CLINICAL APPLICATION OF EVIDENCE-BASED SURGERY: THE ROLE OF AUDITS IN SURGICAL PRACTICE

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Thesis is submitted in total fulfillment of the requirements for the degree of Doctor of Medicine

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Declaration

The work contained within this thesis has not been previously submitted for a degree or diploma at any other tertiary institution. To the best of my knowledge and belief, the thesis contains no material previously published or written by another person except where due reference is made. The thesis is less than 100,000 words in length, exclusive of tables, maps, bibliographies and appendices.

David TW Chiang

Signed: ………………………… Date: …………………………
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Abbreviations Used In This Thesis

ASM – Annual Scientific Meeting
EBHC – Evidence-Based Health Care
EBM – Evidence-Based Medicine
EBS – Evidence-Based Surgery
ICU – Intensive Care Unit
HDU – High Dependency Unit
NCEPOD - The National Confidential Enquiry into Peri-Operative Deaths

RACS – Royal Australasian College of Surgeons

RCT – Randomized Controlled Trial
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Publications

Published Articles


3. Chiang, D. T., Bohmer, R., *Laparoscopic inguinal hernia repair with totally extra-peritoneal approach, but without disposable instruments – Saving the*

5. Chiang, D. T., Tan, E. I., Birks, D., 'To have...or not to have'. Should computed tomography and ultrasonography be implemented as a routine work-up for patients with suspected acute appendicitis in a regional hospital? Ann R Coll Surg Engl, 2008, 90,1, Jan., p17-21


Published Abstracts


4. Laparoscopic inguinal hernia repair with totally extra-peritoneal approach: Cutting the cost, ANZ Journal of Surgery; 2005, Volume 75. May, Supplement1, A 63

5. “To have… or not to have…” Should CT and U/S scan be implemented as a routine work-up for patients with suspected acute appendicitis in a regional hospital? ANZ Journal of Surgery, Volume 76, May, 2006, Supplement 1, A70

Conference Presentations

All six papers in this study addressed individual clinical problems by conducting surgical audits. Data from these papers have been presented for peer reviews at state, national, and international conventions and published in surgical journals. Copies, where available have been included as an appendix of this thesis.

The paper on Management of mild acute gallstone pancreatitis – *So the story continues*, has been presented at Marshall Surgical Symposium, Victorian State Annual Scientific Meeting, and Annual Scientific Congress (ASC) for peers review, and won the best clinical paper presented in Surgical Education Section, Perth, 2005. The abstract was published at *ANZ J of Surg.*, May (suppl.), 2005. The paper was accepted for publication by The Annals.

The paper, Comparative study on acute pancreatitis, was presented at Hepatobiliary Surgical Meeting of Victoria, 2002 and ASC, Brisbane, Australia, in 2003 for peers review. The abstract was published in ANZ J Surg 2003, May, Volume 73, A64 and original paper was published in ANZ J Surg, 2004. 74(4): 218-21.

The paper, “To have… or not to have…” Should CT and U/S scan be implemented as a routine work-up for patients with suspected acute appendicitis in a regional hospital? was presented at ASC (RACS), Sydney, 2006 for peers review. The original paper has been published in the Annals.

The paper, Laparoscopic inguinal hernia repair with totally extra-peritoneal approach: Cutting the cost, was presented at ASC (RACS), 2005 for peers review, and published at *Surgical Practice*; November, 2006; Volume 10, p.154-8.

The paper, Guide wire-assisted urethral dilatation for urethral strictures in pediatric urology, was presented at the Australasian and Pacific Paediatric Surgical Meeting, Sydney, Australia, Victorian State Urology Meeting, and Urological Society of Australasia ASC, Queenstown at New Zealand. The original paper was published in *J of Pediatric Surgery, International*, Volume 38, 12, 1790-92.
Hypothesis

Audits would not influence the current surgical practice.

Three aspects of surgical practice were selected to examine the null hypothesis.
1. Quality care assurance
2. Cost-effective utilization of health-care resources
3. Validation of a surgical technique

Abstract

Evidence-Based Medicine (EBM) is the integration of clinical practice with research evidence. The development aims to respond to the limitations of traditional expert recommendations as a guide to clinical practice. It has become a paradigm shift in the way clinicians learn and practice medicine [1-3].

Audit has been recognized as a form of EBM. Although the basic form has been practiced by some great surgeons since last century, often surgical practice has been based on ‘the tradition’. The universal acceptance and practice of audits in surgery is only recent [4-6].

The aim of the project was to conduct audits for current surgical practice, and observe whether the evidence influence its practice. To achieve the aim, the thesis consisted of six studies, which were designed to investigate three aspects of surgical practice, including quality care assurance, cost-effectiveness of healthcare resources in surgical practice, and validation of a new surgical technique.

1. Management of mild acute gallstone pancreatitis – So the story continues. This study included both retrospective and prospective audits that analyzed the performance at the local hospitals in the management of gallstone acute pancreatitis. The retrospective audit found that there were insufficient gallstone eradication treatments performed, according to the recommended guideline on management
of gallstone pancreatitis. Subsequent changes in the hospital protocol were implemented to improve the patient care. A prospective follow-up was then conducted to show the patient’s outcome, and concluded that timely gallstone eradication treatment was essential for optimal management of gallstone pancreatitis. Audits improved the management of acute gallstone pancreatitis and ensure quality of patient care.

2. **Comparative study on acute pancreatitis.** As a previous English audit study by Dube et al. showed, a poor compliance to the evidence-based guidelines could result in unacceptable morbidity and mortality for patients with acute pancreatitis, and urged clinicians to comply closely with the recommended guidelines for management of this condition [7]. This study aimed to investigate that if local hospitals complied closely with the international guidelines, the patient outcome would also result in the recommended standard. This study audited the management of patients with acute pancreatitis at a tertiary referral center and major regional center in Australia. This paper aimed to investigate the quality of patient care by critically analyzing local practice and compared with the recommended standards. The data indicated that the local hospitals had good compliance on most of the guidelines and the standard of patient’s outcome was within the recommendation.

   a. Specifically though, the guideline on severity stratification was not closely followed by either hospital, there was no mismanagement of patient as the guideline might suggest otherwise. The data concluded that the guideline on severity stratification should be only regarded as a reference. Prudent clinical judgment was still indispensable.

