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THE ROLE OF SURGEON-PERFORMED ULTRASOUND IN THE MANAGEMENT OF THE ACUTE ABDOMEN

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SUMMARY

The overall objective of this thesis was to evaluate the effects of bedside surgeon-performed ultrasound on the diagnostic accuracy and management of the patient admitted to the emergency department for abdominal pain.

Methods

We randomized 800 patients who attended the emergency department at Stockholm South General Hospital, Sweden, for abdominal pain, to either receive or not receive surgeon-performed ultrasound as a complement to routine management. The patients were followed up by a telephone interview after six weeks and by a registry follow-up after two years. Outcome measures included proportion of correct diagnoses, the number of complementary investigations, admission rate, time for surgery if required, time consumption at the emergency department and at hospital if admitted, self-rated patient satisfaction at the Emergency Department and at follow-up, health condition at follow-up, health care consumption and mortality at six-week and two-year follow-up. Diagnostic accuracy and need of further examinations and admissions were measured in specific subgroups as well as timing of surgery among patients with peritonitis.

Results

Several benefits were seen in the group receiving US. Diagnostic accuracy was significantly higher in the group examined with ultrasound (65% versus 57%, $p=0.027$). The number of ordered complementary US examinations was considerably higher in the group who did not receive bedside US (9% versus 28%, $p < 0.001$). The admission rate was lower in the ultrasound group (43% versus 50%, $p = 0.04$) and the proportion of patients requiring surgery submitted for surgery while still at the emergency department was higher in the ultrasound group (34% versus 16%, $p = 0.01$). Self-rated patient satisfaction was slightly higher in the ultrasound group when leaving the emergency department but equal after six weeks. There was no difference found in the two-year health care consumption or mortality between the groups.

Regarding sub group analyses increased diagnostic accuracy of bedside US was seen in the patients with Body Mass Index >25 (67% versus 54%, $p=0.02$), elevated C-reactive protein (63% versus 52%,$p=0.047$), peritonitis (74% versus 54%, age 30-59 years (68% versus 58%, $p=0.042$) and/or upper abdominal pain (72% versus 52%, $p=0.045$). Other benefits such as decreased need of further examinations and/or fewer admissions were seen in all groups except the patients with a first diagnosis of appendicitis where the outcomes were equal between the intervention groups. Among patients with peritonitis admitted for surgery the decision about surgery was taken while still at the emergency department for 61 % in the ultrasound group and 19 % in the control group, $p = 0.003$.

Conclusion

Ultrasound performed bedside by the surgeon on duty when a patient seeks care for abdominal pain, can increase diagnostic accuracy, decrease the need of further examinations, decrease admission frequency and increase self-rated patient satisfaction. There are benefits of different kinds in nearly all subgroups and the health care consumption and mortality on a long term basis are equal. The method is well worth recommending for implementation as a routine for evaluation of the acute abdomen in the ED.

LIST OF PUBLICATIONS

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IV. Lindelius A, Pettersson H, Adami J, Törngren S, Sondén A. Patient factors influencing the effect of surgeon-performed ultrasound on the acute abdomen. Submitted

CONTENTS

LIST OF ABBREVIATIONS

US	Ultrasound
ED	Emergency Department
FAST	Focused assessment by sonography in trauma
EUS	Endoscopic ultrasound
IOUS	Intraoperative ultrasound
CT	Computer Tomography
MRI	Magnetic Resonance Imaging
CRP	C-reactive protein
WBCC	White Blood Cell Count
BMI	Body Mass Index
NSAP	Non Specific Abdominal Pain
AST	Aspartate aminotranferase
ALT	Alanine aminotransferase
ALP	Alkaline Phosphotase

1. INTRODUCTION

Abdominal pain is a common reason for seeking medical care at the Emergency Department (ED) all over the world[1-3]. Some sort of radiological examination is requested for approximately half of the patients[4, 5]. Ultrasound scanning does not expose the patient to ionizing radiation, it is easy to perform bedside and has no contraindications[6] which makes it suitable for use at the ED.

It might also be a benefit for the surgeon to be able to perform a US examination, giving direct additional information to the performed physical examination, and might lead to a faster decision as whether to proceed to surgery or not[7].

In a report from 2004 Tepel et al have shown that bedside US performed by surgeons or radiologists is superior to laboratory testing and scoring for diagnosing appendicitis, with comparable numbers of sensitivity, specificity and accuracy even among less experienced surgeons and experienced radiologists. They propose that because" US in suspected appendicitis is not just a pure imaging procedure but also a physical examination to some degree, experienced clinicians might have some advantage over radiologists, who are usually more experienced in sonographic examination of parenchymal abdominal organs"[8].

There are also timesaving benefits when surgeons or emergency physicians perform US bedside at the ED instead of referring the patient to the radiological department. For diagnosing patients with hepatobiliary disease surgeon-performed US has shown a diagnostic accuracy of 96.2% with a significantly shorter time to scan than if radiological US was peformed[9].

The overall aim of this thesis was to evaluate the method of surgeon-performed ultrasound for examination of patients admitted to the ED for abdominal pain.

2. BACKGROUND

2.1. PHYSICS OF ULTRASOUND

Sound is a mechanical wave that travels through an elastic medium. Ultrasound (US) is sound at a frequency beyond 20 000 Hz, the limit of human hearing. Bats orientate themselves with the help of US waves at 100 000 Hz. Ultrasound at frequencies of 200 000 Hz is used for navigation. The frequency range of diagnostic US is between 1 and 20 MHz.

When sound encounters a boundary between two media of different densities some of the sound bounces back as an echo, a phenomenon called reflection. The rest of the sound continues through the medium but is deflected from its original path, this is called refraction. Acoustic impedance is the resistance of a medium to the propagation of sound and decides how much sound will be reflected at the interface between the media. Some of the energy of the sound is converted by friction into heat when propagating, this loss of energy is called absorption. When ultrasound waves encounter a surface, a small part of their energy is scattered away in random directions while most of the sound continues to propagate, a phenomenon called scatter. Reflection, refraction, impedance, absorption and scatter are all phenomena important for image formation in diagnostic ultrasound use. Artifacts, echoes that do not correspond to an anatomic structure but result from the physical properties of ultrasound propagation in the tissues, are also important to be aware of when using ultrasound. This phenomenon can also be of diagnostic help. One example is the acoustic shadowing of a gallstone, caused by total absorption of the sound by the stone.

Diagnostic ultrasound is based on the pulse-echo principle. The smallest functional units of the transducer are the piezoelectric crystals. The crystals are embedded in the probe, and each crystal has a specific frequency. A pulse is initiated from each crystal in the probe and a longitudinal sound wave propagates through the body. Some of the energy is absorbed in the tissue and some is reflected. The reflected energy is received by the probe, which calculates the depth of the interface by measuring the time taken to return.

We can say that the human body is composed of three basic materials differing in acoustic impedance: gas with a very low impedance, bone with a very high impedance and soft tissue with an impedance somewhere in between. The large mismatch between air and bone and tissue (“impedance mismatch”) causes 100% of the sound to be reflected at air/tissue interfaces and almost all the sound at bone/tissue interfaces. There is a small mismatch between different soft tissues in impedance, a fact that is the basis for diagnostic ultrasound.

Different frequencies of ultrasound are used for different diagnostic examinations. Higher US frequencies (7-16 MHz) have higher resolution but are strongly absorbed by soft tissue and are therefore used for superficial structures. Very high frequencies (16-20 MHz) will only travel for a few millimeters within tissue and are limited to intravascular and ocular examinations. Lower frequencies (3-7 MHz) are used for deeper structures, being less strongly absorbed and of lower resolution.

There are different modes of displaying the amplitude of reflected sound waves: A-mode, M-mode and B-mode. A-mode (amplitude) calculates only the depth of the interface and is mainly of historical interest. M-mode (motion) is used to display moving structures and is used in cardiac ultrasound. B-mode (brightness) is the routine US image for most surgical applications. Here the returning echoes are displayed as shades of grey with the echo amplitudes represented by a grey level ranging from black to white. The individual image lines are stored, assessed and assembled on the monitor to create a two-dimensional B-mode image.

Doppler ultrasound uses the Doppler effect. When US is reflected from a moving structure (i.e. blood) the frequencies of the waves change and the amount of frequency change is determined by the speed and direction of blood flow. The use of Doppler is obvious in vascular US but is also of use in other areas of diagnostic ultrasound [6, 10].

2.2. HISTORY OF ULTRASOUND

Scientists, including Aristoteles, Leonardo da Vinci, Galileo Galilei, Sir Isaac Newton and Leonard Euler, have been studying the phenomena of acoustics, echoes and sound waves for many centuries. It was though not until 1877 that John William Strutt, also known as Lord Rayleigh, published a description of sound as a mathematical equation in “The theory of sound” which became the foundation for the science of ultrasound[11-13]. Some years later, 1880, Jaques and Pierre Curie discovered the piezo-electric effect; that an electric potential is generated when mechanical pressure is applied to a quartz crystal, an important discovery that eventually led to the development of the modern-day ultrasound transducer which contains piezoelectric crystals[12, 14].

The first study of the application of ultrasound as a medical diagnostic tool was published by the Austrian brothers Karl and Friedrich Dussik in 1942. They attempted to locate brain tumours and the cerebral ventricles by measuring ultrasound transmission through the skull and concluded that if imaging of the ventricles was possible, the interior of the human body could also be visualized using ultrasound[12, 15]. Unfortunately it was later determined by Guttner, in 1952, that the images produced by the Dussiks were variations in bone thickness[12]. Nevertheless, their scientific work marked the beginning of diagnostic ultrasonography in the medical field and Dussik wrote in an article a decade later :"As knife and forceps in surgery, the chemical agent in chemotherapy, the high frequency electric field in diathermy and X-ray application, so has medicine taken on a new physical tool in the last decade: the ultrasonic field"[16].

George Döring Ludwig, working together with Francis Struther, was the first scientist to visualize gallstones, implanted in the muscles and gallbladders of dogs, with ultrasound. His studies also resulted in the finding that the mean velocity of ultrasound in soft tissue is 1540 m/sec, a discovery that was to prove very important for future research. Much of his work was however considered restricted information, because he was employed by the military, and therefore not published in medical journals[12].

John Julian Wild and Douglass Howry were also important pioneers in the ultrasound field. Wild was a surgeon who was able to visualize bowel wall thickness with ultrasound, and he also discovered a difference in echogenicity between benign and malignant tissue[17, 18]. Wild also developed transrectal and transvaginal transducers and a scanning device for screening patients for breast cancer[12]. Howry built the first B-mode scanner in 1949 and, together with the two engineers Bliss and Posanky, he also developed the first linear contact scanner[12]. The somascope, the first circumferential scanner, built in 1954, was also developed by Howry[12]. The problem with these scanners was that the patient had to be immobilized and immersed for a long time. In the period 1957-58 an ultrasound scanner was developed by Howry and his colleagues where the patient was strapped to the plastic window of a semicircular pan filled with saline solution. Although not immersed, the patient had still to be immobilized for a long time. Finally, in the early 1960s, Howry developed the first hand-held contact scanner, together with Wright and E Myers[19].

During the same time Ian Donald was carrying out ultrasound research in England and 1958 he published an article that came to be a landmark, (“Investigation of abdominal masses by pulsed ultrasound”), where he describes how ultrasound changed the treatment of a woman diagnosed with advanced gastric cancer dramatically by diagnosing a cystic mass with ultrasound; the mass was later resected and found to be a benign ovarian cyst[20]. Donald contributed significantly to the field of obstetric and gynecological ultrasound for example by discovering the urinary bladder to be a natural acoustic window for the pelvic organs and by measuring the biparietal diameter of the fetus for the first time[12, 21].

A century earlier the Doppler effect had been discovered by the famous Austrian scientist Christian Andreas Doppler and presented in 1842 in a paper called "Über das farbige Licht der Doppelsterne und einiger anderer Gestirne des Himmels" ("On the colored light of the double stars and certain other stars of the heavens")[22].
In Lund, Sweden, the principal pioneers of echocardiography Inge Edler and Carl Hellmuth Hertz, developed the first echocardiogram in October 1953[23]. Subsequently Hertz and Åsberg invented the first two-dimensional real-time cardiac imaging machine 1967 and Edler and Lindström registred the first simultaneous M-mode and intracardiac Doppler blood flow recordings at about the same time[12].

Ultrasound has in the last decades developed quickly and the first digital scanners were released onto the market in 1976, providing better and reproducible images[12].

Interventional ultrasonography dates back to 1969 when Kratochwill proposed the use of ultrasound for percutaneous drainage[12]. Regarding ultrasound for trauma the first report of the method for evaluating blunt trauma was dated 1971, by Kristenson in Germany[12].

The development is still going on and in the light of advances in technology leading to smaller available machines combined with the prices of machines decreasing rapidly speculations have been made about the possibility that doctors in the future will routinely be equipped with their own ultrasound stethoscope for use in their daily clinical work[23].

