SUMMARIZING DISCUSSION

Inguinal hernia repair is one of the most common performed operations done by a general surgeon. Annually over 20 million inguinal hernias are repaired worldwide [1]. Inguinal hernia repair accounts for 10 to 15% of all general surgical procedures [2]. In this thesis several aspects of the clinical pathway of a patient with an inguinal hernia are addressed, extending from indication for surgery to follow-up post-operatively and consensus amongst hernia experts.

The general policy towards symptomatic inguinal hernias is surgical repair. The gold standard for treatment of an inguinal hernia is by means of a tension free repair with a mesh to cover the hernia defect and augment the abdominal wall. The mesh can either be implemented at the anterior side of the hernia defect, by Lichtenstein repair, or at the posterior side, by a laparoscopic repair. Hernia training is started early in the career of a surgical resident. The learning curve of the Lichtenstein repair is considered to be shorter than for laparoscopic repair, with a required number of laparoscopic procedures to achieve competence between 50-100 with the first 30-50 being the most critical [3]. Morbidity and mortality rates of elective inguinal hernia repair are low. The most common short-term complications are hematoma, seroma and wound infection. The most common long-term complications are chronic pain and recurrence. The incidence of chronic pain is much under debate, since high rates are reported. A recently published systematic review reports that approximately 11% of the patients suffer from chronic pain after a mesh repair [4]. However no uniform scoring system is used, resulting in difficulties drawing any conclusions or comparing the outcomes of studies published. The recurrence rates after open Lichtenstein and laparoscopic repair are low and vary between 1-4% [5-12]. Inguinal hernia repair is therefore generally considered to be feasible, reliable and save.

The presenting symptom of an inguinal hernia is either discomfort or pain in the groin in two-thirds of all patients [13]. One third of all patients however, is asymptomatic at consultation and presents with the sign of a non-tender bulge in the groin. Since inguinal hernia repair is associated with a chance of recurring of up to 4% and a risk of chronic pain of up to 11%, surgical repair is not without risk. In addition, with an increasing political climate where health care costs rise and governmental budgets are cutback, critical evaluation is applied to the aptness of certain therapies. Not surprisingly, the appropriateness of surgery in asymptomatic inguinal hernias was questioned. The rationale to recommend surgery for asymptomatic groin hernias is to prevent visceral incarceration and subsequently ischemia (strangulation). Two large randomized controlled studies were performed in 2006, comparing surgical repair versus watchful waiting in two groups of patients with asymptomatic inguinal hernias [14, 15]. Both studies concluded

after a period of follow-up of 1-2 years that watchful waiting is cost effective, showing equal decrease in pain in the watchful waiting group compared to surgical repair and that the risk for incarceration is low. We conducted a review to evaluate the appropriateness of inguinal hernia repair in asymptomatic groin hernias and extracted risk factors for incarceration and increased morbidity and mortality to design a more tailor made approach to patients with asymptomatic inguinal hernias (**Chapter 2**). To patients with an asymptomatic or minimal symptomatic inguinal hernia with a duration of less than 3 months, who are older than 49 years or have an ASA class of 3 or 4, elective repair should be recommended. Watchful waiting in these patients should be discouraged due to an increased risk of incarceration and increased morbidity and mortality when operated in an emergency setting. However, in patients who have an asymptomatic or minimal symptomatic inguinal hernia for more than 3 months, are younger than 50 years and have an ASA class of 1 or 2, a conservative treatment is justified. When the inguinal hernia does incarcerate in such a patient, the risk of morbidity and mortality is low and the hernia can be safely repaired with a mesh technique if bowel necrosis is absent.
Just recently the long-term follow-up outcomes of both randomized trials have been published and reveal remarkable outcomes [16, 17]. Both studies show that eventually most patients with an asymptomatic or minimally symptomatic inguinal hernia become symptomatic requiring repair. Watchful waiting is still a safe option in patients with no or minimal symptoms, but future analysis should be done to re-calculate its cost-effectiveness.