3. “To have..., or not to have...” – **Should CT and/or Ultrasound be implemented as a routine work-up for patients with suspected acute appendicitis in a regional hospital?** Delayed surgery, representation to emergency department, and prolonged hospitalization from suspected acute appendicitis could incur a huge cost of the healthcare resource. Routine medical imaging has been
advocated to assist clinicians making timely diagnosis and prevent complications from delayed treatment. This audit study aimed to investigate the need of implement a routine medical imaging protocol for this condition to improve the utilization of healthcare resource at a regional hospital.

a. The first part of the study was to audit the outcome of patients managed with the conventional approach and medical imaging for equivocal presentations. The second part was to investigate patient’s outcome with a routine medical imaging protocol. Although there were only 8% patients who had an emergency medical imaging in the first series, the data showed that the patient’s outcome (delayed surgery, prolonged hospitalization, and appendix rupture) was comparable with the centers where medical imaging was routinely performed for suspected appendicitis. In fact, the emergency medical imaging in this series was found to be unreliable. With known costs and side effects of the medical imaging, the routine medical imaging for this condition was not implemented and the second part of the study was abandoned.

4. **Laparoscopic inguinal hernia repair with totally extra-peritoneal (TEP) approach, but no disposable instruments – “Cutting the Cost”**. The cost of disposable instruments in laparoscopic inguinal hernia repair with totally extra-peritoneally (TEP) approach was known to be substantial. First part of the study, the technique involved no disposable instrument was described. Secondly, a prospective audit on the cost analysis (theatre time, complication rate, hospitalization, etc) was performed on the two techniques, with and without disposable instrumentation, in one hospital. The data showed that laparoscopic hernioplasty (with totally extra-peritoneal approach) should be performed without the disposable instruments at first attempt. The technique is safe and cost effective.

5. **Glide-wire assisted dilatation for urethral stricture in pediatric surgery**. This part of the thesis involves two studies. Firstly, a new
surgical technique was described for urethral dilatation in pediatric urology, and a short-term audit of the patient's outcome showed that the technique was safe, simple and effective.

6. **Guide-wire assisted urethral dilatation in paediatric urology – Experience of a single surgeon.** The patient’s long-term outcome managed by the surgical technique (described above) has been audited. Audit aimed to validate the safety and efficacy of the surgical technique.
   
   a. Unfortunately, less than half of patients became ‘recurrence-free’ of stricture after two dilatations. The data showed that the technique should only be used in selective cases and emergency settings.
Chapter One: Background Of This Research

INTRODUCTION

Evidence-based Medicine

Quotation from Sackett DL at British Medical Journal (1996), "Evidence based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research. By individual clinical expertise we mean the proficiency and judgment that individual clinicians acquire through clinical experience and clinical practice. Increased expertise is reflected in many ways, but especially in more effective and efficient diagnosis and in the more thoughtful identification and compassionate use of individual patients' predicaments, rights, and preferences in making clinical decisions about their care. By best available external clinical evidence we mean clinically relevant research, often from the basic sciences of medicine, but especially from patient centered clinical research into the accuracy and precision of diagnostic tests (including the clinical examination), the power of prognostic markers, and the efficacy and safety of therapeutic, rehabilitative, and preventive regimens. External clinical evidence both invalidates previously accepted diagnostic tests and treatments and replaces them with new ones that are more powerful, more accurate, more efficacious, and safer."[8].

The idea of Evidence-Based Medicine (EBM) has been around for a long time. In the current era, Professor Archie Cochrane, a Scottish epidemiologist, through his book Effectiveness and Efficiency: Random Reflections on Health Services (1972) and subsequent advocacy caused increasing acceptance of the concepts behind evidence-based practice. Cochrane's work was honoured through the
naming of centres of evidence-based medical research — Cochrane Centres — and an international organisation, the Cochrane Collaboration. The explicit methodologies used to determine "best evidence" were largely established by the McMaster University research group led by and named EBM in 1992 by a group led by David Sackett and Gordon Guyatt in Canada [9-17]. The term "evidence-based medicine" (EBM) first appeared in the medical literature in 1992. Since then, the number of articles about EBM has grown exponentially, and it has become a popular approach to medical decision-making and is increasingly part of undergraduate and postgraduate medical education. Its approach usually follows four steps [9-11, 14-16, 18, 19]:

1. Formulate a clear clinical question from a patient's problem;
2. Search the literature for relevant clinical articles;
3. Evaluate (critically appraise) the evidence for its validity and usefulness;
4. Implement useful findings into clinical practice.

**Evidence-based Practice**

Evidence-based practice (EBP) is an approach to health care wherein health professionals use the best evidence possible, i.e. the most appropriate information available, to make clinical decisions for individual patients. EBP values, enhances and builds on clinical expertise, knowledge of disease mechanisms, and pathophysiology. It involves complex and conscientious decision-making based not only on the available evidence but also on patient characteristics, situations, and preferences. It recognizes that health care is individualized and ever changing and involves uncertainties and probabilities. Ultimately EBP is the formalization of the care process that the best clinicians have practiced for generations" [20, 21].
**Evidence-base Healthcare**

Evidence-based healthcare is the conscientious use of current best evidence in making decisions about the care of individual patients or the delivery of health services. Current best evidence is up-to-date information from relevant, valid research about the effects of different forms of health care, the potential for harm from exposure to particular agents, the accuracy of diagnostic tests, and the predictive power of prognostic factors [16, 22, 23].

**Evidence-Based Surgery or Evidence-Based Medicine in Surgery?**

The use of the terms evidence-based medicine (EBM) and healthcare (EBHC) has become a common place in the medical as well as in the surgical literature. The randomized control trial (RCT) is the undoubted gold standard for the evaluation of medical therapies. However RCTs have specific difficulties in the surgical research, especially when operative variables are involved. The classic RCT design that is commonly used today does not adequately take into account the surgeon’s expertise. Quality items for RCTs, such as blinding or comparing with a placebo intervention, are often difficult or impossible to incorporate in a surgical trial. This may lead to a reduced protection against bias. The equivalence of treatments within each trial arm may represent a major problem. Therefore, the daily practice of evidence-based surgery (EBS) is still limited compared with medicine. Only 3.4% of all publications in the leading surgical journals and limited Cochrane reviews are randomized controlled trials (RCTs) [24, 25]. Much work remains to be done to enlarge the number of high-quality and relevant reviews. Similarly, the number and quality of randomized controlled trials need to be increased in all surgical specialties.

Nevertheless, the fundamental base of evidence-based practice should include three dimensions:
1. The external evidence, e.g. empirical data generated by trials and studies of different levels of validity;
2. The internal evidence, e.g. experience from clinical practice
3. Patient values and preference.

Therefore evidence-based practice should be “using the best available evidence”, and we should accept alternatives to RCTs whenever appropriate.

However, using the best available evidence is not yet a working routine among surgeons because of the large amount and complexity of published research, the lack of user-friendly tools, and necessary skills for the use of research results. In this study, we conducted audits to investigate the outcome of patients with the same surgical condition in a multi-center setting, cost-effectiveness of health resource for surgical practice, and safety and efficacy of a surgical technique. Hopefully, the audits provide the evidence for the current surgical practice.