2.3. SURGEON PERFORMED ULTRASOUND

Surgeons and emergency physicians perform US themselves to a great extent all over the world, both for diagnostic purposes and for help in the management of the surgical patient, as well as for guidance in interventional procedures and in the operation theatre. Since radiologists are not always available for emergency scanning at the ED the use of bedside US is often assessed necessary for a secure medical care of the traumatic and nontraumatic acute abdomen. Surgeon-performed abdominal ultrasound for the evaluation of abdominal pain is presented and discussed in this thesis. The use of surgeon-performed US in other fields is presented in this chapter.

2.3.1. Trauma

FAST (focused assessment by sonography in trauma) is a method used by emergency physicians and trauma surgeons for a rapid evaluation and diagnosis of cardiac, abdominal and thoracic injuries when a patient is admitted to the ED for trauma. The use of FAST is rapidly spreading all over the world and it is now the most common application of US used at the EDs in the United States[24]. FAST has shown helpful for detecting both blood in the abdomen, pleura and pericardium for trauma patients even though there is controversy regarding the accuracy of the findings[25-28]. In a study from 2007 Lee et al also proved FAST helpful in predicting the need for immediate laparotomy of hypotensive trauma patients with a sensitivity of 85 % for the need of therapeutic laparotomy. The sensitivity for detection of blood in the abdominal cavity in normotensive patients was also 85% in this study[29]. A second evaluation with FAST is also of great value, as shown by Blackbourne et al who have shown a sensitivity of 92.1% by the initial FAST examination, increasing to 96.7% on the second evaluation[30]. Pneumothorax can also be accurately diagnosed with the help of US[31].

2.3.2. Vascular

The use of vascular US for different diseases and interventions is increasing among vascular surgeons. Duplex scanning performed by vascular surgeons has shown to be reliable and is recommended to be an integral part of the vascular surgeon's practice[32]. Surgeon-performed US is used for screening and follow-up of patients with abdominal aortic aneurysm[33]. Intravascular ultrasound has shown to be valuable for endovascular stent-graft placement in aortic dissection and aneurysm but also for other arterial and venous pathologies[34] . Surgeon-performed US has also shown to be a rapid an accurate method for screening critically ill patients for common femoral vein thrombosis[35].

2.3.3. Transrectal

Endorectal sonography was introduced to clinical practice in 1983[36]and is a part of the colorectal surgeons equipment for diagnosis and management of patients with various conditions. It is used for staging of rectal and anal neoplasia with relatively high accuracy for T and N categorization[36]. For differentiation between benign and malignant rectal lesions and classification of early rectal cancer it could be considered as the method of choice with a high diagnostic accuracy of about 88% in diagnosing T0 tumours and between 81 – 92% for differentiating between T1 and T2 tumours[37-40]. For N-classification of rectal tumours, transrectal ultrasound and MRI has approximately the same accuracy[40]. MRI and transrectal US should be used as a complement to eachother for evaluation and staging of rectal tumours.
The method of transanal sonography is also used by colorectal surgeons for diagnosis of anal sphincter tears in the case of anal incontinence as well as for diagnosing anorectal abscesses and fistulas[41].

2.3.4. Endocrine

Ultrasound is ideal for preoperative assessment of thyroidea. It is used for differentiation between malign and benign nodula, for detection and characterization of thyroid cancer, for detection of cervical node metastases, for follow-up after thyroidal surgery and for guidance in biopsy taking[42]. Endocrine surgeons are using neck US themselves in their clinical work for assessment of both thyroideal and parathyroidal glands and it is proposed that endocrine surgeons are especially well-suited to perform US examinations of the neck because the knowledge of the anatomy and endocrine disease favours the appreciation of pathological findings[43].
In a clinical situation with indeterminate thyroidal nodula, a recent study has proved surgeon-performed US helpful in predicting malignancy and for determinating the extent of thyroidectomy[44].

A recent study has also shown high accuracy in preoperative assessment of parathyroida with the same accuracy of 82% for US performed by radiologists and surgeons[45].

2.3.5. Breast

The use of breast US to diagnose breast disease is well established and especially helpful in differentiating between a fluidfilled cyst and a solid mass and for identifying small non palpable lesions[46]. Breast surgeons also use US for interventional purposes, such as aspiration of a symptomatic cyst, taking a biopsy from a suspected malignant lesion or identifying and draining a breast abscess[47]. Because US is of great importance in the management of patients with breast diseases there is an increasing opinion that US education is needed for breast surgeons and the American Board of Surgery has listed breast US as a requirement for general surgery residency training[47].

2.3.6. Endoscopic

Endoscopic ultrasound (EUS) was initially introduced in the 1980s and has since then widely spread as a diagnostic and therapeutic imaging modality[48]. It is an excellent tool for staging malignancies within and adjacent to the upper gastrointestinal tract such as adenocarcinoma in the esophagus, stomach and pancreas, gastrointestinal stromal tumours and adrenal tumours. The staging commonly includes fine needle aspiration of suspected malignant lymph nodes nearby the lesions[49-54]. The diagnostic accuracy in detecting and staging small cystic pancreatic lesions is even higher than other modalities such as CT (Computer Tomography) or MRI (Magnetic Resonance Imaging)[49]. EUS is also helpful in diagnosing other pancreatic diseases, such as pancreatitis[48]. Examples of therapeutic purposes are drainage of abscesses and other fluid collections[48].

2.3.7. Intraoperative

Intraoperative US (IOUS) was introduced in 1979 for intraoperative diagnosis of biliar calculi, and the method has since then increased rapidly and spread to different areas of surgery, such as hepatobiliary, pancreatic, gastric, endocrine, cardiovascular, neurologic , endocrine, breast, ophthalmic and laparoscopic surgery[55-66]. In certain operations, such as hepatectomy, IOUS is considered as an essential modality[56]. The main indications for the use of IOUS are to acquire new information (e.g. assessment of tumour extent or cancer staging), as a complement to or replacement for intraoperative radiography (e.g. screening of bile duct for calculi), confirmation of completion of operation (e.g. confirmation of complete resection of tumour) and guidance for surgical procedures (e.g. precise guidance for liver resection)[56]. IOUS is a safe, quick, accurate, and versatile procedure recommended to be mastered by surgeons in order to improve intraoperative decision making and surgical procedures[56].

2.4. VALIDITY OF SURGEON-PERFORMED ULTRASOUND

The validity of surgeon-performed ultrasound has been evaluated in many studies, showing good accuracy in comparison with radiologist-performed US[9, 46, 67-73].

Kell et al, for example, showed an interobserver agreement between surgeon-performed US and radiologist-performed US, in patients with suspected hepatobiliary pathology, of 94.3%[9].

The educational models for surgeons in learning US vary. A study comparing US performed by surgeons after one hour of training with radiological US showed high sensitivity and specificity for gallstones and high specificity for cholecystitis, but the visualization of the common bile duct was poor[73]. In another study by Fang et al for diagnosing cholelithiasis, the US, performed by a surgeon with a basic US education and a minimum of 20 performed examinations, had a sensitivity of 100%, a specificity of 95% and agreed with the radiological US in 92%[67]. Gallagher showed an interobserver agreement in measurement of the gallbladder between surgeons receiving a four week long education in US and an experienced radiologist[68].

2.5. EDUCATION OF THE SURGEON IN ABDOMINAL ULTRASOUND

Education of the physician performing US at the ED is a subject under debate and there is still no standardized instruction model for surgeons in US training. Many studies have been performed in which physicians other than radiologists perform US. The length of the education training provided in these studies differs, from one hour to four weeks[9, 25, 68, 73-79].

In 1976 Dr Thomas Tiling began to study the potential use of US for surgeons. The first course given in ultrasound for surgeons was held at the University of Gottingen in 1982 and 1987 the German Association of Surgery began requiring experience and competence in US for certification in general surgery [80].

In the United States the use of surgeon-performed US is rapidly spreading. In 1993 the use of surgeon-performed ultrasonography was advocated on a national basis at the 79th annual Clinical Congress of the American College of Surgeons (ACS)[81]. ACS sponsored its first US course, entitled "Ultrasound for the general surgeon", conducted by surgeons for surgeons in April 1996[33, 80, 82]and they are now conducting US training modules, and resident participation is encouraged. A voluntary verification process, with three levels of training is available to ensure that surgeons who use ultrasound are qualified and that the ultrasound facilities and equipment they use meet and maintain quality standards[80, 81].

In Great Britain The Royal College of Radiologists (RCR) 2005 writes in their recommendations for ultrasound use in medical and surgical specialties that they "recognize ultrasound as an evolving technology with wide application throughout medical and surgical practice" and that "it is inevitable and appropriate that medical practitioners other than clinical radiologists should seek to develop skills in the performance of ultrasound". They are recommending three levels of competence. For the basic level they recommend a course in physics, technique and anatomy and thereafter supervised training. For gastrointestinal training Level 1 the recommended minimum examinations are numbered at 250, for focused emergency US the minimum examinations required are 50 and for critical/intensive care US 25 examinations per specific area of interest[83].

In the 1980s emergency physician-performed US first appeared in the literature and it is now widely incorporated into emergency medicine residency training programs in the United States. Training in bedside US is required for residents in the specialty and by 2002 nearly all emergency residence programs had some sort of residency training program compared to 50% in 1997. The didactic component and clinical time devoted to bedside US however varies between residency programmes[84]. SAEM (Society for Academic Emergency Medicine) in 1994 presented guidelines for bedside US performed by emergency physicians , recommending a week of didactic instruction and a minimum of 150 performed exams, including gynecological and cardiological US [85, 86]. A recent proposal of guidelines for achieving accreditation in emergency US presented by Stein and Nobay also proposes 40 hours of didactic education and 150 performed examinations, with at least 90% accuracy, and a minimum of 25 documented examinations per year for revalidation of credentials[87].

WINFOCUS (World Interactive Network Focused On Critical UltraSound) is a global organization committed to the development of point-of-care ultrasound in clinical practice. They put considerable focus on education in ultrasound and since there is no world wide standardized education model for emergency ultrasound Luca Neri and his colleagues in the organization have presented a proposed standard core curriculum for ultrasound in critical care medicine. This education program consists of three levels of competence with two sublevels in each level. To achieve a universal approach to ultrasound education in critical care, they have started a multicentre educational study to apply this curriculum model in different countries worldwide ("Continuing Medical Education for Ultrasound in Critical Care Medicine," CME USCCM Project)[88].

It is very important to have a good education and training in US when physicians other then radiologists begin to perform US. It is a good approach to plan the education in cooperation with the radiologists, since they have the greatest experience of US.

In our hospital we have chosen to continue with the standardized education given to the surgeons participating in our study, which is planned and executed in cooperation with the US specialists at the radiological department. This education model, which is described in detail in the Method chapter, we believe is well in concordance with other published instruction models[74].

2.6. USE OF ULTRASOUND IN OTHER SPECIALTIES

US is performed by radiologists in most countries. More and more, other specialties are beginning to use US themselves in their clinical practice. In this thesis I have reported and discussed the increasing use of US in surgical practice, and will now discuss the use of US in some other specialties.

Emergency physicians are using US at the ED for trauma evaluation (FAST scan), identification of pericardial fluid, diagnosis of abdominal pain, diagnosis of venous thrombosis, identification of foreign bodies, valuation of gynecological diseases and pregnancies, musculoskeletal imaging, and as assistance in interventional procedures[89-91]. Emergency physicians have also started using echocardiography to obtain information on cardiac function and volume status[92]. US is also used by emergency physiscians for central venous cannulation [93], and has also been used and shown to be effective as a help for performing cricothyroidectomy[94].

In cardiology echocardiography is fully integrated in their clinical practice and personal handheld imagers as an immediate complement to physical examination have been introduced, with proved cost savings and shortened time to diagnosis[95].

Gynecologists/obstetricians use abdominal and transvaginal US in their daily work for evaluation of the pelvic organs and for obstetric care. The method of transvaginal US was first introduced as a routine in the 1980s and by 1992 a worldwide inquiry showed that obstetricians/gynecologists were using the method themselves to a high extent both in Europe and United States[96].

US has proved effective also for fracture evaluation and is used by orthopedic surgeons also for other orthopedic diseases, such as evaluation of rotator cuff disorders and meniscal lesions [97-100].

Specialists in anesthesia and intensive care medicine are using US for evaluation of the critically ill patient´s heart status, for diagnosis of pathologic conditions in chest and abdomen, and for inventional purpose, such as insertion of central vein catheters and guidance in nerve blocks procedures[101-104].

Gastroenterologists/hepatologists are using US in their clinical work, for example for guidance in taking percutaneous liver biopsies and the opinion that US skill should be integrated into the gastroenterologist fellowship training has gained ground[105].

It has been proposed that General Practitioners carry out US scanning themselves at their practices in the United Kingdom and in some primary care practices US scanning is included even if it is still not a routine in primary care. An evaluation of the introduced US scanning has shown acceptable accuracy and benefits of reduction of hospital scans, in-patient and out-patient visits and emergency admissions and in addition a patient preference for scanning at the primary care practice[106].

Rheumatologists have started integrating US into their practice and in some parts of Europe US training is integrated into the postgraduate training. Musculoskeletal ultrasonography has been described by some rheumatologists as the “stethoscope of the joint”[107].