The diagnosis of an inguinal hernia can be established quite accurately by physical examination and further diagnostic modalities are rarely indicated [18, 19]. When additional imaging is needed, ultrasonography reveals inguinal hernias with a sensitivity and specificity rate greater than 90% [20]. MRI is most commonly employed differentiating the causes of groin pain in absence of a hernia [1]. Differentiation between hernia type, direct or indirect, during physical examination is considered to be difficult and even challenging with imaging techniques [21-23]. As this information seldom modifies the surgical indication or surgical technique, little importance is given to preoperative differentiation between the two types of inguinal hernia. However, some surgeons advocate that in the older patient with a unilateral direct hernia a prophylactic mesh should be placed on the contralateral side, due to the expectation of increased risk for developing a contralateral inguinal hernia in this group. Moreover, in laparoscopic surgery the dissection of the peritoneal sac in reducing an indirect hernia can be technically demanding, while reducing a direct hernia is easily performed. Preoperative differentiation in hernia type would help the surgeon in operative planning and surgical training programs. We conducted a prospective study in which we evaluated two types of

preoperative physical diagnostic tests to differentiate in hernia type in 200 patients (**Chapter 3**). Outcomes of both tests were compared to the intra-operative assessment of type of hernia during laparoscopy (gold standard). In the first one hundred patients the inguinal occlusion test was used as method to differentiate. The inguinal occlusion test implies manual reduction of the protruding hernia together with manual compression on the presumed location of the deep inguinal ring. Patients were asked to perform Valsalva manoeuvre after which it is observed whether the hernia remained reduced until release of the compression (indirect hernia) or immediately protruded while the inguinal internal ring still being compressed (direct hernia). Assessing an indirect hernia was rather accurate with a correct diagnosis in 86% of the patients, while assessing a direct hernia was hardly accurate. Thirty-five percent of all patients with a direct hernia were correctly diagnosed by using the inguinal occlusion test. We concluded that the inguinal occlusion test was not accurate as a method in differentiation in hernia type. In the second one hundred patients the inguinal occlusion test was enriched by a hand-held Doppler device to locate the epigastric vessels, and subsequently the internal ring more precisely. Preoperative differentiation increased substantially and was correct in 79% of the direct inguinal hernias and 93% of the indirect inguinal hernias. It was therefore concluded that our newly developed method in differentiating between hernia type was accurate and reliable.
As it is generally recommended to structure teaching and training of inguinal hernia surgery in specialized centers or high-volume institutions, preoperative differentiation in hernia type can be of growing clinical relevance [3, 24]. This differentiating method can be taught to surgical residents and hernia surgeons in such a specialized or high-volume centre to guide them in preoperative planning (direct versus indirect, unilateral versus prophylactic bilateral) and training programs (different level of experience, different level of difficulty).

When surgical repair is indicated in a patient with a symptomatic inguinal hernia, open or laparoscopic mesh repair are roughly the two treatment modalities. The approach in laparoscopic inguinal hernia repair can be preperitoneally in the so called Total ExtraPeritoneal repair (TEP), or transabdominally in the so called TransAbdominal PrePeritoneal repair (TAPP). An advantage of an open (Lichtenstein) repair is the possibility to perform surgery under local anesthetics, while advantages of laparoscopic hernia repair are less postoperative pain, faster recovery and simultaneous access to the contralateral side for inspection and possible additional treatment peroperatively. With the expansion of the laparoscopic technique the phenomenon of finding a so called “occult” contralateral defect became rather common. In patients diagnosed with a unilateral inguinal hernia occult defects were reported in up to 51% [25-31]. It was

generally advised to commence immediate repair, yet surgical rationale was lacking. We conducted a retrospective study to assess the incidence of occult contralateral defects and assess their natural course (**Chapter 4**). All patients with a unilateral inguinal hernia undergoing laparoscopic hernia repair from 1993-2010 were included. All were diagnosed with a unilateral inguinal hernia and had been subjected to routine physical examination of the contralateral side with negative outcomes preoperatively. In case of diagnosing a bilateral hernia the patient was excluded from analysis. Occult contralateral defects were found peroperatively during laparoscopy in 13% of all 1,681 included patients. Two types of occult defects were found. Firstly, an evident occult hernia was found with an orifice size allowing herniation of intra-abdominal contents. This was the case in 8% of the patients and an immediate repair was undertaken. Secondly, a so called incipient occult defect was found in 5% of the patients. An incipient hernia is a looming or a beginning hernia, with a true peritoneal sac and a true hernia orifice, but the orifice is too small and too shallow to allow any actual herniation of intra-abdominal contents through the abdominal wall. In these patients no immediate repair was undertaken and patients were followed. After a follow-up period of more than 9 years, 21% of the patients developed a symptomatic inguinal hernia at their contralateral side. Immediate repair of such an incipient hernia will prolong surgery with 5-10 minutes and will add operative costs with the prize of an additional mesh. Yet, it will prevent a second operation in the future, diminish convalescence, saves preoperative assessment by surgeon and anesthesiologist, saves actual operative time and hospital admittance, and is therefore in most countries cost-beneficial, with no differences in morbidity compared to unilateral repair [32, 33]. Patients should preoperatively be informed about the possible contralateral finding and consent on immediate repair. We consequently concluded that immediate repair of an occult contralateral defect is recommended no matter its size.