**Surgical Audit**

Audit is now recognized as a form of EBM. An audit cycle aims to evaluate and to initiate change in the practices of individual clinicians and hospital systems for quality assurance, training, and education [26, 27]. It is a systemic and critical analysis of the quality of surgical care that is reviewed by peers against explicit criteria or recognized standards, and then used to further inform and improve surgical practice with the ultimate goal of improving the quality of care. The concept of surgical audits has further extended for clinical trials and research. [6, 9-11, 14-16, 18, 28-31].

Although a surgical audit seems to be a novel idea, conducting an audit and practicing EBS can be a complex and expensive exercise, it requires substantial personal and institutional resources to educate surgeons and
maintain its standard [32, 33]. Is it necessary to conduct audits for surgical practice.

**Background**

The oldest method of audit is the simple counting of results. Lord Lister used simple statistics to convince the profession of the value of antiseptic surgery. In a paper published in 1870 entitled ‘On the Effects of the Antiseptic System of Treatment upon Salubrity of Surgical Hospital’, he compared the mortality after amputation before and after the use of antisepsis [34]. Theodore Kocher was a prime example of a surgeon performing a self-audit of the result of a specific operation; thyroidectomy [34]. Edoardo Bassini revolutionized hernia surgery. He not only described a new method for hernia repair, but also audited his results which were indeed impressive [34].

Although surgical audit in its basic form has been practiced by the great surgeons since the last century, its universal acceptance and practice is only recent [4-6]. Early attempts at formal audit of surgical results within American hospitals began early this century, but they were described as 'polite and restrained discussion'. The first serious attempts to introduce national audits of outcome were made in Britain by Ernest Hey Groves (1908) and in US by Ernest Amory Codman (1910). As Codman commented:

"**Every doctor cares more for his reputation than his efficiency and is tempted to spend his time in concealing his ignorance rather than increasing his knowledge**"[35].

Surgical audits were not well practiced and the quality assurance was not in place. As Bohnen suggested, physician’s (and surgeon’s) behavior is complex, further research is necessary to understand what will induce physicians and surgeons to alter their behavior and practice patterns [36].

In modern competitive industry, quality assessment of the end product is necessary for survival. The quality assurance process were pioneered by Juran and Deming with their lessons learned at Japan after the World War Two [37]. The quality assurance is more than simple auditing of costs but
auditing the quality and standard of the end product. The concept of ‘total quality’ pervades the whole manufacturing industry in which ‘quality improvement teams’ interlace within management and employees.

Transferring this idea to the patient care seemed to be the natural progression. In Australia, the surgical audit was pioneered by Smyth in the 1950s, and his papers still remain as the ‘gold’ standard of audit methods. Although not initially welcomed by the profession, surgical audit is becoming an essential part of surgical practice, hospital accreditation, and registrar training [4-6, 38, 39].

Objectives of Surgical Audits

Audit of a structure[40]

The structure is the organisation, within which surgical practice is carried out, could be the hospital per se, the department or the operating theatre. Standards, to change the working environment for the better, can be set to improve the patient care, operative system, and resources utilization.

Audit of the structure should include

- Adequacy of surgeons, nurses, paramedical staff
- Educational standards of the staff
- Standard of OT, equipment
- Efficiency of ICU care
- Availability of drugs
- Optimal functioning of blood bank

Audit of a process[40]

Some performance indicators include

- Actual length of stay
- Expected length of stay
- Turn over interval
- Actual throughput
- Expected throughput
- Percentage of day cases
- Percentage of cases not operated
- Pre-operative stay
- Post-operative stay
- Waiting list per 1000 population

Most important of these from a surgeon's viewpoint concern is the use of beds, of outpatient clinics and of operating theatres.

\[
\text{Actual length of stay} = \frac{(\text{Number of occupied beds}) \times (\text{Number of days in study period})}{(\text{Number of patients discharged or dead during the study period})}
\]

Expected length of stay is the average of all hospitals in a particular district/country, corrected for age, gender and diagnostic category.

Turn over interval is a valuable indicator of the efficiency of bed management.

\[
\text{Turn over interval} = \frac{(\text{Number of available beds} - \text{Number of occupied beds}) \times (\text{Number of days in study period})}{(\text{Number of discharges in study period})}
\]

\[
\text{Actual throughput per year} = \frac{(\text{Number of days in the year})}{(\text{Length of stay} + \text{turn over interval})}
\]

**Audit of outcome**

There are several factors to assess outcome of a practice:

**Patient satisfaction**

It is essential to have honest and comprehensible communication with the doctor, taking time to listen to the patient's story and then to explain the disease and treatment options. Ovretveit et al underlined ten features for assuring patient's satisfaction.

- reliability
• responsiveness
• security
• understanding/concern
• physical appearance
• competence
• courtesy
• access
• communication
• credibility

Morbidity/Mortality assessment

The following are examples used in the assessment of post-operative morbidity

• Actual length of post op stay with reference to the expected length of stay.
• Rate of unscheduled returns to OT and of unscheduled re-admission to hospital.
• Post-operative infections.

Nosocomial infections - surveillance

Prospective surveillance has four elements

• stratification of surgical operations
• detection of wound infections
• reporting of infection rates
• feedback to the operating team

*It was found that the regular feedback regarding the nosocomial infection to the surgeon kept the wound infection rate low.*

Perioperative Deaths [41-50]

The objective of Perioperative Death, as investigated extensively at UK as the National Confidential Enquiry into Peri-operative Deaths (NCEPOD),
was to identify any deficiencies in the care offered, so that corrective measures can be adopted later on. Patients who die within 30 days of surgery are studied. Two independent assessors (one surgeon, one anesthetist) are involved. Confidentiality is maintained by removing identity of patient, hospital and surgeon. Details of the case with an assessment form sent to the assessors and the report given to the surgeon.

Assessment is based on

- appropriateness of the operation
- appropriateness of preoperative preparation
- appropriateness of grade of surgeon
- soundness of the organisation
- equipment failure
- adverse drug reaction
- human failure
  - lack of knowledge
  - failure to apply
  - lack of experience
  - lack of care
  - fatigue
  - physical/mental impairment
  - inadequate supervision
  - others

*NCEPOD found that disaster arose frequently when surgeons attempted procedures for which they possessed insufficient skills and training.*

*A study of NCEPOD in 1987 in London found that*

- <50% of hospitals had regular mortality/morbidity conferences
- there was a poor attendance at these conferences
- the autopsy rate was only 30-44%
Types of Audits

Basic clinical audit

Broad analysis of case type, complications, mortality and morbidity was undertaken on a regular basis.

Incident review

Discussion of strategies to be adopted in certain clinical scenarios which would result in the production of guidelines for a given scenario, e.g. uncontrolled variceal bleed.

Clinical record review

Clinical records to be audited by a member of same speciality from another hospital in the presence of a third person to avoid too much concentration on quality of record keeping than on patient care.

