Per- and post-operative manometry of the biliary tract; an assessment of its diagnostic value, using an improved technique
Hesselink, Erik Jan

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SUMMARY AND CONCLUSIONS

This thesis is the report of an investigation into the value of biliary manometry in diagnosing common bile duct pathology in patients suffering from choledolithiasis. The report is divided into two parts:

Firstly a description of the equipment which was developed to carry out the pressure measurements and secondly the results which were obtained from taking those measurements on a group of patients.

Chapter I includes an introduction of the aims of the investigation and gives a brief summary of the contents.

Even nowadays, potential obstructive pathology in the common bile duct of patients with cholelithiasis can be overlooked during a cholecystectomy. On the other hand doubts as to the presence of this pathology result in many negative common bile duct explorations, which in turn result in a quadrupling of the operative mortality.

By means of a nationwide inquiry in 1981, information was collected about the different kinds of per-operative diagnostic techniques used in the teaching hospitals throughout the country.

Per-operative cholangiography was found to be the most widely used diagnostic technique, whereas per-operative manometry was used in only approximately 15% of the teaching hospitals.

The limitations of per-operative cholangiography, particularly when it is used for examining the choledocho-duodenal junction, are discussed. This is the area where obstructive lesions mostly occur due to the naturally small lumen of the distal common bile duct. As the pressure in the common bile duct is an indication of the patency of the choledocho-duodenal junction, it seemed that pressure measurements are an added benefit to per-operative cholangiography. The motivation for this research was the discrepancy between the limited practical applications on the one hand and the theoretically large number of possible applications of biliary manometry on the other hand. The aim was to determine the true value of this diagnostic technique by carrying out pressure measurements on a representative group of patients, using accurate and practical equipment.

Chapter II includes a short description of the anatomy of the bile ducts and the physiology of bile production.

The anatomical variations at the junction of the cystic duct and the com
mon bile duct make cannulation of the cystic duct for manometry and cho-
langiography difficult and sometimes impossible. Anatomical variations also
occur at the choledocho-duodenal junction: The common bile duct and the
pancreatic duct enter the duodenum through a gap in its muscle wall, either
via a joint canal or totally separately.

The bile which is produced by the liver is made up of three components:
- bilesalt-dependent component (30-60%);
- bilesalt-independent component (30-60%);
- ductular component (20%).

The bile can be secreted against a maximum pressure of 3 kPa (30 cmH₂O),
which is designated the liver secretion pressure.

During the interdigestive period there is a preferential flow of bile coming
from the liver into the gallbladder, due to an increased tone in the sphincter
muscle around the distal common bile duct. Due to a concentration process,
substantially more bile duct can be stored in the gallbladder than could be
expected considering the volume of the gallbladder. In the digestive period
the tone of the sphincter reduces and the muscle wall of the gallbladder con-
tracts due to the action of cholecystokinin which is produced in the duodenal
wall. This results in bile flowing into the duodenum at a flow rate of 1 to 2 ml
per minute. The common bile duct pressure depends mainly on the duodenal
pressure and the perfusion pressure of the bile ducts although this pressure
is also influenced by variations in abdominal pressure due to respiration,
physiological or artificial. The perfusion pressure of the bile ducts (the
difference in pressure, Δp, between the beginning and the end of the bile
ducts) depends on the bile flow per minute into the duodenum (the bile flow
rate) and the resistance that this bile flow encounters in the bile ducts:

\[ \text{perfusion pressure} = \text{flow rate} \times \text{resistance}. \]

The resistance is determined mainly by the relatively narrow choledocho-
duodenal junction. The resistance is high if there is an obstruction. In that
case, the pressure measured is mainly determined by the correspondingly
high perfusion pressure.

Chapter III outlines the techniques involved in the application of biliary
manometry.

There is a short historical summary indicating that originally the techni-
que was only applied post-operatively. The various techniques are divided
into three categories:
1. The method with a reservoir at an adjustable height;
2. The method which involves rapid injecting a fixed amount of a solution;
3. The method with a constant infusion rate of a solution.
1. This method was initiated by Caroli and later simplified by Daniel and White. It makes use of gravity and it enables one to measure two pressure levels:
   - the opening pressure: the pressure at which the sphincter opens;
   - the closing pressure: the pressure at which the sphincter closes.
It is also possible to measure the so called standard flow by fixing the reservoir at a standard height of 30 cm and using a stopwatch. The standard flow is the number of millilitres which flows into the duodenum per minute at this constant pressure of 3 kPa (30 cm H₂O).
2. In this method a fixed amount of a solution is injected rapidly into the common bile duct. The most important criterium is the time it takes for the pressure to regain its original value.
3. In this method the solution is not injected rapidly, but it is gradually pumped into the common bile duct. It appears from the literature, that varying rates are used namely between 0.5 and 10 ml per minute. Not only can the opening- and closing-pressure be measured with this technique but also the balance pressure. This is the pressure in the common bile duct when there is a balance between the inflow from the pump into the common bile duct and the outflow from the common bile duct to the duodenum.

Finally, the recent applications of post-operative manometry are discussed: They appear to be mainly of an experimental nature.

Chapter IV describes the method chosen for this study and the instructions for applying it.
It is based on the third method mentioned, namely, manometry during a constant infusion rate. The equipment can be divided into a mechanical and an electronic part.

The mechanical part consists of a pump with a flow of 10 ml saline solution per minute, a system of tubes, with an overflow which also functions as a rising tube manometer, and a step-motor which can move a cassette up and down. A pressure transducer and the rising tube manometer are wedged into the cassette.