2.7. USE OF ABDOMINAL ULTRASOUND FOR THE ACUTE ABDOMEN

2.7.1. Appendicitis

Ultrasonic findings of appendicitis include a thickened, noncompressible, blind-ended wall that is greater than 6 mm in diameter, absense of gas in the appendical lumen, presence of blood in the appendical wall and appendicocolitis[108-110]. The method of using US for diagnosing appendicitis is regarded as operator dependent and the results are controversial[108, 111, 112]. It has however been shown that the sonographist with the longest experience in abdominal US does not always have the best results in diagnosing appendicitis[8, 113]. Sensitivity for diagnosing appendicitis with US of 55-94% and a specificity of 78-100 % for acute appendicitis has been reported[6, 8, 108, 109, 114, 115]. Ooms et al have shown an improvement in diagnostic accuracy and patient management for appendicitis with the help of US, and they recommend US as a complement to clinical examination when the diagnosis is suspected clinically[112]. In 2004 Terasawa et al have, in a systematic review, reported an overall sensitivity of 86% and a specificity of 81% in diagnosing appendicitis with US[116]. A recently published meta-analysis comparing CT scan and US for diagnosing appendicitis showed a mean sensitivity of 78% and a mean specificity of 83% for US; CT scan showed better results but with a higher prevalence of appendicitis the difference between the imaging modalities being rendered smaller[117]. Bedside US performed by emergency physicians when appendicitis was suspected clinically showed a sensitivity of only 65% and a specificity of 90%, the authors however conclude that bedside US is insufficient to rule out appendicitis but might be a tool for ruling in appendicitis with further training of emergency physicians performing US[114].

2.7.2. Gallbladder disease

Transabdominal ultrasonography is the golden standard for the diagnosis of gallbladder stones with high sensitivity and specificity (above 95%) for detection of gallstones larger than 1.5 mm in size[118]. Gallstones are identified as echogenic structures casting an acoustic shadow and if inside the gallbladder they are usually surrounded by echofree substance (bile)[119]. For diagnosing cholecystitis it is also the method of choice with a sensitivity ranging from 85 to 94%[27]. The signs of cholecystitis include gallbladder wall thickening (>3mm), gallbladder wall oedema, positive sonographic Murphy´s sign, debris in the bile, increased Doppler flow in the wall and pericholecystic fluid[27]. Measurement of the common bile duct is usually performed during a hepatobiliar scanning and a dilatation greater than 6 mm is considered abnormal even if the size increases with age (approximately 1 mm per decade over 60 years)[119]. Bedside hepatobiliary US performed by emergency physicians has shown high accuracy in comparison with radiological US and has also been shown to reduce length of stay in the ED[119]

2.7.3. Urological diseases

US has a major role in identifying unilateral hydronephrosis in patients with suspected renal colic[120]. For renal stone detection CT is more sensitive even though a sensitivity of 96%, and even 100% for stones bigger than 5 mm, has been reported for US[27]. Renal calculi are recognized as highly echogenic foci with well-defined posterior acoustic shadowing[27]. Heidenreich et al have, in a review of diagnostic modalities of flank pain, reported a sensitivity of only 19% for visualization of ureteral stones, increasing to 73% considering secondary signs of ureteral stones such as calyceal dilatation and ureteral dilatation[121].

2.7.4. Diverticulitis

Ultrasonic signs of diverticulitits are mural thickening, pericolic inflammation and visualization of the diverticula[108]. Another sonographic finding for acute diverticulitis is the “dome sign”, a hypoechoic mass protruding at the outer surface of the intestinal wall, a sign that was shown by Kori et al to differentiate from acute appendicitis in the occurrence of right side diverticulitis[122]. Hollerweger et al have shown a sensitivity of 77% and specificity of 96% in visualization of an inflamed diverticula in diverticulitis by US. In uncomplicated diverticulitis the sensitivity was however higher, 96%, being difficult to identify the inflamed diverticula in complicated disease[123]. Zielke et al showed similar results in their study, reporting a sensitivity of 84 % and a specificity of 93 % for diagnosing diverticulitis[124]. Even higher numbers are shown by Chou et al who diagnosed right side diverticulitis in patients with right side lower quadrant pain of unknown origin with a sensitivity of 91.3%, a specificity of 99.8% and an accuracy in differentiating diverticulitis from appendicitis in 100%[125].

2.7.5. Abdominal Aorta

Aortic aneurysm is described as an aortic diameter of 30 mm or more[126]. Physical examination for detecting aortic aneurysm has a sensitivity ranging from 33 to 100% and a specificity of 75 to 100% and can not be relied on to rule out aneurysms, especially not in obese patients where the aneurysm is difficult to palpate[127]. Abdominal US reaches 100% accuracy in detecting the presence of an aneurysm and a bedside US scan may help to refute or confirm the diagnosis in unstable patients who are not suitable for other imaging studies such as CT scan[128]. When screening 179 at-risk patients for abdominal aortic aneurysm with US performed by emergency physicians 12 aortic aneurysms were detected. The US examination took less than three minutes to perform and the discrepancy between US and formal imaging was only 3.9 mm[126]. In another study of emergency physicians performing US for suspected aortic aneurysm a sensitivity of 96.3% and a specificity of 100% was reached[129].

2.7.6. Gynecological diseases

Pelvic ultrasound is the first-line imaging investigation in gynecological disorders. With a transabdominal approach a distended urinary bladder is required to get an optimal visualization of the pelvic organs, whereas a transvaginal approach an emptied bladder is preferred. Adnexal masses due to for example ovarian cysts, neoplasies, ovarian torsion, hydrosalpinx and tubo-ovarian abscess as well as myoma of the uterus and fluid in the rectovesical pouch can be visualized with transabdominal US[130]. In a study of patients admitted for suspicion of appendicitis examination with abdominal US showed a sensitivity of 80% in diagnosing a gynecological disease as the origin of the pain[115].

2.7.7. Tumours

Approximately 3% of the patients admitted to the ED for abdominal pain have a previously unknown intrabdominal malignancy[74, 131]. The most common tumours not diagnosed at discharge are colorectal tumours and malignancies of the liver, biliary tract and pancreas[131] An age of more than 65 years, long duration of pain and signs of constipation and abdominal distension are associated with a higher risk of abdominal malignancy[131]. It is therefore of great importance to find easy examinations for screening for tumours in these patients.

Sonographic criteria for identifying colonic carcinomas were described 1994 by Shirahama et al as " a localized and irregular thickening of the colonic wall with heterogenous low echogenicity, an irregular contour, a lack of demonstrable movement or change of configuration of the bowel on real-time scanning and a presence of wall stratification" [132]. Richardson et al identified colonic tumours by using US performed by experienced radiologists with an accuracy of 91%, a specificity of 67% and a sensitivity of 96% in patients referred for suspected colonic carcinoma[133]. In patients admitted to the ED with a complaint of distended abdomen Chen et al achieved a sensitivity of 92.8%, a specificity of 98.8% and an accuracy of 97.7% for diagnosing colonic carcinoma with US performed by staff emergency physicians or staff surgeons[134].

A pancreatic tumour, as well as chronic pancreatitis, reveals as a hypoechoic area in the pancreas, and the diagnostic accuracy for pancreatic tumours with conventional US is only 50-70%, but newer more advanced technology using contrast-enhanced Doppler US has shown higher accuracy of 90-95%[49].

2.7.8. Non Specific Abdominal Pain

Acute Non Specific Abdominal Pain (NSAP) is a condition of abdominal pain of unknown origin, generally defined as acute abdominal pain of under 7 days' duration and for which there is no diagnosis after examination and baseline investigations, and is a common cause to seek medical care at the ED and often requires in-ward observation and the need of diagnostic surgical procedures to exclude a serious condition[135, 136]. The diagnosis might include serious unknown conditions, especially in elderly patients, and US is recommended as a tool for evaluating ruptured aortic aneurysm specifically in these patients [128]. NSAP is a common discharge diagnosis for patients with malignancy admitted to the ED for abdominal pain[131]. US might be a possibility to discover the malignancy earlier if examination of especially older patients with NSAP is performed, though US has proved beneficial for diagnosing tumours[132-134]. US is also useful for diagnosing other life-threatening , occasionally missed conditions in patients with NSAP, such as appendicitis, diverticulitis and bowel obstruction[128].

2.7.9. Other gastrointestinal disorders

US has shown helpful for evaluation of several colonic diseases, such as infectious colitis, inflammatory bowel disease, large bowel obstruction and perforation of the colon[137]. For diagnosis of gallstone ileus, a rare condition causing mechanical obstruction, US has also shown helpful[138]. For diagnosis and classification of groin hernias US has shown to be an excellent tool with high accuracy[139]. For diagnosis of incisional hernias US is also of value, with a specificity of 100% but a rather moderate sensitivity of 71% shown in a recent study[140]. Obstruction of the small bowel can also be diagnosed with the help of US, including prediction of the level of obstruction in many cases, and the cause of obstruction is also sometimes identified by US[141].

2.8. OTHER RADIOLOGICAL EXAMINATIONS PERFORMED EARLY FOR THE ACUTE ABDOMEN

2.8.1. Computer Tomography (CT) scan

CT is becoming more and more common as a method for evaluating abdominal pain at the ED. The examination has a sensitivity of 94% and a specificity of 95% in diagnosing appendicitis according to a systematic review from 2004[116]. A recent published meta-analysis comparing US and CT for diagnosing appendicitis showed similar numbers, a mean sensitivity of 91% and mean specificity of 90% for CT scan in the included studies[117]. For diagnosing diverticulitis CT scan, with a sensitivity ranging from 85% to 97%, is regarded as the method of choice, although the scientific evidence for CT is poor[108, 142]. For detection of gallstones CT is rarely useful[118]. CT, without contrast, has shown to be superior for evaluation of flank pain, with a sensitivity and specificity from 98 to 100% in detection of ureteral stones, regardless of size, location and chemical composition, and with the possibility of detecting extra urinary causes of flank pain in about one third of the patients presenting with flank pain[121]. For intestinal obstruction CT has reported sensitivities at 90% both for the diagnosis of obstruction and the cause of obstruction[6]. For detecting free gas CT has higher sensitivity than plain films[6].

In a randomized study by Ng et al including patients with abdominal pain of unknown origin, randomizing to early CT scan or standard evaluation, they showed that serious conditions were missed more often in the standard arm and a reduction of mortality was seen in the CT group[143]. Mortality was however not an a priori endpoint in the study and a later larger randomized study could not show any reduction in mortality with the use of CT scan for the acute abdomen[144]. Nor could Salem et al show any reduction of mortality with the use of CT scan for the acute abdomen in a later study but they did show an increased diagnostic accuracy and an improvement of the management of the patients with the method[145].

2.8.2. Magnetic Resonance Imaging (MRI)

MRCP (Magnetic Resonance Cholangio Pancreatography) has gained increasing importance for the diagnosis of choledocholithiasis (specificity 100%, sensitivity 89%)[118]. MRI without oral contrast has shown high diagnostic accuracy for pelvic and abdominal pain in both pregnant and non pregnant women, with a sensitivity of 90-100% in detecting appendicitis[146-148]. MRI may also be used to evaluate renal colic, especially when radiation dose is of concern, as in children and pregnant women[149]. The disadvantages of the method are the high cost and the limited availability of equipment and trained radiologists[147] , which makes the method unsuitable for implementation as a routine for evaluation of abdominal pain.

2.8.3. Plain abdominal radiograph

Plain abdominal radiographs can be used for detecting bowel distension, abnormal calcification, free air, large abdominal masses and organomegaly, but many specific serious diagnoses causing abdominal pain will be undiagnosed with this method[150]. Plain radiographs are becoming less common in the management of the acute abdomen but are still recommended particularly in the initial management of suspected intestinal perforation, intestinal obstruction and for missile injuries[6]. For detecting free gas in the diagnosis of perforated ulcer disease the sensitivity ranges between 80-85%[6]. The sensitivity of plain x-ray to detect ureteral stones ranges from 44% to 77% and specificity from 80% to 87%, and a plain film is often performed as an initial examination prior to application of intravenous contrast agents and for follow-up[121].

3. AIMS

The overall objective of this thesis was to evaluate the effects of bedside surgeon-performed ultrasound on the diagnostic accuracy and management of the patient admitted to the emergency department for abdominal pain.

The specific aims of this thesis included in the studies were

1. To evaluate the diagnostic accuracy of surgeon-performed ultrasound on the acute abdomen and the way in which the ultrasound examination contributed to the diagnosis (Paper 1)

2. To evaluate the effect of surgeon-performed ultrasound on the management of the patient with abdominal pain regarding admission frequency, need of further examinations, time spent in the ED and in hospital if admitted and timing of surgery when required (Paper 2)

3. To evaluate the effects of surgeon-performed ultrasound on the patient with abdominal pain on a short- and a long-term basis and to evaluate the self-rated patient satisfaction at the emergency department and at six-week follow-up (Paper 3)

4. To determine the effect of surgeon-performed ultrasound bedside at the emergency department, based on several patient characteristics, such as Body Mass Index, age; C-reactive protein and signs of peritonitis; appendicitis or gallbladder disease, on diagnostic accuracy and further management of patients admitted to the emergency department for abdominal pain (Paper 4)

4. SUBJECTS AND METHODS

4.1. HYPOTHESES

4.1.1. Primary hypothesis

That diagnostic accuracy is higher in patients admitted at the ED for abdominal pain of unknown origin, if examined with bedside surgeon-performed US than if not examined with bedside surgeon-performed US.