Criterion audit

Retrospective analysis of case records is made to judge against a set of chosen criteria like assessment of

- quality of writing OT records
- quality of discharge summary
- appropriateness of investigations for a particular diagnosis
- appropriateness of treatment

Adverse occurrence screening

Details of adverse occurrences such as wound infections, unplanned readmissions, delay/error in diagnosis are reviewed to identify trends and perform comparative analysis.

Specific audit studies
Outcome from any area of audit may dictate the need for a more closely specific area of research or academic requirements

**Global audit**

The entire process of health care delivery during a patient's stay in hospital including the spectrum of administration, nursing staff, allied health staff and doctors, is assessed as outcome which is an important measure of the quality of care.

**National studies**

These are vital to study the overall health trends in the country.

For the audit to be meaningful, it should satisfy the following

- Open debate /self evaluation
- Interesting
- Confidentiality of surgeon/patient to be maintained.
- Demonstrate change with improvement of patient care
- Resources spent for audit should be kept bare minimum

**Current Situation**

Recently, there is an enormous effort being implemented to improve the compliance of surgical audits for quality assurance. In the States, the American College of Surgeons Oncology Group (ACOSOG) represents a national-wide effort by general and specialty surgeons to collectively participate in clinical trials research, from both academic medical centers and community practices [51]. In Scotland, the Scottish Audit of Surgical Mortality (SASM) aims to peer review all patients who die under surgical care in 46 hospitals, excluding obstetric and cardiothoracic deaths which are audited separately [52]. In Canada, Royal College of Physicians and Surgeons of Canada (RCPSC) established the first 5-year cycle of the Maintenance of
Certification program (MainCert). MainCert certification is now required for admission to the RCPSC and to renew Fellowship privileges [53].

**Aims And Rationale Of The Study**

The aims of this project were to examine the process of applying the principles of evidence-practice in surgery by conducting audits, and observe how audits would influence the practice. Based on the objectives and principles of audits noted above, studies were designed to examine different facets of surgical practice.

In Chapter Three and Four of the thesis, the patients’ outcome with acute pancreatitis was audited and compared with the established guidelines. The aim of these two studies, Management of mild acute gallstone pancreatitis – *So the story continues* and Comparative Study on management of Acute Pancreatitis, was essentially to conduct audits to investigate the structure (the hospitals), process (patient management), and the outcome (complications of patients from untreated acute gallstone pancreatitis). By performing timely gallstone removal treatment, the quality of care was ensured for patients with mild gallstone-related acute pancreatitis, as shown in Chapter Three. In Chapter Four, the recommended standard of patient’s outcome was able to reproduced at local hospitals when complied closely with the international guidelines.

Within current medical literature, there were studies either supporting or opposed to the routine use of medical imaging for patients with suspected acute appendicitis. To investigate the need of routine medical imaging for this common surgical condition in a regional hospital, “*To have…, or not to have…*” – Should CT and/or Ultrasound be implemented as a routine work-up for patients with suspected acute appendicitis in a regional hospital? , was conducted to examine the process and patient’s outcome of management of this surgical condition in a regional hospital. The aim was to investigate whether routine medical imaging prevents complications from delayed treatment which could incur large cost to health resource. Firstly, a retrospective surgical audit (criterion audit) was conducted to investigate the
patients’ outcome managed with traditional approach (without a routine medical imaging protocol for this condition). The audit cycle would be repeated after a routine medical imaging protocol was implemented. Then the patient outcome with these two approaches would be compared. The aim of the study was to justify the utilization of healthcare resource for a common surgical condition.

Surgeons are not longer the only individuals interested in the outcome of audits. In fact, the hospital administration, policy-makers, and consumers are highly supportive of the idea, too, especially if audits can provide the evidence for utilization of healthcare resource. Although there were similar laparoscopic techniques described previously, there was not much evidence available in literature on cost analysis on different techniques of laparoscopic hernia repair. A prospective audit was conducted for cost-effective comparison on the two different laparoscopic techniques for inguinal hernia repair in a local hospital.

For a new surgical technique, conducting a series of surgical audits would be an option to investigate its safety and efficacy. The final two parts of this study, a new technique for dilatation of a paediatric urethral stricture was firstly described and short-term patient outcome reported. This was followed by a long-term audit, two and a half years after the publication of the first study, to validate this surgical technique. All operations were performed by the same surgeon, so the confronting factor of different surgeons with different levels of expertise could be eliminated.

Chapter Two: Methodology Of This Research

Key Areas

Six papers were reviewed to investigate how audits influence the current surgical practice with emphasis on

1. Quality assurance of patients’ care in a multi-centers setting
2. Cost-effectiveness of heath-care resource  
3. Validating a new surgical technique

Methodology

The first two studies focused on the quality assurance in management of patients with acute pancreatitis. In Chapter Three, “Management of Acute Gallstone Pancreatitis - So the story continues - Audit improves management of Gallstone Pancreatitis “, medical records of patients with mild acute gallstone pancreatitis between January 2000 and March 2002 were audited. The pathology results and medical imaging of patients diagnosed with acute gallstone pancreatitis were analyzed. Patients with a score of less than three Ranson criteria were reviewed. Information on the course of treatment, method of stone eradication (laparoscopic cholecystectomy or ERCP+ES), timing of surgery, reason of non-operation, and outcome were recorded and compared with the guidelines [54].

Reasons for failing to remove stones in a timely fashion were identified. Strategies to improve compliance with new policy were implemented. An audit was repeated ten months later to assess changes in practice.

In Chapter Four, “Comparative Study on Acute Pancreatitis Management”, patients with a primary diagnosis of acute pancreatitis were identified retrospectively. Eighty-four admissions from the Austin Hospital (AH), a tertiary referral centre, and 83 from The Geelong Hospital (TGH), a regional health centre were treated in these two hospitals. The histories were collected and examined for compliance with the guidelines recommended by the British Society of Gastroenterology [54]. We also compared our data with the results from the two UK hospitals in a previous study [7].

Chapter Five and Six focused on the cost-effectiveness of resources on management of surgical conditions. Chapter Five investigated the use of medical imaging for management of patients with suspected acute appendicitis at a regional centre. The patient cohort was identified from the Unit Registry and an International Classification of Diseases-based Review of medical records. Between 12/01/2004 to 27/05/2005, patients’ medical
records were audited. This study reviewed all patients admitted in one district general hospital with suspected acute appendicitis. The medical records were analysed, and the outcome of patients were followed up, especially medical image, time of diagnosis, operative notes, hospital stay, and complications.

