding complication occurred in 3.1% of the patients receiving thromboembolic prophylaxis whereas it only occurred in 1.4% of patients without thromboembolic prophylaxis. After adjusting for all other variables in a multivariate analysis, the increase in OR for any bleeding complication when given thromboembolic prophylaxis was 1.35 (1.17-1.55). However, the risk of deep vein thrombosis or/and pulmonary embolism did not differ between the two groups [6,7].

Probably the most debated issue of all times regarding cholecystectomy is whether the surgeon should perform a routine intraoperative cholangiography during laparoscopic cholecystectomy or not. This question has to some extent been addressed by Törnqvist et al. [8] in a study based on data from GallRiks of 51,041 cholecystectomies. They found that patients with bile duct injuries had a significantly increased mortality rate at one year of 3.9% compared with 1.1% for those without injury. Furthermore, the intention to use intraoperative cholangiography reduced the risk of death after cholecystectomy by 62%. The results of this study indicate that the routine use of intraoperative cholangiography, although it prolongs the duration of the procedure somewhat, may be worth considering.

Another issue that has been intensely debated is when and how to remove common bile duct stones. Cuschieri et al. [1] in a multicenter prospective randomized trial showed that in patients with gallstone disease and bile duct stones it is preferable to remove both gallbladder and the ductal calculi at the same operation. In their study the technique used to remove the bile duct stones was by the laparoscopic transcystic technique. Our group has promoted intraoperative ERCP over a guidewire as a good technique to remove common bile duct stones [2,7]. We think that the advantages of this technique compared with the transcystic laparoscopic technique is that it is easier to remove big stones as well as stones that are located high up in the bile ducts. Theoretically, when compared with conventional ERCP, the technique may decrease the post-ERCP pancreatitis risk since the cannulation is performed over a guidewire already in place in the bile duct. This makes accidental cannulation of the pancreatic duct less likely. In order to study our hypothesis we analyzed data from the GallRiks database of 12,718 ERCP procedures. In our study we found that the risk of PEP when using the rendezvous technique was reduced from 3.6 to 2.2% [6]. Intraoperative ERCP over a guidewire is now the most used technique to remove common bile duct stones in Sweden.

Conclusion

The Swedish Register of Gallstone Surgery and Endoscopic Retrograde Cholangiopancreatography, GallRiks, is a validated database of more than 130,000 procedures (cholecystectomies and ERCP) that enables researchers to address important clinical issues. At

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the moment there are 33 projects listed (ongoing or terminated) on the GallRiks webpage <http://www.ucr.uu.se/gallriks/index.php/projekt> that hopefully will improve outcome and surgical techniques as well as improved quality of life for the patient.

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