4.1.2. Secondary hypotheses

That the amount of required further examinations is lower,
that the admission frequency is lower,
that the number of surgical procedures is less,
that decision of surgery is taken earlier (if admitted for surgery),
that time spent at the ED is shorter,
that time spent at the hospital ward is shorter (if admitted),
that the self-rated level of patient satisfaction is higher at the ED and after six weeks,
that self assessed health condition is better at six-week follow-up
that health care consumption is less at six-week and at two-year follow-up

> for patients, admitted at the ED for abdominal pain of unknown origin, if examined with bedside surgeon-performed US than if not examined with bedside surgeon-performed US.

We have also examined in which subgroups the patients benefit most, and in which way, from surgeon-performed US. The contribution of US in setting diagnosis has also been evaluated. Mortality has been measured in a six-week and two-year follow-up.

4.2. STUDY DESIGN

This is a randomized study with randomization of patients admitted to the ED for abdominal pain of unknown origin to bedside surgeon-performed US or not. A total of 800 patients were included in the study, 400 in each intervention group.

4.2.1. Setting

The study was conducted at the ED of Stockholm South General Hospital between February 2004 and June 2005. Stockholm South General Hospital is a public general hospital with 505 beds and with a catchment area of about 600 000 inhabitants. The ED of Stockholm South General Hospital has an average of 100 000 visits per year by patients aged 15 years and older.

4.2.2. Enrolment criteria

All patients, 18 years or older, admitted to the emergency ward for abdominal pain were considered eligible to participate in the study. The exclusion criteria were: pregnancy, previously diagnosed abdominal condition, acute conditions needing immediate care, inability to communicate with the investigator, drug or alcohol addiction and dementia.

4.2.3. Baseline management

A total of 800 patients were enrolled in the study. After inclusion, the patients were examined by the study surgeon. Medical history was taken, and clinical examination and routine laboratory testing were performed. The blood laboratory testing included hemoglobin, WBCC (White Blood Cell Count), thrombocytes, CRP (C-reactive protein), AST (aspartate aminotransferase), ALT (alanine aminotransferase), ALP (alkaline phosphotase), bilirubin, pancreas amylase, sodium, potassium and creatinine. The urine testing included tests for leucocytes, blood, protein and nitrite as well as a pregnancy test for all fertile women.

4.2.4. Randomization

This was an unblinded randomized clinical trial. The patients and the study surgeons were aware of which group the patient had been randomized to. We used a computerized randomization generator for randomization.

After receiving the laboratory results, the study surgeon set a first preliminary diagnosis on a form containing 36 different pre-defined diagnoses. The form was then put in a sealed envelope. After this, the sealed randomization envelope was opened and the patient was randomized to surgeon-performed US or no surgeon–performed US.

4.2.5. Intervention

US examination was performed with one out of two handheld, 2,5-5 MHz or 4,3-6 MHz, curved array transducers (B-K medical, Denmark, Hawk 2102, transducers type

8801 and 8802) screening the entire abdomen. After US had been performed the study surgeon filled out a form with the results of the examination and set a second preliminary diagnosis.

4.2.6. Further management

The two groups were subsequently managed according to clinical routine as decided by the study surgeon. In both groups it was possible to request abdominal US from the radiological department, as well as other complementary radiological examinations and blood tests if required.

4.3. TRAINING IN ABDOMINAL ULTRASOUND FOR THE PARTICIPATING SURGEONS

Each participating surgeon went through a standardized education with one week of didactic education and three weeks at the radiological department performing US examinations under the supervision of an US expert. The initial week was led by an US specialist and included theory of physics, technique, knobology, US anatomy and hands-on training on each-other and on patients with specific findings. The surgeons were trained in detecting gallbladder stones, wide bile ducts, hydronephrosis, abdominal aortic aneurysms, ovarial cysts, free abdominal fluid, pleura fluid collections and large abdominal masses. The surgeons were also expected to have good knowledge about, and in selected cases be able to identify an inflamed appendix, diverticulitis, intestinal obstruction, liver disease and large kidney stones. During the following three weeks the course participants were based at the radiological department working exclusively with examining patients with US under the supervision of a US specialist.

After this four week long education the surgeon worked for four weeks at the ED exclusively managing study patients, performing US on the patients randomized to US.

4.4. FOLLOW-UP AND COLLECTION OF DATA

All information on the patients collected in the ED was entered by the study surgeon on a case report form. After the first examination of the patient, including patient history, clinical examination and laboratory testing, the study surgeon set a first preliminary diagnosis on a form containing 36 different pre-defined diagnoses. The form was then put in a sealed envelope. The second preliminary diagnosis was set after performed US for the US group exclusively on an identical form and put in another sealed envelope.

Before leaving the ED the patients were asked to anonymously indicate their satisfaction with the visit on a ten-grade visual analogue scale where 0 represented the lowest satisfactory level and 10 the highest level. This paper was sealed by the patient and handed over to the ED staff.
Additional data about the patients who were admitted to the hospital for in-patient care were collected from the patient records and entered on a complementary case report form, designed for the admission period.

After discharge from the ED or hospital ward, all patients were contacted by telephone by a study nurse four to six weeks after their first visit. The study nurse performed a structured interview including questions on health condition, performed and planned examinations and admission to other health care units. The patients was also asked to report their self-rated level of satisfaction with the emergency visit on a ten-grade scale where 0 represented the lowest level of satisfaction and 10 the highest. The study nurse was blinded as regards which group the patient belonged to.

In our regional registry, containing all health contacts in Stockholm with public health care providers, we followed up all patients during a two-year period after the ED visit. On a special case report form, a study nurse recorded all out-patient visits and in-patient admissions during the time period. From the same registry we also recorded radiological examinations and endoscopies as well as total mortality within two years of the first visit. Exact date of mortality was checked for in the personal registry. We excluded medical care that was obviously not related to the ED visit for abdominal pain, such as hearing and vision examinations, dermatology and medical treatment related to pregnancy and delivery. The study nurse was blinded to which randomization group the patient belonged to.

4.5. OUTCOMES, DEFINITION AND MEASUREMENT

4.5.1. Primary outcome:

4.5.1.1. Correct diagnosis (Paper 1 and 4)

The correct diagnosis was defined as the final diagnosis set by a senior surgeon six to eight weeks after the patient had entered the study, based on information in the patient records. When determining the final diagnosis, the senior surgeon was not aware of the preliminary diagnosis set by the surgeon at the ED. The final diagnosis was compared with the preliminary diagnosis set at the ED, with or without US examination. The primary outcome of the study was defined as the proportion of correctly set diagnoses in the ED.

4.5.2. Secondary outcomes:

4.5.2.1. Contribution of ultrasound when making a diagnosis (Paper 1)

The diagnoses of the patients in the US group were further analysed to elucidate the way in which ultrasound had contributed. We defined five groups with different contributions:

1. US had contributed to the diagnosis either by changing an earlier incorrectly set diagnosis to a correct diagnosis, or by confirming an earlier correctly set diagnosis.

2. US was misleading, either by confirming an earlier incorrectly set diagnosis or by changing an earlier set diagnosis (correct or other incorrect) to another incorrect diagnosis. All cases where the surgeon had missed or incorrectly set the diagnosis of any of the conditions that he or she was supposed to diagnose according to the goal of education were defined as misleading. If the surgeon had changed to or confirmed an incorrect diagnosis by US it was defined as misleading even if the final diagnosis was not included in the education goal.

3. US had no influence on making the diagnosis.

4. Non-specific abdominal pain (NSAP) was confirmed after US was performed. In this group US contributed in securing the diagnosis by an ultrasound examination that did not show any pathological findings leading to another diagnosis. In this group NSAP was a correct set diagnosis.

5. No correct diagnosis was set at the ED but US contributed to a correct diagnosis that was set later.

4.5.2.2. Number of complementary examinations (Paper 2 and 4)

The study surgeon filled in a form, reporting whether the patient was admitted to hospital, whether further examinations were ordered and specifying which examinations were ordered.

4.5.2.3. Admission rate (Paper 2 and 4)

The study surgeon filled in a form, reporting whether the patient was admitted to hospital or not.

4.5.2.4. Admission to surgery (Paper 2 and 4)

If admitted to hospital, the patient files were checked to find out if surgery was performed during admission or not.

4.5.2.5. Time for decision of surgery (Paper 2 and 4)

The study surgeon filled in a form, reporting whether the patient was admitted for surgery while still at the ED.

4.5.2.6. Time spent at ED (Paper 2)

The study surgeon filled in a form, reporting time for admission to ED and submission from ED. These time reports were checked for, and correlated if needed, in AKUSYS, a computerized registry for activities performed at the ED.

4.5.2.7. Length of hospital stay if admitted (Paper 2)

Length of hospital stay, if admitted, was checked for in the patient files.

4.5.2.8. Patient satisfaction at the ED and at six week follow-up (Paper 3)

The patients anonymously filled in a form that indicated their satisfaction with the visit on a ten-grade visual analogue scale where 0 represented the lowest satisfactory level and 10 the highest level. In the telephone interview six weeks after the ED visit the study nurse asked the patient about their self-rated level of satisfaction with the emergency visit on a ten-grade scale where 0 represented the lowest level of satisfaction and 10 the highest and filled in the number in a special form.

4.5.2.9. Health condition at six-week follow-up (Paper 3)

In the telephone interview six weeks after the ED visit the study nurse asked the patient about their health condition (Totally well, partly well or not well). The answer was reported on a special form.

4.5.2.10. Health care consumption at six-week follow-up and at two-year follow-up (Paper 3)

In the telephone interview six weeks after the ED visit the study nurse asked the patient about their health care consumption (Further examinations planned, completed or not planned). If further examinations were completed or planned the patient was questioned about the examinations that had been or were to be performed. In our regional registry a study nurse, blinded, checked all health care consumption within two years after the ED visit and reported this on a special form. Medical care that was obviously not related to the ED visit for abdominal pain, such as hearing and vision examinations, dermatology and medical treatment related to pregnancy and delivery, was excluded.

4.5.2.11. Mortality (Paper 2 and 3)

Mortality was checked for in our regional registry. If deceased the exact date of death was checked for in the personal registry to find out if death occurred within seven days, six weeks or two years after the ED visit.

4.6. STATISTICAL METHODS

The sample size was calculated on the basis of the primary outcome of the study, diagnostic accuracy, and based on results from a previous prospective study[151]. Thus, the sample size was calculated to detect a nine-percentage points difference for a proportion between the control and the ultrasound groups (specifically 70% versus 79%). It would be necessary to have 400 patients in each group to detect a difference of this size with 80% power at 5% significance level, two-tailed**.** We used SamplePower 2.0 to perform the sample size calculation.

Regarding the sample size in the subgroup analyses we calculated the power for different sample sizes and effect sizes to have an idea about the power in the present study. To detect a difference in the proportion between two groups with 30 patients in each group, a difference of for example 50% vs 83% or 70% vs. 96% would have been detectible with 80% power at 5% significance level, two-tailed. With 100 patients in each group the corresponding detectible effect sizes would decrease to 50% vs. 69% or 70% vs. 86%. For 200 patients in each group the corresponding numbers are 50% vs. 64% or 70% vs. 82%. We used Sample Power 2.0 to perform the sample size calculation.

We used the Chi-square test to compare the groups regarding proportion of correct diagnoses, i.e. the primary outcome measure (Paper 1) as well as for requested complementary examinations, admissions and surgery (Paper 2) and for health care consumption and health condition at six-week follow-up as well as for mortality on a short and long term basis (Paper 3). For the comparing analyses of the primary outcome diagnostic accuracy and the secondary outcomes of requested further examinations and hospital admissions in the subgroups we also used the Chi-square test (Paper 4).

The Mann-Whitney U test was used to compare times between the groups (Paper 2) and for comparison of the medians between the intervention group and the control group regarding patient satisfaction at the ED and at six-week follow-up and for health care consumption at the two-year follow-up (Paper 3).
The results were regarded as significant if *p* was less than 0.05, two-tailed. The corresponding 95% CI for the difference between the proportions are based on the normal approximation.

All analyses were performed according to ITT. SPSS 14.0 was used for statistical analysis in the three first Papers and SPSS 16.0 in the fourth Paper.