Another prevalent phenomenon encountered during laparoscopic preperitoneal exploration in hernia surgery is the finding of an inguinal lipoma that can accompany or mimic an inguinal hernia. The incidence of inguinal lipomas discovered during hernia surgery is as high as 21-26% [34, 35]. Lipomas in the groin are regarded as of significant importance since they can mimic an inguinal hernia or a recurrence after inguinal hernia repair [36, 37]. The patient presents with an inguinal bulge, but during surgical exploration no hernia sac is found. Lipomas in the groin are therefore considered as a pitfall in hernia surgery [38]. With the extension of our experience with laparoscopic inguinal hernia repair and these lipomas, we noticed that two different lipomas exist. In the literature so far, no distinction as such is made, presumably because the origin of the lipomas remains unrevealed in the anterior approach of the inguinal canal. We conducted a study to describe the different lipomas in the inguinal region, their origin, clinical behaviour and

the according treatment (**Chapter 5**). We analyzed 854 consecutive laparoscopic inguinal hernia repairs. In 24% of the patients an inguinal lipoma was found. The first most common inguinal lipoma in our series is the plica lipoma, originating from the plica umbilicalis medialis. This lipoma was found in 68% of the patients in whom an inguinal lipoma was present. The plica lipoma is closely related to the peritoneum and can present with or without a peritoneal sac. As plica lipomas protrude through the insufficient abdominal wall or a dilated internal ring, they present as a direct or indirect hernia. In due time, they may develop to true hernias with a peritoneal sac, since these lipomas are closely related to the peritoneum. A peritoneal protrusion gradually comes along with the herniating lipoma, resulting in a paraperitoneal hernia. Therefore, plica lipomas that herniate without a peritoneal sac should also be regarded as incipient true hernias and be treated as such. The second most common lipoma in our series is the Bogros lipoma, originating for the preperitoneal Bogros space, lateral to the internal ring. This lipoma was found in 32% of the patients in whom an inguinal lipoma was present. As these lipomas run along the spermatic cord through the internal ring they can mimic an indirect inguinal hernia. Bogros lipomas are not related to the peritoneum, but to the preperitoneal fat. A Bogros lipoma should therefore not be regarded as a true hernia. When a solitary Bogros lipoma is found without simultaneous herniation of a peritoneal sac in a patient with an asymptomatic bulge in the groin, treatment is not necessary from a medical point of view. There is no evidence that reduction of a solitary herniating Bogros lipoma leads to any risk reduction of developing an inguinal hernia or improved health. When a Bogros lipoma is encountered with a concomitant peritoneal sac, the Bogros lipoma should always be reduced to prevent confusion postoperatively and during follow-up. A Bogros lipoma left in situ can easily be mistaken for a recurrence.
If it would be possible with imaging studies to distinguish between a solitary Bogros lipoma and a true inguinal hernia or plica lipoma, one could refrain from surgical treatment in the case of a solitary Bogros lipoma. In our studies 28 (3%) out of 854 patients had a solitary Bogros lipoma. In the Netherlands approximately 30,000 inguinal hernia repairs are done annually. If according to our studies 3% of the patients present with a solitary Bogros lipoma surgery can be dispensable in 900 patients annually. We suggest to use our proposed nomenclature for inguinal lipomas. Future studies should reveal whether preoperative differentiation with imaging modalities is possible to apply such strategy towards inguinal lipomas.