In Chapter Six, Laparoscopic inguinal hernia repair with totally extra-peritoneal approach, but without disposable instruments - Cutting the cost, we firstly described a surgical technique of laparoscopic inguinal hernia repair without disposable instruments. Prospectively, in a single center, detail information on the patient's pre-, intra-, and post-operative finding has been audited for two laparoscopic inguinal hernioplasty techniques, both with and without disposable instruments. In-hospital cost analysis was conducted for theatre time, cost of laparoscopic and disposable instruments, patient's medication requirements, and complications for comparison.

Chapter Seven and Eight investigated the safety and efficacy of a new surgical technique for urethral stricture in paediatric urology. In Chapter Seven, the new surgical technique was described and short-term follow-up was conducted. In Chapter Eight, patients had this surgical technique performed by a single surgeon were included and information on cause of urethral stricture, operation notes, post-operative recovery, follow-up cystoscopic appearance, and patient's long-outcome were audited and analyzed.
Chapter 3

Management of Acute Gallstone Pancreatitis -

*So the story continues…*

Audit improves management of Gallstone Pancreatitis

Abstract

**Introduction**

A retrospective audit on management of mild acute gallstone pancreatitis at Western Health showed that failure to perform laparoscopic cholecystectomy or ERCP+ES within four weeks of presentation resulted in a high re-admission rate.

A policy of early cholecystectomy was instituted, and the audit repeated to assess the outcome.

**Method and Patient Selection**

Medical records of patients with mild acute gallstone pancreatitis between Jan. 2000 and Mar. 2002 were audited. The pathology results and medical imaging of patients diagnosed with acute gallstone pancreatitis were analysed. Patients with less than three Ranson criteria were reviewed. Information on the course of treatment, method of stone eradication (laparoscopic cholecystectomy or ERCP+ES), timing of surgery, reason of non-operation, and outcome were recorded.

Reasons for failing to remove stones in a timely fashion were identified. Strategies to improve compliance with new policy were implemented. An audit was repeated ten months later to assess changes in practice.

**Result**

The rate of performing timely stone removal has improved from 57% to 83% at the prospective audit, and the re-admission rate has significantly reduced. The rate of performing laparoscopic cholecystectomy during the same admission for suitable patients only improved marginally.
**Conclusion**

Surgical audit is imperative in surgical practice. It helped us to identify the deficiency in the management of mild acute gallstone pancreatitis in Western Health. By complying closely with an accepted standard and guideline, the outcome of patient care has improved.

**Keywords:** Surgical Audit, Acute Mild Gallstone Pancreatitis, Laparoscopic Cholecystectomy, Endoscopic Retrograde Cholangiopancreatography and Sphincterectomy (ERCP+ES)

**Introduction**

Acute pancreatitis is a common general surgical condition in both community and tertiary hospital settings. It accounts for approximately three percent of hospital admissions with abdominal pain [55]. Acute pancreatitis often presents as a difficult clinical problem with a range of severity from a mild, self-limiting course to sepsis, multi-organ failure and death. In order to reduce the mortality and morbidity from this condition, evidence-based guidelines on timely management have been recommended [54, 56-58]. Patients with mild gallstone pancreatitis without complications should have definitive management of gallstones (cholecystectomy and bile duct clearance if necessary), within two weeks and no longer than four weeks from the time of presentation[54]. For elderly and medically unfit patients, endoscopic retrograde cholangiopancreatography and sphincterectomy (ERCP+ES) with duct clearance can be acceptable definite treatment without the need for cholecystectomy.[59, 60].

Surgical audit is a regular documented critical analysis of the outcome of surgical care [61-63]. It aims to evaluate how closely local practice meets the known standards. Any deficiency identified by an audit should be corrected by a change in policy or management targeting the identified
deficiency [63-66]. Although Smyth brought the concept and standard of surgical audit to Australia in 1950, the compliance to perform regular audit has been scanty [4-6, 38]. The universal acceptance by surgeons has only happened in the recent time after immense resource support, re-enforcement and by Royal Australasian College of Surgeons [38, 67, 68].

Previous surgical audit at the Western and Sunshine Hospitals (Western Health), showed that non-compliance with a guideline requiring stone removal (cholecystectomy or ERCP+ES) for patients with mild gallstone pancreatitis within a month resulted in a high re-admission rate of 23% [69]. These results were presented to the general surgical group and compliance with the policy was re-enforced at weekly audit meetings when patients were identified with biliary pancreatitis. The members of the Upper GI / Hepatobiliary Surgical service made themselves available to manage these patients in a timely manner. Patients presenting with biliary pancreatitis were individually discussed at weekly audit meetings to encourage compliance with the policy of early intervention. The aim of this study was to assess the outcome of a change in policy.

**Method and Material**

The initial audit period was from January 2000 through March 2002. The Medical records of patients presenting to the Western and Sunshine Hospitals (Western Health) with acute gallstone pancreatitis were collected and retrospectively reviewed. The information on the presence of abdominal pain, serum level of amylase three times more than normal, and ultrasound evidence of gallstone or sludge was used to determine acute gallstone pancreatitis. Ranson’s criteria [70] were used to assess the severity of acute pancreatitis. Patients scoring less than three Ranson’s factors were classified as having mild acute pancreatitis and included in this study. Information on the course of treatment, including the method (laparoscopic cholecystectomy or ERCP+ES), timing, reason for non-operation, and outcomes were recorded.
A second audit was conducted from January 2003 to April 2005. Patient details and timing of definitive treatment were collected in identical manner to the initial audit period.

Results of the follow-up audit were compared with the initial period.

Results

There were 101 episodes of acute gallstone pancreatitis presenting to the Western Health, from January 2000 to March 2002. Eighty-two of 101 (81%) episodes were mild cases and 19 episodes were severe, according to Ranson’s criteria.

Forty-seven patients with mild gallstone pancreatitis (57%) underwent stone removal (laparoscopic cholecystectomy or ERCP+ES) within a month after resolution of the initial attack. Eighteen of these patients (22%) had treatment during the same admission (Table 1).

Among the patients who did not have stone removal within a month, 18 patients (23%) were re-admitted with gallstone-related conditions, and four of these had severe acute pancreatitis (Table 2). One patient who had multiple co-morbidities represented with biliary colic, and subsequently died of pneumonia.

At the prospective audit, 101 episodes of acute gallstone pancreatitis presented to Western Health between January 2003 and April 2005. Eighty-seven episodes (86%) were mild cases. Seventy-two patients (83%) had stone removal (69 laparoscopic cholecystectomy and three ERCP+ES) within one month. Among them, 42 patients (48%) had the treatment during the same admission.

The re-admission rate was 8% among the non-treated patients (surgery or ERCP), and it was significantly lower than the previous audit (chi-squared < 3.84 and p-value < 0.05). There was no mortality in this group.

At the second audit, the seven patients who didn’t have stone removal within four weeks, three had been waiting for laparoscopic cholecystectomy for more than one month, and two of them presented with recurrent episodes of acute gallstone. Laparoscopic cholecystectomies were performed for both of these cases within three weeks. The other two did not have recurrence,
and cholecystectomies were performed six and eight weeks after resolution of acute pancreatitis.