4.7. ETHICAL CONSIDERATIONS

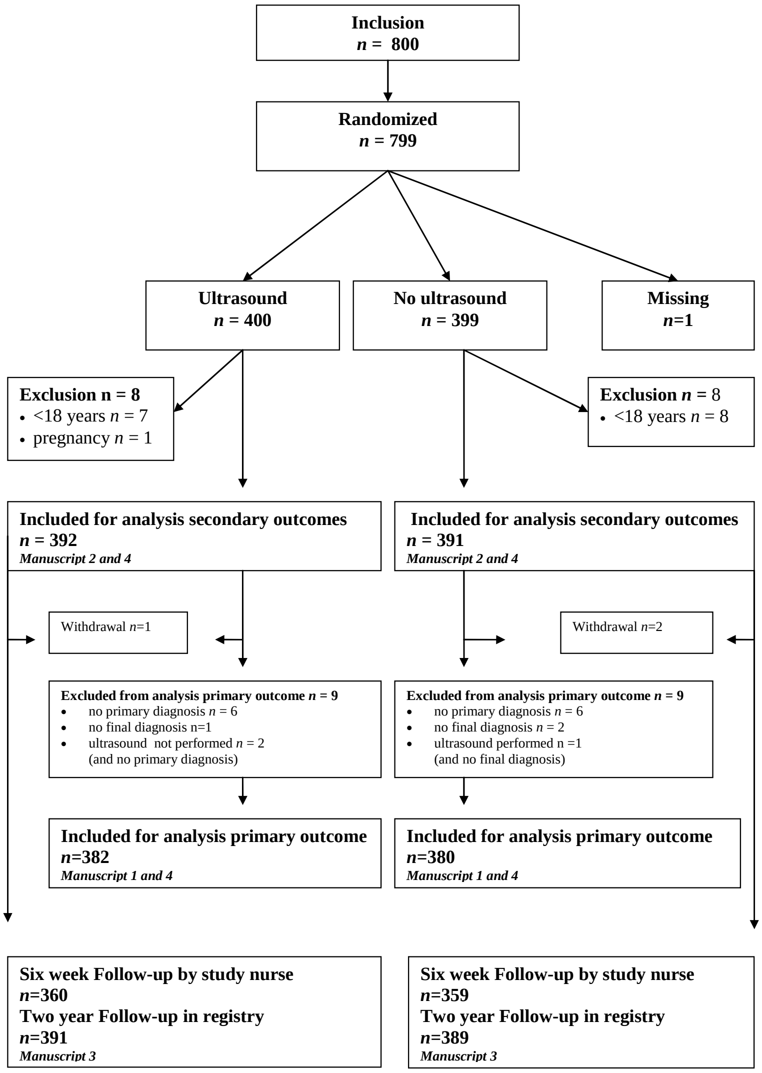
The study was approved by the Institutional Review Board at Karolinska Institutet, Stockholm, Sweden (Dnr 216/03 and 2007/727-32). The study has been registered in ClinicalTrials.gov ID NCT00550511. The patients received oral and written information about the study and were included after informed consent.

5. RESULTS

5.1. PARTICIPATION

A flowcart showing the participation in the study and follow-up is shown in Figure 1. After exclusion of patients not fulfilling the inclusion criteria and one missing patient there were 392 patients left for analysis in the US group and 390 in the control group. For analysis of primary outcome there were 382 patients in the US group and 380 in the control group with valid data for analysis. In the US group 360 patients were followed up in the six-week follow-up and 391 in the two-year follow-up. In the control group 359 patients were followed up in the six-week follow-up and 389 in the two-year follow-up.

Figure 1. Flow chart of randomization and follow-up



5.2. BACKGROUND RESULTS

The background factors were similar in the both groups except for the referral pattern where more patients were referred to the ED from other physicians in the control group (24% /33%). Mean age was 47 years in the US group and 48 in the not US group. The proportion of male patients was 41% in the US group and 44% in the not US group. Body Mass Index (BMI) was 25 in both groups.

In table 1 all the background data is shown.

Table 1. Baseline characteristics of patients with abdominal pain at the ED, who were enrolled in this study.

Characteristics	**Ultrasound (n = 392)**				**Not ultrasound (n = 391)**			
	Mean	**(SD)**	**n**	**(%)**	**Mean**	**(SD)**	**n**	**(%)**
Age	47	(20)			48	(19)		
Height	172	(9)			172	(10)		
Weight	73	(16)			73	(16)		
BMI (Body Mass Index)	24.8	(4.5)			24.8	(4.3)		
Gender Male			160	(40.8)			171	(43.7)
Female			232	(59.2)			220	(56.3)
Abdominal related comorbidity			76	(19.4)			78	(19.9)
Comorbidity related to heart or diabetes			66	(16.8)			74	(18.9)
History of abdominal malignancy			6	(1.5)			12	(3.1)
History of other malignancy			11	(2.8)			14	(3.6)
Other comorbidity			132	(33.7)			123	(31.5)
Admission for abdominal pain within one year			124	(32.0)			137	(35.3)
Referral for admission			92	(24.4)			126	(32.9)
Duration of pain 0-8 hours			44	(14.8)			43	(14.4)
8-24 hours			99	(33.2)			97	(32.4)
>24 hours			147	(49.3)			151	(50.5)
Cannot answer			8	(2.7)			8	(2.7)
Affected general condition			90	(23.3)			74	(19.1)
Tenderness			338	(86.4)			347	(89.2)
Rigidity			51	(13.1)			49	(12.6)
Palpable mass			23	(5.9)			29	(7.5)
Actual VAS (of pain)*	4.3	(2.8)			4.4	(2.6)		
Maximal anamnestic VAS (of pain)*	7.6	(2.6)			7.6	(1.8)		
Temperature	37.0	(0.8)			37.0	(0.7)		

* VAS (of pain) = Visual Analogue Scale (scale 0-10. 0 represents no pain at all, 10 represents unbearable pain)

5.2.1. Laboratory tests

The laboratory tests taken were quite normal. The values are shown with percentiles in Table 2. A small difference was seen in the CRP-level with a higher CRP-level for the control group, otherwise the levels were equal between the groups.

Table 2. Laboratory results of patients with abdominal pain at the Emergency Department enrolled in this study.

Laboratory test	Ultrasound (n=392)			No ultrasound (n=391)		
	Median	25th percentile	75th percentile	median	25th percentile	75th percentile
Hemoglobine	138	128	147	139	129	150
WBCC	9,1	7,0	11.9	9.2	6.9	12.2
CRP	<10	<10	28	13	<10	50
ASAT	0.42	0.34	0.56	0.42	0.34	0.55
ALAT	0.37	0.26	0.64	0.36	0.26	0.55
ALP	2.7	2.0	3.5	2.7	1.9	3.5
Bilirubin	11	8	16	11	8	17
Pancreasamylase	0.36	0.27	0.52	0.38	0.27	0.52
Sodium	139	136	141	139	136	141
Potassium	3.9	3.7	4.1	3.9	3.7	4.1
Creatinine	74	63	87	73	63	85

5.3. FINAL DIAGNOSES

The final diagnoses set are reported in Table 3. There were more patients with the final diagnosis of diverticulitis in the control group, otherwise the groups were equal regarding final diagnoses.

Table 3. Final diagnoses set by the senior surgeon for patients with abdominal pain at the Emergency Department enrolled in this study.

	Ultrasound (n = 392)		**Not ultrasound (n = 391)**		**Total (n = 783)**	
	n	**%**	**n**	**%**	**n**	**%**
Non-specific abdominal pain	148	(37.9)	148	(38.1)	296	(38.0)
Cholelithiasis (sympthomatic, with or without cholecystitis)	34	(8.7)	27	(7.0)	61	(7.8)
Appendicitis	34	(8.7)	29	(7.5)	63	(8.1)
Diverticulitis	17	(4.3)	35	(9.0)	52	(6.7)
Ureteral calculi (sympthomatic, with or without hydronephrosis)	22	(5.6)	23	(5.9)	45	(5.8)
Urinary tract infection (cystitis or pyelonephritis)	18	(4.6)	14	(3.6)	32	(4.1)
Dyspepsia/reflux/esophagitis	16	(4.1)	12	(3.1)	28	(3.6)
Gastroenteritis/Virosis	14	(3.6)	10	(2.6)	24	(3.1)
Choledocholithiasis (with or without cholangitis or pancreatitis)	9	(2.3)	13	(3.4)	22	(2.8)
Tumour (not previously known)	10	(2.6)	11	(2.8)	21	(2.7)
Ovarial cyst (sympthomatic, with or without rupture/bleeding)	7	(1.8)	11	(2.8)	18	(2.3)
Pancreatitis (without concrement)	11	(2.8)	5	(1.3)	16	(2.1)
Muscular-related pain	9	(2.3)	5	(1.3)	14	(1.8)
Ileus/subileus	3	(0.8)	10	(2.6)	13	(1.7)
Constipation/fecaloma	6	(1.5)	4	(1.0)	10	(1.3)
Hydronephrosis (without uretary concrement)	4	(1.0)	3	(0.8)	7	(0.9)
Abscess	4	(1.0)	3	(0.8)	7	(0.9)
Salpingitis	6	(1.5)	1	(0.3)	7	(0.9)
Hernia	5	(1.3)	1	(0.3)	6	(0.8)
Colitis/terminal ileitis	0	(0.0)	5	(1.3)	5	(0.6)
Duodenal ulcer without perforation	2	(0.5)	0	(0.0)	2	(0.3)
Perforated duodenal ulcer	1	(0.3)	1	(0.3)	2	(0.3)
Abdominal Aortic Aneurysm	0	(0.0)	1	(0.3)	1	(0.1)
Other diagnosis	11	(2.9)	16	(4.1)	27	(3.4)

5.4. DIAGNOSTIC ACCURACY (PAPER 1)

The proportion of correct primary diagnoses was 7.9 percentage points higher in the group undergoing US compared with the control group, 64.7% compared with 56.8% (p=0.027, 95% confidence interval for difference 0.01-0.15). Data is shown in Table 5. Mean time between first and second diagnosis was 23 minutes.

5.5. CONTRIBUTION OF ULTRASOUND WHEN MAKING A DIAGNOSIS (PAPER 1)

US showed helpful for making or confirming a specific diagnosis in 24.1%. In 22.3% of the patients NSAP was confirmed by a normal US and in 2.9 % US findings contributed to making a correct diagnosis, but the correct diagnosis was set after leaving the ED. This makes a figure of 49.3% where US proved helpful for diagnosing. In 10.2% of the patients US was considered misleading. Of these cases, defined as misleading, 3 patients had a specified correct diagnosis changed into an incorrect one, in 8 patients a correct diagnosis of NSAP was changed into an incorrect diagnosis, in 7 patients a specified incorrect diagnosis was confirmed by US and in 20 patients US was misleading in another way. In 40.0% of the cases, US had no influence on making a diagnosis, and in two patients data were missing. Data is shown in Table 4.

Table 4. Contribution of ultrasound in diagnosing patients (n = 382)

	N	**(%)**
Leads to or confirms the correct diagnosis	92	(24.1)
Misleading (leads to or confirms an incorrect diagnosis)	39	(10.2)
No influence on diagnosing the patient	153	(40.0)
Confirms non-specific abdominal pain by normal findings	85	(22.3)
US contributes when further diagnoses are made but incorrect diagnosis set	11	(2.9)
Missing data	2	(0.5)
Total	382	(100.0)

5.6. FURTHER MANAGEMENT (PAPER 2)

The proportion of admitted patients was significantly lower in the group receiving bedside ultrasound (43%/50%, p=0.04) (Table 2). The number of ultrasound examinations ordered from the radiological department was significantly lower in the group receiving bedside ultrasound (9%/28%, p<0.001). There was no difference found between the groups regarding number of ordered Computer Tomography (CT) scans or other examinations.The proportion of admitted patients undergoing surgery was the same in both comparison groups (34%/39%). Data for complementary examinations and admission are shown in Table 5.

The proportion of patients admitted to hospital needing surgery who were referred for surgery while still at the ED was significantly higher in the ultrasound group (34%/16%, p=0.013).

Among the patients admitted to hospital 14% in the US group and 31% in the control group went through a US examination at the radiological department (p<0.001). 59% in the US group went through any examination at all while admitted compared to 75% in the control group (p=0.001). CT scans were ordered in 14% in each group. (These data are not reported in any Paper).

Table 5. Diagnostic accuracy, complementary examinations and admission

	Not ultrasound n = 391* n (%)	**Ultrasound n = 392* n (%)**	**Percentage point difference**	**95% CI for difference**	**p-value**
Ultrasound at radiology department	107 (27.5)	34 (8.7)	18.8	0.135 - 0.240	<0.001
Computer Tomography	39 (10.0)	31 (7.9)	2.1	0.194 - 0.061	0.311
Abdominal X-ray	21 (5.4)	23 (5.9)	-0.5	-0.037 - 0.027	0.763
Urography	30 (7.7)	35 (9.0)	-1.3	-0.051 - 0.026	0.524
Consultation	52 (13.3)	50 (12.8)	0.5	-0.042 - 0.053	0.821
Other examinations	71(18,2)	59 (15,1)	3.1	-0.021 - 0.084	0.243
No further examination	119 (30.6)	191 (49.0)	-18.4	-0.251 - -0.116	<0.001
Admission to hospital	196 (50.1)	168 (42.9)	7.2	0.003 – 0.142	0.041
Admission for surgery	75 (39.0)	58 (34.5)	4.5	-0.056 - 0.145	0.382
	Not ultrasound n = 380 n (%)	**Ultrasound n = 382 n (%)**	**Percentage point difference**	**95% CI For difference**	**p-value**
Diagnostic accuracy	216 (56.8)	247 (64.7)	-7.9	-0.01- -0.15	0.027

* Partially missing data from two patients in each group for all variables except "Admission to hospital", "Admission to surgery" and "Decision about surgery" where there were no missing values.