Almost 10-15% of all hernia repairs concern repairs of recurrent groin hernias and are therefore considered to be an important surgical problem [39, 40]. The risk for a hernia to recur increases every time a hernia recurs as demonstrated by the outcomes of the Swedish Hernia Register. At 24 moths of follow-up the risk for having a reoperation is 4.6%

after recurrent hernia repair compared to 1.7% after primary hernia repair [41]. A definite method still needs to be found for dealing with recurrent groin hernias to prevent that surgical repair fails in 1 out of 20 patients. It is unclear which technique should be used to correct a recurrent hernia after previous laparoscopic repair. The European Hernia Society Guidelines recommend a recurrence to be repaired posteriorly after an anterior repair and vise versa, based on consensus of an expert committee. A repeated posterior laparoscopic approach is considered to be more difficult, due to scarring of the peritoneum that has occurred following the previous posterior approach and subsequently an increased risk of complications. In a retrospective study, we determined the safety, the feasibility and the reliability of a repeated laparoscopic repair for a recurrent hernia after previous posterior inguinal hernia repair (**Chapter 6**). Fifty-three repairs were done in 51 patients for recurrent hernias after previous posterior repair. In two-thirds of the patients the recurrence was located medially or caudally from the previous placed mesh. Two attempted repairs had to be converted to an open technique due to severe adhesions. One intraoperative complication was encountered when the vas deferens was ligated during surgery due to adhesions of the previous placed mesh. Nine patients encountered a postoperative complication such as hematoma or seroma. No mesh infections were reported. At a mean follow-up of 70 months 4 patients developed a portsite hernia. Four patients had complaints of post-operative pain and were restricted in daily activities due to groin pain. The mean VAS-score (scale 0-100) of all patients was 5.7 (range 0-61). No recurrences were found at physical examination. It is concluded that the repeated laparoscopic procedure is a definite repair for any recurrent inguinal hernia. The procedure is feasible, safe and reliable. We do consider the repeated laparoscopic technique to be difficult and we think that the number of required procedures to reach competence is larger compared to primary laparoscopic inguinal hernia repair. In a specialized or high volume centre such techniques might be easier adopted and taught to surgical residents or hernia surgeons.

Since the introduction of tension-free mesh repair, new meshes and fixation techniques are continuously introduced by the medical industry. It is of utter importance as a surgeon to receive feed-back on the technique and material used by adequate follow-up. The gold standard in follow-up is clinical visit with a physical examination. This method is time consuming, and most patients in absence of any complaints will apt to refraining. There is some experience with different methods of follow-up, such as written questionnaires. Even though this method is much less laborious, many false-positive test results were found and asymptomatic recurrences remained unidentified. Written questionnaires were concluded to be unreliable as method of follow-up [42-44]. In search of a simple, practical and reliable method of follow up to detect asymptomatic and symptomatic recurrences

we developed a new method, the "Post-Inguinal repair Questionnaire by telePHONE" (PINQ-PHONE) (**Chapter 7**). A telephonic questionnaire was designed containing 4 elements; 3 questions about the operated groin and instructions for a physical examination carried out by the patient himself including a do-it-yourself Valsalva-maneuver. We conducted a prospective study including 300 patients to validate the PINQ-PHONE by comparing it to a physical examination at clinic (gold standard). Altogether 5 recurrences were diagnosed; of which 3 were symptomatic and 2 were asymptomatic. None of these patients had consulted a physician yet. All of them scored positively to one or more elements of the PINQ-PHONE. Two-hundred-fifty-two patients scored negatively to all elements and none of them had a recurrence. The overall sensitivity of the PINQ-PHONE was 1.00, meaning that all recurrences, either symptomatic or asymptomatic, were detected by the PINQ-PHONE. The outcomes of the PINQ-PHONE imply that when a patient responds negatively to all elements of the PINQ-PHONE, the physician can be 100% sure that the patient has no recurrence, symptomatic or asymptomatic. If the patient responds positively to one of the elements of the PINQ-PHONE a recurrence cannot be excluded. These patients should be invited for a clinical assessment. In our series 48 patients responded positively to one of the elements, of which 5 patients had a recurrence and 43 patients had not. This implies that 14% of the patients will be invited to clinic to exclude a recurrence. This outcome has a huge impact on the daily practice of a hernia surgeon. Follow-up after inguinal hernia repair can now firstly be carried out by the PINQ-PHONE and if scored positively to one of the elements, subsequently at clinic. By implementing this method 84% of the patients can refrain from visiting clinic, saving large amounts of time of the physician and also of the patient. None of the recurrences will be missed, all of them will be detected. For physicians to gain reliable feedback of the outcomes of their inguinal hernia surgery, it is of utter importance to detect asymptomatic recurrences as well. Until now, this could only have been obtained by examining all patients at clinic. We conclude that the PINQ-PHONE is a reliable, practical and simple method of follow-up after inguinal hernia repair to detect both symptomatic and asymptomatic recurrences.