Two patients who did not have laparoscopic cholecystectomy were frail with multiple co-morbidities. Both patients even refused to undergo ERCP+ES. One of them presented with an episode of biliary colic two months after the initial attack and died from congestive heart failure during a different hospital admission.

One patient, who was otherwise medically fit, refused laparoscopic cholecystectomy. He was recently contacted by telephone and no recurrence since then.

**Discussion**

Surgical audit involves critical assessment of performance by identification of deficiencies, modifications of management, and re-appraisal of outcomes. The activity should be conducted regularly in an encouraging environment, reviewed by peers, and aims to improve the quality of care and patient’s outcome. It is common to require support from the appropriate body and hospital authority for development of the database and modification of the existing management.

Delaying cholecystectomy can result in recurrent attacks of acute pancreatitis in 20-40% of cases [71, 72]. We learned from an initial audit that non-compliance of performing timely surgery to eradicate gallstones for patients with mild acute gallstone pancreatitis led to a high re-admission rate. This was an unacceptably high rate of failure to comply with an accepted guideline and a policy of early intervention was introduced and compliance with the policy reinforced at the weekly general surgical audit meeting. Timely intervention and stone eradication has lowered the re-admission rate from recurrent episodes.

A further improvement in the management of patients with acute gallstone pancreatitis is for all such patients to have intervention and stone eradication during the same admission. Cholecystectomy with operative cholangiography during the same admission has been shown to be the treatment of choice, since the optimum timing of operation appears to be
immediately following resolution of the attack [73, 74]. For those with poor co-
morbidity or severe cholangitis, early ERCP and stone clearance from the 
common bile duct is indicated. At the follow-up audit in this study, the rate of 
stone removal during the same admission has remained low at 48% although 
some improvement from the initial audit at 23%. It is hoped that the next audit 
cycle will show an improvement in this regard.
## Appendix

### Table 3.1: Two consecutive surgical audits (2000-2002 and 2003-2004) on patients with mild episodes of acute gallstone pancreatitis and timely lithiasis eradication treatment

<table>
<thead>
<tr>
<th>Year</th>
<th>No. of mild episodes of acute gallstone pancreatitis</th>
<th>Stone eradication (LC or ERCP+ES) within a month</th>
<th>Stone eradication (LC or ERCP+ES) during the same admission</th>
</tr>
</thead>
<tbody>
<tr>
<td>2000 (Jan) – 2002 (Mar)</td>
<td>82</td>
<td>47 (57%)</td>
<td>17 (22%)</td>
</tr>
<tr>
<td>2003 (Jan) – 2005 (Apr)</td>
<td>87</td>
<td>72 (83%)</td>
<td>42 (48%)</td>
</tr>
</tbody>
</table>
Table 3.2: Comparison of re-admission rate on two consecutive audits (chi-squared = 3.84; p=0.05)

<table>
<thead>
<tr>
<th>Year Range</th>
<th>Re-admission rate from recurrent gallstone-related episodes</th>
</tr>
</thead>
<tbody>
<tr>
<td>2000 (Jan) – 2002 (Mar)</td>
<td>23% (19/82)</td>
</tr>
<tr>
<td>2003 (Jan) – 2005 (Mar)</td>
<td>3% (3/87)</td>
</tr>
</tbody>
</table>
Chapter 4

Comparative Study on Acute Pancreatitis Management

Abstract

Purpose

Guidelines have been published regarding the management of acute pancreatitis by the British Society of Gastroenterology (BSG) [54]. The aim of this paper is to compare the management of patients with acute pancreatitis in a tertiary referral medical centre and a regional health centre in Australia during 2001, evaluate compliance with the published BSG guidelines, and compare our data with those of a similar UK study [7].

Materials and Methods:

Patients with a primary diagnosis of acute pancreatitis were identified retrospectively. Eighty-four admissions from the Austin Hospital (AH), a tertiary referral centre, and 83 from The Geelong Hospital (TGH), a regional health centre were treated in these two hospitals. The histories were collected and examined for compliance with the guidelines recommended by the British Society of Gastroenterology (BSG) [54]. We compared our data with the results from the two UK hospitals in a previous study [7].

Results:

Only 38% of patients from these two centres had all the investigations performed for severity stratification as recommended by BSG. In other
respects, AH and TGH managed these patients with acute pancreatitis according to the recommendations. The overall mortality rate from acute pancreatitis was 3.0%, and within the group of severe acute pancreatitis the mortality rate was 22.7%. Sixty-five point five percent of patients from AH with gallstone related acute pancreatitis had a cholecystectomy or sphincterotomy and extraction of gallstones within four weeks of presentation. There were five re-admissions to AH in 2001 due to non-operated gallstone-related acute pancreatitis. In contrast, 84.3% of patients from TGH had definitive treatment within 4 weeks and there were 3 re-admissions to TGH.

**Conclusion:**

Overall, both a tertiary referral centre and smaller regional hospital in Australia managed acute pancreatitis according to recently published BSG guidelines. The guidelines emphasised the importance of expertise in hepatopancreatobiliary surgery, availability of ICU/HDU and dynamic CT scanning. The recommendations for definitive treatment of patients with gallstone-related pancreatitis within four weeks of presentation reduced the morbidity and mortality in this group. Although compliance with the guidelines on investigation for severity stratification of acute pancreatitis was poor, this lack of formal severity assessment did not appear to influence the outcome.

**Key Words:** Acute pancreatitis, Severity Stratification, the Modified Glasgow Scoring System

**Background**

Acute pancreatitis is a common general surgical condition in both community and tertiary hospital settings. It accounts for about three percent of hospital admissions with abdominal pain [55].

Acute pancreatitis often presents a difficult clinical problem with its range of severity from a mild, self-limiting course to sepsis, multi-organ failure and death. In order to reduce the mortality and morbidity from this condition, evidence-based guidelines on management have been recommended [54, 57, 58]. Published BSG guidelines state that (a)overall mortality should be lower
than 10%, and less than 30% in those diagnosed with severe disease (b) correct diagnosis of acute pancreatitis should be made within 48hrs of admission (c) severity stratification should be made in all patients within 48hrs using the Glasgow score and CRP (d) dynamic CT scanning should be performed in all severe cases between three and ten days after admission (e) the aetiology of acute pancreatitis should be determined in 75-80% of cases and no more than 20-25% should be classified as idiopathic (f) all cases of severe acute pancreatitis should be managed in an HDU or ITU setting (g) facilities for ERCP and sphincterotomy should be available and (h) patients with mild gallstone pancreatitis should have a cholecystectomy within two weeks and no longer than four weeks.