5.7. TIME CONSUMPTION (PAPER 2)

The mean time spent in the ED was similar in both groups: 4 hours and 22 minutes in the ultrasound group, and 4 hours and 38 minutes in the group not receiving ultrasound. For the patients admitted to hospital the groups were similar regarding duration of hospital stay (Median 3.5 days and mean 4.3 days in the US group. Median 3.0 days and mean 5.4 days in the control group).

5.8. PATIENT SATISFACTION (PAPER 3)

The self-rated patient satisfaction when leaving the ED was slightly, but significantly, higher in the US group (Median 9.5/9.2, p=0.005). At the six-week follow-up the patient satisfaction measured was equal in both groups (Median 8 in both groups).

5.9. SHORT-TERM FOLLOW-UP (PAPER 3)

31% of the patients in the US group had completed or planned complementary examinations after the ED visit compared to 42% in the control group (p=0.004). When analyzing examinations separately there was only a significant difference in US examinations and colonoscopies with a higher frequency of these examinations in the control group (US examinations 4% versus 8%, p=0.01 and colonoscopies 6% versus 11%, p=0.013). The proportion of patients reporting that they six weeks after the visit felt totally or partly well was equal between the groups (82% versus 81%). Data for short-term follow-up is shown in Table 6.

There was no significant difference between the groups regarding mortality within six weeks. Three patients were dead in the US group and none in the control group. The deaths were not associated with US: an 80-year-old woman that was admitted with acute leukemia, transferred to another hospital and died there two days later; a 68-year-old woman who died of metastatic lung carcinoma three weeks later; and a 93-year-old woman who died of acute myocardial infarction at a geriatric clinic five days after the ED visit.

Table 6. Health condition and health care consumption at six-week follow-up

	Ultrasound n= 360 n(%)	Not ultrasound n=359 n(%)	p-value
Further examinations (performed or planned)*	111(31.1)	146(41.4)	0.004
Planned	40(11.2)	60(17.0)	
Completed	71(19.9)	86(24.4)	
Not planned	246(68.9)	206(58.6)	
Computer tomography	12(3.4)	12(3.4)	0.989
Ultrasound	13(3.7)	29(8.2)	0.010
Laboratory tests	3(0.8)	1(0.3)	0.319
Gastroscopy	16(4.5)	15(4.2)	0.867
Colonoscopy	20(5.6)	38(10.7)	0.013
Urography	19(5.3)	23(6.5)	0.512
Other examinations	46(12.9)	58(16.4)	0.192
Doctor consultation	88(24.7)	77(21.6)	0.329
Health condition**			0.984
totally well	218(60.7)	215 (59.9)	
Partly well	78(21.7)	77(21.4)	
Not well	59(16.4)	63(17.5)	
Can not tell	4(1.1)	4(1.1)	

*Missing data in 3 patients in US group and 7 patients in not US group
** Missing data in 1 patient in US group

5.10. LONG-TERM FOLLOW-UP (PAPER 3)

There was no significant difference between the groups concerning health care consumption or mortality during two years after the ED visit Median outpatient admissions were 5 admissions in US group and 7 in not US group. Median outpatient radiological examinations were 1 examination in both groups. Median inpatient admissions were 0 in both groups and mean was 1.1 in both groups. Data is shown in table 7.

After two years 4% of the patients were dead in the US group and 6% in the control group.

Table 7. Health care consumption at two-year follow-up

	Ultrasound (n=388*)			**Not ultrasound (n=383**)**			
	Median	**Mean**	**SD**	**Median**	**Mean**	**SD**	**p-value**
Outpatient admissions	5.0	13.8	31.6	7.0	13.5	19.9	0.220
Outpatient radiological examinations	1.0	1.4	2.0	1.0	1.5	2.1	0.294
Outpatient endoscopies	0.0	0.2	0.5	0.0	0.2	0.5	0.108
Inpatient admissions	0.0	1.1	2.3	0.0	1.1	2.2	0.774
Total amount of hospital days	0.0	6.0	26.3	0.0	8.7	35.6	0.733

*Missing data for 3 patients
**Missing data for 6 patients

5.11. SUBGROUP ANALYSES (PAPER 4)

Increased diagnostic accuracy, if examined with bedside US, was seen in the patients with Body Mass Index >25 (67% versus 54%, p=0.02), elevated C-reactive protein (63% versus 52%,p=0.047), peritonitis (74% versus 54%), age 30-59 years (68% versus 58%, p=0.042) and/or upper right abdominal pain (72% versus 52%, p=0.045).

Decreased need of US examination at the radiological department was seen in all groups except for the patients with a first diagnosis of appendicitis, where the numbers were equal between the groups.

Request for any other additional examination was lower in the US group in all groups except for the patients with symptoms of or first diagnosis of appendicitis, where the numbers were equal.

In the group of patients with first diagnosis Non Specific Abdominal Pain (NSAP) fewer patients were admitted to in-patient care in the US group (31% versus 45%, p=0.007).

Among patients with peritonitis, 23 patients in the ultrasound group and 26 in the control group were admitted for surgery. Of these patients 61 % in the ultrasound group and 19 % in the control group were admitted for surgery with the decision being taken while still at the ED, p= 0.003.

In Table 8 we summarize the benefits of bedside US in the different evaluated subgroups.

Table 8. Benefits of US examinations in different subgroups**.**

	Diagnostic Accuracy	**Admission Frequency**	**Requested US at radiological department**	**Requested CT at radiological department**	**Any other examination Requested**
BMI <25			X		X
BMI >=25	X		X	X	X
CRP<10			X		X
CRP>=10	X		X		X
Lower abdominal symptoms			X		
Upper abdominal symptoms	X		X		X
Gallbladder disease			X		X
Appendicitis					
NSAP		X	X		X
Peritonitis	X		X		X
Age <30			X		X
Age 30-59	X		X	X	X
Age >=60			X		

(X= statistically significant benefits,)

6. DISCUSSION

6.1. INTERPRETATION OF RESULTS

6.1.1. Key findings

We have demonstrated several benefits of bedside US performed by the surgeon for patients admitted to the ED for abdominal pain: increased diagnostic accuracy, decreased admission frequency, less need of further examinations, higher patient satisfaction at the ED and an earlier decision about surgery when required. We have not seen any negative effects of the method on a short- or long-term basis.

Time spent in the ED and in hospital, if admitted, did not differ between the groups. We have also found the method of bedside US worth using in different subgroups of patients, for example we have found it very useful for overweight patients, a group that is usually believed not to benefit from US to such a high extent because the procedure is considered difficult to perform[6, 152]. In our study we found it difficult to perform but still reliable and of especially great benefit for these patients. Patients with elevated CRP, indicating a more serious condition, achieved a higher diagnostic accuracy with bedside US. Among patients with normal CRP, however, the groups were equal regarding diagnostic accuracy. In patients with first diagnosis of Non Specific Abdominal Pain (NSAP), admission frequency was significantly lower.

Bedside US made it easier for the surgeon to decide about surgery at an earlier stage: decision about surgery, if required, was taken at the ED more often in the US group (18 percentage points difference). If the patient presented with peritonitis there was an even higher difference between the groups: 42 percentage points. This, we believe, is a very important finding, because an earlier decision about surgery might save both time and suffering for the patients.

6.1.2. Possible mechanisms and explanations

The benefits of bedside US, performed by surgeons or emergency physician, for diagnostic accuracy and management of the patient with abdominal pain has already been demonstrated in several studies[7-9, 33, 69, 73, 74, 76, 77, 153], even though this is the first randomized study evaluating the effect of surgeon-performed US. As mentioned earlier there are several studies showing an acceptable validity for surgeon-performed US when compared to radiologist-performed US[9, 46, 67-73]. Therefore we believe that the main explanation for our results is actually the complementary US examination performed, which is valid and reliable for the diagnosis and further management of the patient.

Another possible additional explanation for our results regarding the benefits of US might be that the surgeon actually performed an additional examination of the patient in the US group. After randomization the surgeon went back to the patient and performed the US examination, and probably also talked to the patient again, and in some cases maybe even palpated the abdomen again. This might be part of the explanation for the demonstrated benefits. Anyway, we wanted to examine the real situation and this will probably be the real situation, because the surgeon in most cases will probably examine the patient first, before deciding to perform US or not.

The decision to proceed to surgery, if required, was taken at an earlier point in the US group. This might reflect a higher degree of security in the diagnosis after performed US, thereby facilitating the decision to perform surgery. The results of fewer admissions in the US group might also be due to a higher degree of security in the diagnosis after performed US. The patient might also feel more secure in the diagnosis and more ready to be discharged from the ED than if no examination had been performed. This feeling of confidence might be especially marked in the group of patients with first diagnosis of NSAP, a group of patients where different diagnoses are included, from self-limiting conditions to life-threatening conditions. Since there was a 14 percentage points difference in admission frequency in this group, and still fewer additional examinations, we believe that the US examination performed made both the surgeon and the patient more confident about sending the patient home with the knowledge that the condition was not serious.

If emergency radiological examinations are to be performed the patient is often admitted to the hospital, and this might of course also be an explanation for the decrease in admissions in the US group. This can also be an explanation for the results of equal time spent at ED between the groups. Most patients needing a complementary examination are either admitted for an inpatient examination or referred for an outpatient examination at a later date.

The decreased need of further examinations in the US group shows that the surgeon had confidence in the performed US, not needing to refer the patient to the radiological department to the same extent as if US had not been performed at the ED.
Factors shown to be related to patient satisfaction at the ED include number of treatments in the ED, provider-patient interactions and explanation of causes of problem and tests[154 155, 156]. A possible explanation for our results with higher satisfaction for the US group at the ED could though be the additional examination performed and possibly a better explanation of the patient's problem with the help of the US examination results. One earlier study assessing patient satisfaction after different radiological examinations at the radiological department found that the patients recorded dissatisfaction with the information they received, probably because they had to wait for information from the referral physician[157]. Consequently the immediate information given to the patient could be an explanation for the higher patient satisfaction shown at the ED in our study.

US was shown to be especially helpful for diagnostic purposes in the group of overweight patients. This might be due to the fact that this group is known to be more difficult to examine physically and subsequently an additional US examination might be more beneficial as a complement to a palpation of the abdomen, which is difficult to interpret[127, 158].

We believe our US training is a key factor in the results showing several benefits of surgeon-performed US. The surgeon went through a training program of four weeks in cooperation with the radiological department and, even if not validated in this study, the training probably made the surgeon more secure in interpreting the US findings than if he or she had not had such a solid training.

6.1.3. Other published studies

Systematic reviews have been performed evaluating US as a diagnostic tool for appendicitis and biliary disease. These showed US to be superior to CT scan for imaging biliary disease and CT scan superior to US for imaging of appendicitis, however US showed quite high sensitivity of 78 - 86% and a specificity of 81 - 83% for diagnosing appendicitis[116-118, 159]. Systematic reviews evaluating imaging of diverticulitis have shown results for US in line with those for CT scan, with an even higher degree of scientific evidence for US scan than for CT scan[137, 142, 160]. Consequently there is enough evidence indicating the value of US for abdominal pain imaging.

These systematic reviews are however based on US performed by radiologists. There is a review evaluating the use of surgeon-performed US in different modalities that maintain that surgeons, with proper training, can accurately perform and interpret focused US examinations and use the results in the management of patients[33]. The use of surgeon-performed US in the evaluation of abdominal pain is just a small part of the review and no randomized studies have been performed regarding the issue[33]. For evaluation of surgeon-performed US of abdominal pain we thus have to rely on the relatively few available, non-randomized, studies performed.

There is one earlier randomized study published, evaluating the role of immediate US for the acute abdomen. However, in this study radiologists performed the US examination. The results of this study is in line with ours, showing an earlier establishment of a final diagnosis but without influence on the duration of inpatient care[161].

Nevertheless, there are studies supporting surgeon-performed US as a diagnostic tool when a patient presents with abdominal pain[9, 67, 69, 151, 162-166] and there are also several studies performed supporting the role of surgeon- or emergency physician-performed US in the trauma situation[25, 30, 78, 167-169]. We however believe there is enough support in the literature for recommending the use of surgeon-performed US for abdominal pain, on the basis of the additional evidence shown in this randomized study.

6.1.4. Limitations

6.1.4.1. Study design

All reports are based on the same randomized study, reporting six-week and two-year follow-up in the third study and analyses of subgroups in the fourth study. It was not possible to blind the study, because the aim was to measure diagnostic accuracy and further management as well as patient satisfaction based on the performed US examination.

Selection bias due to inclusion patterns of patients is a possibility, due to different timing of inclusion and because some surgeons included more patients than others. The diagnostic panorama at night is not the same as in daytime. The surgeons were supposed to include patients in the study during the day, but since there were far fewer patients in the morning the surgeon often started later in the day and worked until evening, and sometimes also included patients at night or during weekends. Some surgeons also dealt with more patients than others and if these surgeons included patients differently, despite of the strict inclusion criteria, some selection bias may be introduced.