Waiting for elective surgery is one of today's concerns in health care. The consumption of health care increases and consequently waiting lists are prolonged. The Canadian "Health Services Access Survey" showed that two-thirds of the patients who are waiting for elective surgery, such as hernia repair, experience worry, anxiety and stress and one third of the patients has problems with their daily activities due to waiting [45]. To improve access to surgery for groin, umbilical and epigastric hernias an initiative for a joint Hernia Clinic was developed in February 2006 at the Queen Elizabeth II (QEII) Health Sciences Centre in Halifax, Nova Scotia, Canada. Until that time, patients with hernias had been

referred to any of the general surgeons at the QE II. Patients were assessed by the individual surgeons and booked for surgery in the operating time allotted to the individual surgeons. Waiting times for initial consultation and surgery varied widely across the general surgeons' offices due to variation in case load and focus of practice. Some patients had to wait as long as 18 months for surgical repair of a hernia. One of the concerns regarding a group model of care is patient compliance. We designed a patient survey to assess patient compliance with this group model of care in the Hernia Clinic (**Chapter 8**). The Hernia Clinic is a joint clinic run by general surgeons, surgical residents, medical students, nurses, data managers and administrative assistants. When surgery is indicated, patients are placed on a common waitlist for hernia surgery. The administrative office books surgery in the operating time designated for hernia surgery. Patients are operated by the first available surgeon whom they would meet the day of surgery, or by their attending surgeon on request. The wait time from referral by the family doctor to intial consult in the Hernia Clinic decreased from 208 days in 2007 to 59 days in 2009. A questionnaire of 19 items was developed to assess patients' compliance with the Hernia Clinic and their comfort with different physicians involved in their care. Altogether, two-thirds of all patients were comfortable having their surgery done by a surgeon whom they meet the day of surgery. Patients showed high confidence in the operating surgeon, even if they had only just met this surgeon (86%). These results show the great public support to a group model of care and results stimulate expanding the group model of care to decrease waiting times and use health care resources more efficiently. Ongoing documentation and uniform analysis of patient compliance data is mandatory to enhance transformation to patient centered health care.

In the last decade two guidelines on inguinal hernia repair have been developed by international surgical societies, the European Hernia Society (EHS) Guidelines in 2009 and the International EndoHernia Society (IEHS) in 2011 [3, 24]. Both guidelines are written by a group of hernia experts based on best available evidence and expert opinion. The guidelines provide hernia surgeons with tools for the daily hernia practice. In 2012 the European Association of Endoscopic Surgery (EAES) initiated a Consensus Development Conference. The aim of this conference was to develop guidelines, based not only on best available evidence and expert opinion, but also on consensus amongst members of the EAES. An international expert panel critically appraised the available evidence and made statements on a variety of aspects of laparoscopic inguinal hernia repair prior to the conference with the members of the EAES. During the conference members were enabled to vote for all the statements and level of consensus per statement was calculated. A manuscript was written, providing best available evidence, expert opinion and opinion of the members of the EAES expressed in level of consensus (**Chapter 9**). Remarkably, the

level of consensus was not related to the level of evidence, showing the true meaning and additional value of such a conference. For example, in case of a statement based on a level of evidence of 1A according to the Oxford Classification, recommendations are based on a systematic review of (homogenous) randomized controlled studies. The Oxford Classification however, is a methodological classification, but does not refer to the level of quality of surgical technique being studied or the applicability of such a technique in daily practise. The opinion of the members of a surgical society is therefore not equivalent to best available evidence and of additional value in providing tools to the hernia surgeon.