A number of methods have been devised to predict the severity of acute pancreatitis. These incorporate measures of the physiological derangement associated with the inflammatory process and require a period of observation and repeated assessment. Estimation of C-reactive Protein (CRP) has recently been suggested as a simple parameter that is predictive of the outcome [75, 76]. Nevertheless, it remains unclear if prediction of a severe episode of pancreatitis is of great clinical value in the absence of specific therapy that will influence the outcome of an acute attack.

In this study, we evaluated the current practice in the management of acute pancreatitis in two hospitals in Australia, and compared our experience with the recommendations suggested by the British Society of Gastroenterology, and the experience from the two hospitals in UK [7, 54].

**Materials and Methods:**

The period of study was from 1st January 2001 to 31st December 2001, which was after the publication of the BSG guidelines. We compared our practice of managing patients with acute pancreatitis with the guidelines.

Case records of patients discharged during the study period with a diagnosis of acute pancreatitis and with an elevation of serum amylase and/or lipase over three times above normal were reviewed.
Severity classification was based on the Modified Glasgow Scoring System and C reactive Protein estimation. Three or more positive criteria based on the initial Glasgow score and repeated over 48hrs and a peak level CRP measurement of > 210mg/l in the first 4 days of the attack indicated a severe attack [77].

Eighty-four patients from AH and 83 from TGH had acute pancreatitis on review of the notes. Results of investigations were obtained from case notes or traced through the laboratory department computer systems. Demographic information and data regarding aetiology, prognostic investigations, imaging, and various aspects of management including use of antibiotics, intensive care unit (ICU) stay and nutritional support were analysed.

The timing and results of any endoscopic retrograde cholangiopancreatography (ERCP) and of any cholecystectomy were recorded. The final outcomes and incidence of complications during the episode of pancreatitis were also studied.

All results were compared with outcomes from the British study which compared the management of acute pancreatitis in a Teaching Hospital (TH) and District General Hospital (DGH) in a similar setting [7].

**Results:**

The demographic profile of the patients and aetiological factors in the two hospitals were not significantly different. TGH had more female patients than AH. The age distributions were similar in both AH and TGH, with the same median age of 60 (Table 1).

Gallstones remained the leading cause of acute pancreatitis in both AH and TGH. Alcohol was the second most common cause (Table 2).

Thirty nine point three percent of patients (33/84) in AH and 48.2% (40/83) of patients in TGH were investigated according to the Modified Glasgow Scales and had estimation of C-reactive protein (CRP). Compliance with the severity stratification guidelines was lower than the two hospitals in the UK study. As a result, 73 patients had complete sets of MGS + CRP and 90 had incomplete MGS + CRP. Despite incomplete investigations 22 patients
at AH and 15 at TGH were predicted to have severe acute pancreatitis (Table 3).

Clinically severe acute pancreatitis is associated with organ failure and/or local complications such as necrosis (with infection), pseudocyst, or abscess [54, 78-81]. Of the 22 patients from AH predicted for severe acute pancreatitis, only nine (40.9%) developed clinically severe acute pancreatitis, and all were admitted to ICU/HDU. These nine patients recovered and were discharged from the hospital. Fifteen patients from TGH were predicted to have severe acute pancreatitis, but only five of them (33.3%) developed clinically severe acute pancreatitis and all were admitted to ICU/HDU. Four of them recovered and were discharged from the hospital. The final patient presented with multi-organ failure and died two weeks later in ICU. The overall sensitivity of severity stratification in these two Australian hospitals by the BSG guideline was 37.0%. No patients in either hospital were transferred to ICU/HDU more than 48 hours following admission. Thus no patient was incorrectly classified during the first 48 hours due to a lack of compliance with the severity stratification.

Nevertheless, among 33 patients from AH and 40 from TGH who had complete sets of investigations performed, two patients in AH and five patients in TGH didn’t score three or more positive factors in the first 48 hours, but each developed either cardiovascular and/or respiratory compromise and required ICU/HDU management.

With respect to the use of dynamic Computed Tomography (CT)(Table 4), 66.7% of patients at AH and 75% of patients at TGH with severe acute pancreatitis had a dynamic CT scan performed according to the BSG guideline. By comparison, the TH in UK had poor compliance with performing dynamic CT in these patients and both dynamic CT and ERCP were unavailable in the DGH. The DGH had a relatively higher mortality rate compared to the other three centres.
Two thirds of patients from AH and 84.5% of patients from TGH had definitive treatment for gallstone-related acute pancreatitis within four weeks of presentation (Table 5). By comparison, the rate of cholecystectomy in the two hospitals in the UK was around 20%. Although the rate of timely cholecystectomy in the TH from the UK study was only 22.2%, the mortality rate was no different than the two hospitals in Victoria. ERCP and sphincterotomy was more commonly performed as definitive treatment in the TH in the UK [82, 83]. By comparison, in the DGH in the UK, ERCP was unavailable, and timely cholecystectomy for gallstone-related acute pancreatitis was infrequent. The mortality, re-admission and complication rates for non-operated gallstone pancreatitis were significantly higher than in the other three hospitals.

The overall mortality rate at AH was 3.5% and 2.4% at TGH. All three patients who died at AH had a Modified Glasgow Scale of three or above and multiple medical problems on presentation. Admission to ICU/HDU was refused by all three patients and they were managed conservatively on the surgical ward. One patient with poor quality of life prior to admission requested palliative care. One patient was initially being treated for another condition and died with unrecognised acute pancreatitis on the ward, the diagnosis only being revealed during autopsy. The final patient had multiple pre-existing medical conditions and presented with gallstone-related acute pancreatitis. The patient and relatives refused all definitive treatment and the patient died 27 days after admission.

There were two patients who died at TGH, both of whom presented with severe pancreatitis and multi-organ failure and were admitted to ICU/HDU. The first patient had significant respiratory and cardiovascular compromise at presentation, and she died three weeks later. The other patient had a significant history of cardiac and renal insufficiency prior to presentation, which was worsened by his gallstone related pancreatitis. Despite extensive cardiac and renal support in ICU, his condition continued to deteriorate and he died four weeks after admission.
Discussion

Acute pancreatitis is a very common general surgical condition with a frequently protracted course. Pathology ranges from interstitial inflammation to necrotising pancreatitis, sepsis, multi-organ failure, and death.

The prevalence of clinically severe pancreatitis is around 20-30%. Early detection (within 48 hours of hospital admission) of severe cases and appropriate choice of management can decrease the mortality and morbidity of this condition [54].

Current severity prediction is based on the presence and degree of systemic failure (cardiovascular, respiratory, and renal), and extent of pancreatic necrosis. Scoring systems, such as Ranson [84], Glasgow, and Acute Physiology and Chronic Health Evaluation (APACHE) [85] have been used with some success.