A potential confounding factor, possibly influencing the results, is referral pattern with 24% being referred from other physicians in the US group and 39% in the control group. We do not believe the diagnostic accuracy by clinical examination to be lower in the referred group but there might be a higher degree of admission if referred to the hospital and thereby the result of fewer admissions in the US group might partly be due to confounding bias. The same could be discussed regarding the slightly higher CRP-level in the control group, with CRP-level also being a confounder; the diagnostic accuracy by clinical examination would hardly be lower with elevated CRP, but possibly the admission frequency would be.

Another difference between the groups was regarding final diagnosis, with more patients given the diagnosis diverticulitis as their final diagnosis in the control group. We know that the diagnostic accuracy with only clinical examination is quite high, although it varies in different studies[4, 151, 170, 171], and the difference would however not affect the result of higher diagnostic accuracy in the US group, but possibly marginally affect the results of fewer admissions in the US group.

However, the differences between the groups regarding these potential confounding factors are small and since this is a randomized study with a large sample size we do not believe that they will influence the conclusion.

6.1.4.2. Follow-up

A study nurse called all the patients after four to six weeks. The exact time for following up could of course differ between patients. Some patients were called many times before they were reached and the follow-up time therefore differs between patients, even though we have called it six weeks because the intention of the follow-up was four to six weeks. There might be a recall bias due to a different follow-up time. The memory and satisfaction of the US examination might differ between patients depending on follow-up time.

Since the questions about health condition, health care consumption and self-rated satisfaction were asked by the study nurse personally there might be an observer bias concerning the answers. Since the interview was structured, following a specific form, and the nurse did not know which group the patient belonged to, the risk for this is less. There might also be a response bias if the patients receiving US gave a more positive answer to the questions, since they knew the aim of the study and were not blinded regarding which intervention group they belonged to.

6.1.4.3. Outcomes, definition and measurement

The primary outcome, diagnostic accuracy, is based on a comparison between the diagnosis set at the ED with or without US and the final diagnosis set by a senior surgeon, defined as the correct diagnosis. This final diagnosis is set on the basis of the medical files, which might be biased. Sometimes the surgeon has set a study diagnosis at the ED but the medical file might be written by the emergency physician. A possible information bias might then be introduced if the emergency physician does not believe in the diagnosis set by the surgeon after performed US, thinking for example that US is of no value, and therefore sets another diagnosis and reports results supporting this other diagnosis. The senior surgeon then sets a biased diagnosis, based on the information given in the files.

Even though the senior surgeon was not told which group the patients belonged to it was mentioned in the medical files and the senior surgeon might be biased by this information. Of course the senior surgeon was not informed about the diagnosis set by the study surgeon (this diagnosis was put in a sealed envelope) but if the study surgeon wrote the files and set a preliminary diagnosis in the files it would most probably be the diagnosis set in the study and the senior surgeon might set that diagnosis even if other results pointed towards another diagnosis, with a subconscious desire to obtain results supporting US. One way of dealing with this observer bias when designing the study would have been to let a senior surgeon, totally aware of the design and aim of the study, set all the final diagnoses. But even then the surgeon might have been biased by the information in the medical files. Furthermore, to not mention the performed US examination in the medical file would interfere with the aim of the study, and this possible bias was consequently unavoidable.

If the patient was admitted, the final diagnosis would be based on more information and of course more reliable even if the submission diagnosis might also be biased: the doctor sending the patient home, setting the submission diagnosis, might even be the same person as the study doctor setting the ED diagnosis. This will however happen very seldom or never, because the study surgeon worked exclusively at the ED for four weeks when participating in the study.

Another possible bias would be if the study surgeon sets more unsecure diagnoses before randomization in order to make it easier to set a better diagnosis if US is performed, subconsciously wanting to show US helpful in setting diagnosis

The outcome "US contributing to diagnosing" was set based on whether the diagnosis was changed or confirmed after performed US. When reading through the literature the description of misleading in setting diagnosis is a bit confusing[150, 161, 172, 173]. We defined an examination as misleading when US contributed to an incorrect diagnosis by confirming an incorrect diagnosis or setting an incorrect diagnosis. We have not checked whether the US examination was correct or not compared to a radiologist-performed US, which is another definition of misleading; we chose only to look at the contribution to a correct ED diagnosis as compared to the final diagnosis defined as the correct diagnosis.

The outcome of admission or not is an outcome easy to measure and should have been correctly set in all patients without any bias.

The outcome ordered examinations is an outcome that might have been misclassified. The outcome we have measured is what is noted in the report written by the study surgeon in the study protocol of ordered examinations. In reality the US ordered could have been changed to a CT scan at the radiological department or even earlier at the ED if the study surgeon for example asked the emergency physician to order the US. The emergency physician might believe it to be more appropriate to order a CT scan because US had been performed and might do so without telling the study surgeon.

The study surgeon might write that no further examinations were to be performed but the emergency physician might anyway have ordered a US at the radiological department, feeling insecure of the US performed by the study surgeon. The outcome of less further examinations in the US group would then be misclassified with a false low amount, a differential misclassification. Since the ordered examinations could also be performed as outpatient examinations in other hospitals, it was not possible to check the reliability of the performed examination. However, when we checked the examinations performed in the event of the patient being admitted, the results of fewer examinations in the US group reported in the study remained, as well as at the follow-up.

There might be a response bias regarding patient satisfaction and health condition. At the ED the data of patient satisfaction was reported anonymously and would therefore be more valid. At the six-week follow-up they had to tell the study nurse their satisfaction rate directly, as well as their self-assessed health condition, and it might therefore be a higher risk of introduced response bias.

Regarding the two-year follow-up, the outcome of health care consumption is very inexactly measured, because many different contacts were registered for the patients. In some cases visits could even have been registered twice or even three times. In these cases the nurse only registered one visit. The reported outpatient visits were consequently impossible to measure correctly. However, the data were the best possible achieved and the examinations would have been measured equally in both groups, because the study nurse was blinded as regards which group the patient belonged to, so any possible misclassification would be classified as non-differential misclassification and would consequently not influence the conclusion. The measurement of inpatient visits should have been correctly measured as well as mortality.

In Paper 4 one limitation is that these examinations are subgroup analyses, which reduces the statistical power and the detected differences yield lower evidence than when the results are generalized. Anyway, one strength is that all the data were collected prospectively and the large number of patients included makes the power in the subgroup comparisons acceptable.

Another strength regarding the whole study is of course the study design, being a randomized study. The number of included patients is high and the follow-up of the patients is also nearly complete, both on a short- and a long-term basis.

6.2. CLINICAL AND RESEARCH IMPLICATIONS

6.2.1. Clinical implication of the findings

This is the first randomized study showing that surgeon-performed US increases diagnostic accuracy and is helpful in the management of patients with abdominal pain. Our findings will hopefully make surgeons more motivated to learn US and implement the method as a routine at the ED.

The findings of decreased admission frequency is important, indicating potential to save both money, hospital beds and time for the patient and the hospital staff.
The decreased need for US examinations at the radiological department will save time for the radiologists, enabling ordered US examinations to be performed within a shorter time.

One might argue that bedside US examinations take time. A total of 23 minutes elapsed between the first and second diagnoses in the US group. Some of this time was probably due to administrative tasks, filling in the reports etc. The actual time for performing a US scan at the ED is estimated at ten minutes for emergency physician-performed US[174] and we do not believe this time to be longer when surgeons perform US. Taking into account the benefits of the examination we think this time is well worth spending on the scanning.

We also regard our finding of increased diagnostic accuracy in overweight patients as important, though these patients are usually believed not to benefit from US to such a high extent because US is considered difficult to perform[6, 137, 152, 175]. Since CT scan is also considered more difficult to interpret in obese patients[175], and overweight patients often are more difficult to examine physically by palpation[127, 158] , this finding of US contributing to diagnosing might make the physician more motivated to perform a US examination, thereby reaching an earlier diagnosis and facilitating better management of the patient.

The result of higher diagnostic accuracy in the group of patients with elevated CRP is also an important finding, because elevated CRP indicates a more serious condition with a higher risk of required surgical intervention[8, 176].

Bedside US made it easier for the surgeon to decide about surgery at an earlier stage: decision about surgery, if required, was taken at the ED more often in the US group (18 percentage points difference). If the patient presented with peritonitis there was an even greater difference between the groups: 42 percentage points. This, we believe, is a very important finding, since an earlier decision about surgery might save both time and suffering for the patients.

6.2.2. Research implications and future challenges

Even if this is the first randomized study performed proving several benefits of surgeon-performed US for evaluation of the acute abdomen we believe that our results, in concordance with results from other performed studies[8, 9, 73, 151, 163, 165, 166], are sufficient proof for recommending implementation of the method at the ED.

What is not adequately evaluated is the effect in different subgroups. Our study has shown effect in nearly all studied subgroups of specific patient factors. These results indicate that US is always to be used at the ED for abdominal pain. We think that this is not really time and cost-effective and request future studies evaluating this specific question.

The diagnostic groups were too small to achieve any great differences between the intervention groups in the subgroups. To establish the real effect of US in the subgroups with suspected appendicitis or gallbladder disease a randomized study with tighter inclusion criteria is warranted and of great interest.

A study evaluating the validity and benefits in management of the acute abdomen based on BMI level would also be of great value. A larger study, specifically evaluating the effect of US in overweight patients would have great impact on the use of US on overweight patients in clinical work, since there is an existing opinion among many sonographers that obesity hampers US examination[6, 152]. More research showing US to be of even higher value in this specific group of patients could make the method of bedside US on overweight patients a possible routine as a complement to physical examination of these patients, who are often difficult to examine.

The result showing earlier decision of surgery in patients with peritonitis is also of great interest and a study specifically studying this subject is warranted. Suggested outcomes could be time to surgery and days spent in hospital. Since the role of waiting time to surgery for perforation of an inflamed appendix is not clarified by recent research indicating that outpatient waiting time, but not inpatient waiting time impacts on perforation rate[177], such a study should include the incidence of perforation of an inflamed appendix as an outcome.

The effect of bedside US on admission frequency is also an issue that needs further evaluation. The decreased admission frequency was most pronounced in the diagnostic group of NSAP, a group of patients covering a diagnostic spectrum from life threatening diseases to self-limiting conditions. In our study we have checked for readmissions seven days after the ED visit and did not find any more readmissions in the US group. Neither did we find any indications of complications due to submission from ED at follow-up. Regarding this result of fewer readmissions without any side effects more studies are warranted because a decrease in admissions with the help of a quickly performed bedside US examination could be very cost effective in addition to the time saved for the patients.

A validation study of surgeon-performed US after the surgeon had undergone training at our hospital is also warranted. There is no standardized education model for surgeons in abdominal US accepted worldwide and since we plan to continue with our training model, and will probably expand it to other hospitals, a validation study is warranted. The US performed by the surgeon would in a study be compared to a radiologist-performed US firstly after the training and then after three months and one year.

6.3. GENERALISABILITY

6.3.1. Validity of the performed US in the study

The validity of the US compared to radiological examinations or surgical procedures is not examined in this study. Many studies have however been performed earlier showing a high accuracy of surgeon-performed US compared to radiological US in evaluation of the abdomen[9, 67, 69-73]. With our study design it was impossible to do a comparison of the surgeon-performed US with radiologist-performed US. Our aim in this study was to show the impact of surgeon-performed bedside US on diagnostic accuracy and management of the acute abdomen. By having another US performed at the radiological department the results of further management would not have been accurate and it would have been unethical to perform a radiological US without using the provided information for further management of the patient. The US examinations ordered in the US group were too few to make a comparison between surgeon-performed US and radiologist-performed US, and the group of patients where the surgeon ordered other examinations is anyway not representative for the US group, because these examinations were probably assessed as more difficult to perform. The results of validity would then not be valid anyway.

We know that US performance is operator-dependent[108] and this is of course also the case regarding the participating study surgeons. However, since there were nine surgeons participating we believe the results in our study to be valid for the actual future situation in our hospital as well as other hospitals, since the skills between surgeons performing US will always differ.

6.2.2. External validity

The study was performed in a large hospital with 100 000 visits a year at the ED. Reporting about the same distribution of diseases in our study as reported in other studies performed in the western world[4, 5, 74, 178, 179],the results of our study would be valid for most of the western world.

Mean BMI was 25 and might be different in many other countries which might influence the validity. Bedside US at the pediatric ED is used for many purposes but the research regarding abdominal pain is not assessed sufficiently for recommendation of bedside US as a routine in the evaluation of abdominal pain[180]. Only adults were included in our study and the results could not be directly transferred to be valid also for children.

There were nine experienced surgeons participating. This is not always the situation at the EDs, often there are less experienced physicians taking care of patients, a situation that might affect the generalization of the results. The results would nevertheless be valid for experienced surgeons using US at the ED, and probably also for experienced emergency physicians.