The electronic part consists of the pressure transducer, signal amplification, filtering and registration, the servo control of the step-motor and a foot switch.

Two aspects of this method are particularly noteworthy:
The semi-automatic zero-leveling of the pressure in the common bile duct: When the pump is working, the tip of the canula is kept at the level of the cystic duct. The servo system which works the step-motor is activated by the foot switch. The zero level of the apparatus is adjusted to a level (height) which corresponds with the perfusion pressure of the tubing and the canula. The pressure transducer indicates the zero pressure, after which the canula for manometry can be inserted into the cystic duct.

An automatically safeguarded measuring system with a large compliance: The maximum pressure during the measuring procedure cannot exceed 3kPa (30 cmH₂O) because of the length of the open rising tube manometer. This corresponds to the liver secretion pressure, thus ensuring that, should there be infected bile, bacterial backflow from the bile ducts into the blood circulation is prevented.

The open rising tube also has a smoothing effect on pressure changes during the manometric procedure. The compliance of the measuring system is increased tenfold so that possible mechanical irritation of the sphincter due to pressure fluctuations is minimalized.

Four parameters were measured using this method:
- the opening pressure, \( p_o \);
- the balance pressure, \( p_b \);
- the closing pressure, \( p_c \);
- the compliance, which can be derived from the recorded curve and was expressed in millilitres of saline per 10 cmH₂O (1 kPa).

The respiratory pressure is the only external influence on the common bile duct pressure in the per-operative situation. This is apparent from the serrated curve which necessitates the taking of the mean value. The pressure parameters were read twice in order to trace the reproducibility of the results.

Chapter V describes the research on 133 patients who underwent a cholecystectomy in the period between 30-01-1980 and 07-09-1981. Cannulation of the cystic duct was unsuccessful in 9 cases, therefore 124 patients underwent per-operative manometry. Twenty five patients underwent post-operative T-tube manometry.

The investigations on these patients were divided into four periods of time: — the pre-operative period;
— the per-operative period;
— the post-operative period;
— the period of one year post-operatively.

Strong and relative indications applied pre- and per-operatively as regards to common bile duct exploration. The per-operative indication for a common bile duct exploration was based on inspection and palpation, manometry and cholangiography. During the research period the provisional critical values of the balance and closing pressure were 2 kPa (20 cmH₂O) and 1.5 (kPa (15 cmH₂O) respectively. These provisional values also applied to the post-operative T-tube manometry. The examination one year post-operatively was to rule out the existence of obstructive pathology in the common bile duct which was newly formed or missed at common bile duct exploration.

A protocol of rules for per-operative manometry was aimed at preventing chemical and mechanical irritation of the sphincter around the distal common bile duct. Therefore, where possible, morphia-derivates were not used during anaesthesia and the manometry was carried out as soon as possible during surgery to prevent irritation as a result of dissection in the vicinity of the distal common bile duct. The 124 patients who underwent per-operative manometry were divided into four groups:

Group A, in which no abnormalities other than gall stones in the gallbladder were found - 85 patients;
Group B, in which either gall stones or inflammatory processes resulting in obstruction, or both, were found in the common bile duct - 23 patients;
Group C, in which an iuxta-papillary duodenal diverticulum was found - 3 patients;
Group D, in which per-operative manometry was not carried out along the lines of the protocol - 13 patients.

The 72 patients in group A in which no abnormalities other than gall-stones in the gallbladder were diagnosed during the four diagnostic periods, were used as the control group: Sub-group A. The critical values of the parameters mentioned in chapter IV were obtained from the measuring results in this control group. The provisional critical values for the balance pressure and the closing pressure used during the research period, were used because they were almost the same as the final critical values calculated from the control group. The critical value for the opening pressure was comparable with those found in the literature. The disadvantage of this parameter was,
however, that unlike the other two pressure parameters, it was impossible to carry out precise measurements in 25% of the patients, whereas the measurement of the other two pressure parameters was always possible. Moreover, non-reproducible measurements occurred more frequently at the opening pressure.

The compliance parameter was also unacceptable due to the high number of false negative and false positive results. Therefore only the balance pressure and the closing pressure were used in assessing the manometric results.

All the measurements were taken twice. The lowest value of each pressure parameter was used. The fact that this was virtually always the first value obtained from the two measurements suggests that there could be some degree of mechanical irritation from the pump flow.

The importance of having a protocol, especially with regards to the form of anaesthesia, is apparent from the results. A false positive manometric result was found in more than 50% of the patients in group D. On the other hand, per-operative manometric measurements, taken according to the protocol in this research, proved to be the most reliable diagnostic aid to an indication for a common bile duct exploration.

However, when the results of post-operative T-tube manometry are compared to those of other post-operative diagnostic techniques, it does not seem to give any new information, which is relevant to the treatment.

The following conclusions can be drawn from this research:

- Manometry is essentially a patency test of the choledocho-duodenal junction, because the common bile duct has its narrowest diameter at this point.
- Manometry is, therefore, only then of use in diagnosing obstructive pathology in the common bile duct, if there is a negligible chance that the obstruction is caused by sphincter spasm.
- Sphincter spasm is unavoidable, and the manometry therefore, unreliable, if there is not a good and safe technique as well as a protocol regarding the kind of anaesthesia and the timing of the measurements.
- If the aforementioned conditions are conformed to, per-operative manometry serves as a real improvement in the diagnostics in view of the indications for a common bile duct exploration.
- Due to better radiological techniques, post-operative T-tube manometry does not serve to improve the post-operative diagnostics of pathologic conditions in the common bile duct.