6.4. GENERAL INTERPRETATION

We have shown that the use of bedside US performed by the surgeon is beneficial for diagnosing and further management of patients with abdominal pain. We have also presented evidence for the beneficial use of US in the management of abdominal pain. As mentioned before we have found one earlier randomized study showing early US at the ED to be beneficial for diagnostic purpose of the patient with abdominal pain[161]. The reason for performing a randomized study to specifically evaluate diagnostic accuracy of surgeon-performed US in the management of the acute abdomen is that surgeon-performed US is not the same examination as radiologist-performed US. Radiologists have more experience in performing US, which in most cases naturally would make their examinations more reliable. The surgeons have by contrast more knowledge about the patient with abdominal pain at the ED. The physical examination is performed by the surgeon and the additional US examination is providing extra information. The decision about setting the preliminary diagnosis, deciding about further management, including eventual surgical procedure, is multifactorial with the result of the US examination being just a part of the panorama. To visualize the abdomen just after doing the palpation might help the surgeon more in decision making then just reading a report describing the results of an examination. We believe that the additional effect of the surgeon having the option of US closer to hand is of great importance.

Even though the results shown in this thesis suggest that US is beneficial in nearly all subgroups of abdominal pain we stop short of recommending US as a screening method for all patients with abdominal pain. We recommend it to be used as an additional tool in the management of the acute abdomen. The strongest argument for this is the fact that there is not enough evidence in the literature for the use of US on every patient seeking the ED for abdominal pain, without discrimination[181]. Maybe in the future, with more performed randomized studies for evaluation of the method, and physicians using handheld US as a routine in their clinical work, screening of all patients with abdominal pain will be a routine at the ED, but we still have some way to go before this is reality.

This thesis has shown, in line with other studies, that bedside US at the ED is a beneficial method for evaluation of the acute abdomen and we believe it will spread all over the world and become a routine at the ED. We also believe that surgeons will integrate US more and more in their daily work on hospital wards, outpatient clinics and operating theatres, as well as in the ED.

7. CONCLUSION

From the studies of which this thesis consists, the following conclusions could be drawn:

Examination of patients, admitted to the ED with abdominal pain, with surgeon-performed bedside US increases diagnostic accuracy.

Examination of patients, admitted to the ED with abdominal pain, with surgeon-performed bedside US decreases admission frequency, especially in the patient group with first diagnosis of Non Specific Abdominal Pain.

Examination of patients, admitted to the ED with abdominal pain, with surgeon-performed bedside US decreases the need to perform further examinations.

For patients requiring emergency surgery, the decision about surgery can be taken at an earlier stage if US is performed bedside by the surgeon, especially in patients with signs of peritonitis.

Health care consumption is decreased on a short-term basis if examined with bedside US but no effect on health care consumption is shown on a long-term basis.

There are several benefits (increased diagnostic accuracy and/or decreased admission frequency and/or decreased need of further examinations) of surgeon-performed US bedside for the acute abdomen in certain subgroups of patient factors, such as overweight, elevated CRP-level, signs of appendicitis or gallbladder disease, first diagnosis of gallbladder disease, first diagnosis of NSAP, peritonitis and age (different benefits in different age groups).

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9. SAMMANFATTNING PÅ SVENSKA

Ultraljud är en beprövat effektiv undersökningsmetod vid akuta buksmärtor. Vanligtvis utförs denna undersökning av radiologer i Sverige och många andra länder. Detta kan leda till väntetider samt undantar undersökande kirurg från möjligheten att själv få en visualisering av organ möjliga att undersöka med ultraljud som ett tillägg till sin fysikaliska undersökning av patienten. På senare år har det blivit mer och mer förekommande att kirurger själva undersöker patienterna med ultraljud. Utbildningar i metoden har startats och studier har gjorts men ingen tidigare randomiserad studie som utvärderar metoden har utförts.

Det övergripande målet med denna studie var att utvärdera effekten av att patienter som söker på akutmottagningen med buksmärtor undersöks av kirurg med ultraljud direkt på akutmottagningen

.

Samtliga delstudier baseras på en randomiserad studie omfattande 800 patienter (400 i varje randomiseringsgrupp) som sökt Södersjukhusets kirurgiska akutmottagning för buksmärtor mellan februari 2004 och juni 2005. Patienterna randomiserades till ultraljud utfört av kirurg som tillägg till standardiserad undersökning eller enbart standardiserad undersökning inkluderande standardiserad anamnesupptagning, kroppsundersökning samt blod- och urinprovstagning. Uppföljning har skett med telefonintervju har sex veckor efter akutbesöket samt registergranskning två år efter akutbesöket.

Inklusionskriterier för deltagande i studien var buksmärtor, fyllda 18 år samt okänd orsak till de aktuella buksmärtorna. Exklusionskriterier var graviditet, gravt alkohol- eller narkotikamissbruk, demens samt oförmåga att medverka vid undersökning och uppföljning.

I första delarbetet presenteras primärhypotesen för studien, i övriga delarbeten presenteras sekundärhypoteser.

9.1. DELARBETE 1

9.1.1. Hypotes

Att ultraljud utfört av kirurg när en patients söker för akuta buksmärtor kan öka andelen rätt ställda diagnoser på akutmottagningen.

9.1.2. Metod

Diagnos sattes av studieläkaren efter den standardiserade undersökningen och därefter randomiserades patienten till ultraljud utfört av kirurg eller inte. En andra akutdiagnos sattes i gruppen som undersökts med ultraljud. För ultraljudsgruppen räknades denna diagnos satt efter ultraljud (diagnos 2) som akutdiagnosen och för kontrollgruppen räknades den först ställda (och i denna grupp enda diagnosen, diagnos 1) som akutdiagnos. Akutdiagnosen jämfördes sex veckor senare med den slutliga diagnosen som ställts av en senior kirurg med ledning av befintliga journalanteckningar och undersökningsresultat Denna slutliga diagnos räknades som den korrekt ställda och huvudfrågeställningen, diagnosöverensstämmelsen mellan akutdiagnos och slutlig diagnos, beräknades.

Diagnoserna indelades också i grupper beroende på om de lett till korrekt diagnos, konfirmerat korrekt diagnos, konfirmerat diagnosen "buksmärtor UNS"(där ingen diagnos kunnat ställas) med ett normalfynd vid ultraljudsundersökningen, bidragit till diagnossättningen med fynd, vilselett diagnossättandet med att en tidigare ställd korrekt diagnos ändrades till felaktig eller att en felaktig satt diagnos konfimerades eller att ultraljudsundersökningen inte alls påverkade diagnossättandet.

9.1.3. Resultat

Andelen rätt ställda diagnoser var 64.7% i interventionsgruppen och 56:8% i kontrollgruppen. Denna skillnad var statistiskt signifikant, p= 0.03. Den del där korrekt diagnos ställdes eller konfirmerades med hjälp av ultraljud var 24.1, den del där diagnosen "Buksmärtor UNS" konfirmerades genom att ultraljud visade normalfynd var 22.5%, I 2.9% bidrog ultraljud till korrekt diagnos. I 10.2% betecknades undersökningen som missvisande då felaktig diagnos ställdes eller konfirmerades. I 39.8% var ultraljudsundersökningen utan betydelse och i 0.5% saknades data.

9.2. DELARBETE 2

9.2.1. Hypotes

Att ultraljud utfört av kirurg på akutmottagningen när en patient söker för buksmärtor kan leda till färre inläggningar, färre antal ytterligare undersökningar, kortare tidsåtgång på akutmottagning och vårdavdelning om inlagd, färre operationer och snabbare beslut om operation

9.2.2. Metod

Efter interventionen handlades patioenterna på samma vis i interventionsgruppen och kontrollgruppen. Ytterligare undersökningar inkl ultraljud på radiologiska kliniken om befogat, beställdes, pat lades in eller skickades hem, anmäldes till operation eller inte. Alla åtgärder antecknades i ett speciellt protokoll. Tidsangivelser hämtades från AKUSYS (akutmottagningens datoriserade tidsregistreringsprogram). Uppgifter om inlagda patienter hämtades från journlanteckningar och registrerades i ett specifikt protokoll.

9.2.3. Resultat

Antalet ytterligare undersökningar var signifikant högre i gruppen som inte undersöktes med ultraljud (18.8% skillnad, $p<0.001$). Inläggningsfrekvensen var lägre i ultraljudsgruppen (7.2% skillnad, $p=0.041$) och andelen patienter som anmäldes för operation direkt på akutmottagningen av dem som genomgick inneliggande akut operation var högre i ultraljudsgruppen (18.5% skillnad, $p=0.013$). Det fanns ingen påvisbar skillnad i antalet utförda operationer.Vi kunde inte påvisa någon skillnad i tidsåtgång på akutmottagningen eller i vårdtid för de patienter som lades in.

9.3. DELARBETE 3

9.3.1. Hypotes

Att ultraljud utfört av kirurg vid akuta buksmärtor kan leda till att patienttillfredsställelsen på akuten och vid uppföljning ökar och att vårdkonsumptionen på kort och lång sikt minskar. Vi har också undersökt hälsotillståndet vid sex veckors uppföljning samt mortalitet vid sex veckor respektive två år.

9.3.2. Metod

En tiogradig VAS-skala, där 0 representerade den lägsta tillfredsställelsen och 10 den högsta, lämnades till patienten efter avslutat akutbesök. Denna fylldes i med ett kryss på linjen och lämnades till personalen i ett slutet kuvert. Vid en standardiserad telefonuppföljning av en forskningssköterska sex veckor efter akutbesöket tillfrågades patienten om sin självupplevda tillfredsställelese av akutbesöket och ombades gradera denna på en tiogradig skala där 0 var absolut lägsta tillfredsställelse med besöket och 10 högsta. Vid telefonintervjun tillfrågades också patienten om sitt självupplevda hälsotillstånd. Alla patienterna följdes upp i GVR (Gemensamt Vårdregister) som är ett vårdregister gemensamt för Stockholms Läns Landsting där alla vårdkontakter registreras. Mortalitet hämtades från samma register och exakt dödsdatum togs fram ur personuppgiftsregistret (PU).

9.3.3. Resultat

Patienttillfredsställelsen var högre i ultraljudsgruppen på akutmottagningen men ingen skillnad sågs vid uppföljningen. Färre patienter hade genomförda eller planerade undersökningar vid sexveckorsuppföljningen i ultraljudsgruppen (30.8% jmf med 41.5%, p=0.004). Ingen skillnad sågs i två års hälsokonsumption. Ingen skillnad sågs mellan grupperna avseende mortalitet vid sex veckor eller två år.

9.4. DELARBETE 4

9.4.1. Hypotes

Att andelen rätt ställda diagnoser är högre, beställlda ytterligare undersökningar lägre och inläggningsfrekvensen lägre i specifika subgrupper av patienter om ultraljud utförts av kirurg, samt att operationsbeslut kan tas snabbare med hjälp av ultraljud utfört av kirurg hos patienter med bukhinneinflammation och behov av operation.

9.4.2. Metod

Subgruppsanalyser är utförda på patientgruppen. Patienterna delades in i subgrupper beroende på Body Mass Index (BMI), värde av C-reaktivt protein (CRP), ålder, symptom tydande på blindtarmsinflammation, gallblåsesjukdom eller bukhinneinflammation samt efter första preliminärdiagnos satt på akutmottagningen (blindtarmsinflammation, gallblåsesjukdom eller Buksmärta UNS). Utfall mättes i form av andel rätt ställda diagnoser, antal beställda ultraljudsundersökningar, antal beställda datortomografiundersökningar, antal ytterligare undersökningar samt inläggningsfrekvens.

9.4.3. Resultat

Denna studie visade att ultraljud utfört av kirurg har olika effekt i olika subgrupper. Ökad andel rätt ställda diagnoser visades hos patienter med BMI>25, förhöjt CRP, tecken på bukhinneinflammation och/eller högersidig övre buksmärta. Andra vinster i form av minskat antal beställda ytterligare undersökningar och/eller minskad inläggningsfrekvens sågs i alla subgrupper förutom hos patienterna som fått preliminärdiagnosen blindtarmsinflammation innan randomisering, där inga skillnader påvisades mellan grupperna. Största skillnaden i inläggningsfrekvens påvisades hos patienter som fått första diagnosen Buksmärtor UNS, d v s en grupp av patienter med oklar diagnos som både kan innefatta svåra sjukdomstillstånd men också ofarliga självläkande tillstånd. I gruppen med tecken till bukhinneinflammation anmäldes större andel patienter med operationsbehov för operation redan på akutmottagningen (60.9% i ultraljudsgruppen och 19.2% i icke ultraljudsgruppen, p=0.003).

9.5. SLUTSATS

Ultraljud utfört av kirurg när en patient söker akutmottagningen med buksmärtor kan

- öka andelen rätt ställda diagnoser. Denna effekt visade sig vara mest uttalad i gruppen överviktiga patienter samt hos patienter med förhöjt CRP-värde, patienter med bukhinneinflammation och patienter med symptom tydande på gallvägssjukdom.
- minska inläggningsfrekvensen. Denna effekt var mest uttalad i patienter med oklar diagnos, Buksmärtor UNS.
- minska behovet av ytterligare undersökningar beställda vid akutbesöket samt vid sex veckors uppföljning.
- leda till ett tidigare beslut om operation. Denna effekt var mest uttalad i patienter med bukhinneinflammation, ett tecken på allvarlig sjukdom.

Inga skillnader har kunnat påvisas beträffande hälsokonsumption under två år efter akutbesöket.

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