The Modified Glasgow Scale (MGS) and CRP estimation is a modification of Ranson’s criteria and originally comprised nine factors. This has since been reduced to eight components with improved predictive value. Three or more positive criteria, based on initial admission score and subsequent repeat tests over 48 hours, constitute severe disease and the necessity for transfer to ICU/HDU [54, 77].

In this study, both AH and TGH had poor compliance on performing investigations for severity stratification. Nevertheless, the overall mortality rate was still around 3.0%, which is well below the guideline and there was no patient incorrectly classified during the first 48 hours of admission. Moreover, two patients from AH and five from TGH with complete sets of investigations performed did not score three or more positive factors. However they clearly required ICU/HDU management for cardiovascular or respiratory support. Thus, guidelines on severity stratification should be regarded as a reference only, whereas prudent clinical judgment is indispensable to guide the management.

The role of early admission to ICU/HDU for prevention and/or management of sepsis and multi-organ failure in cases of severe pancreatitis has been emphasised [54, 56, 86]. When comparing our results with the
previous study, ICU/HDU was more readily accessed in Australia than the UK. In both Australian centres, patients with predicted severe pancreatitis were assessed by the surgical and intensive care teams, and no patient was rejected for ICU/HDU due to a lack of beds. In contrast, Dube et al noted that there was difficulty in accessing ICU/HDU beds in both TH and DGH, which might have contributed to the high mortality rate in their study [7].

The expertise of the hepatopancreatobiliary service has been identified as another important factor in the successful management of gallstone-related acute pancreatitis [7, 54, 56, 87]. ERCP and sphincterotomy were available in the TH in the UK study and both hospitals in Australia, but not in the DGH. The mortality rate from severe acute pancreatitis was similar in the first three hospitals but significantly higher in the DGH.

The advantages of having definitive treatment for gallstone-related acute pancreatitis within four weeks of presentation has also been emphasised [54, 87-89]. This study has again demonstrated the importance of this guideline. TGH achieved the highest rate of patients having timely definitive treatment after gallstone-related acute pancreatitis, which was reflected in the lowest re-admission, morbidity, and mortality rates among the four hospitals. Although the percentage of gallstone-related patients in the TH having a cholecystectomy within four weeks was low, some of the patients had ERCP and sphincterotomy as definitive treatment and the re-admission rate was similar to the two hospitals in Australia.

As previous studies have suggested, there was a benefit from performing dynamic CT in management of severe acute pancreatitis when clinical suspicion and laboratory results were suggestive of pancreatic necrosis [54, 56, 90, 91]. Both hospitals in Australia complied with the guideline on performing the CT with contrast. Despite this, in comparison with the TH in UK, where the compliance with this guideline was only 26.7%, the mortality rate from severe acute pancreatitis was not affected.

**Conclusion:**

The two hospitals in Australia complied with most of the guidelines recommended by the BSG. The availability of ERCP and sphincterotomy and
the ICU/HDU service has a significant role in the management of severe acute pancreatitis. The results from our study showed that the overall mortality rate from acute pancreatitis was well within the recommended range of 10%.

Definitive treatment for gallstone-related acute pancreatitis within four weeks of presentation reduced the morbidity and mortality rates from gallstone-related acute pancreatitis.

Although there was a lack of compliance with the guideline on severity stratification in both Australian hospitals, this did not seem to influence the outcome.

<table>
<thead>
<tr>
<th></th>
<th>AH</th>
<th>TGH</th>
<th>TH (Dube et al)</th>
<th>DGH (Dube et al)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients</td>
<td>84</td>
<td>83</td>
<td>95</td>
<td>52</td>
</tr>
<tr>
<td>Males</td>
<td>50</td>
<td>30</td>
<td>44</td>
<td>24</td>
</tr>
<tr>
<td>Females</td>
<td>33</td>
<td>52</td>
<td>51</td>
<td>28</td>
</tr>
<tr>
<td>Median age</td>
<td>60</td>
<td>60</td>
<td>60</td>
<td>52</td>
</tr>
</tbody>
</table>

Table 4.1: Demographics of Patients With Acute Pancreatitis

<table>
<thead>
<tr>
<th></th>
<th>AH</th>
<th>TGH</th>
<th>TH (Dube et al)</th>
<th>DGH (Dube et al)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gallstone</td>
<td>50.9%</td>
<td>53.7%</td>
<td>47%</td>
<td>52%</td>
</tr>
<tr>
<td>Alcohol</td>
<td>26.5%</td>
<td>21.7%</td>
<td>14%</td>
<td>17%</td>
</tr>
<tr>
<td>Idiopathic</td>
<td>15.7%</td>
<td>18.3%</td>
<td>19%</td>
<td>21%</td>
</tr>
<tr>
<td>Others</td>
<td>6.9%</td>
<td>6.3%</td>
<td>20%</td>
<td>6%</td>
</tr>
</tbody>
</table>

Table 4.2: Aetiology of Acute Pancreatitis
### Table 4.3: Patients with Predicted Severe Acute Pancreatitis and ICU/HDU Admission

<table>
<thead>
<tr>
<th></th>
<th>AH</th>
<th>TGH</th>
<th>TH (Dube et al)</th>
<th>DGH (Dube et al)</th>
</tr>
</thead>
<tbody>
<tr>
<td>MGS + CRP (No LDH)</td>
<td>39.3% (33/84)</td>
<td>48.2% (40/83)</td>
<td>43%</td>
<td>48%</td>
</tr>
<tr>
<td>Predicted Severe AP</td>
<td>22</td>
<td>15</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Clinically Severe AP</td>
<td>11 (13.3%)</td>
<td>10 (12.2%)</td>
<td>15 (15.8%)</td>
<td>8 (15.3%)</td>
</tr>
<tr>
<td>Clinically Severe AP</td>
<td>2</td>
<td>5</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>With Low Scores Initially</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All admission to ICU/HDU in 1st 48 hrs</td>
<td>81.8% (9/11)</td>
<td>80% (8/10)</td>
<td>40% (6)</td>
<td>50% (4)</td>
</tr>
</tbody>
</table>

### Table 4.4: Dynamic CT Performed for Severe Acute Pancreatitis, and Mortality Rates from severe acute pancreatitis

<table>
<thead>
<tr>
<th></th>
<th>AH</th>
<th>TGH</th>
<th>TH (Dube et al)</th>
<th>DGH (Dube et al)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dynamic CT in Severe AP</td>
<td>66.7%</td>
<td>75.0%</td>
<td>26.7%</td>
<td>No</td>
</tr>
<tr>
<td>ERCP available</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Overall Mortality</td>
<td>3 (3.6%)</td>
<td>2 (2.4%)</td>
<td>5 (4.2%)</td>
<td>4 (7.7%)</td>
</tr>
<tr>
<td>Mortality in Severe AP</td>
<td>25.0%</td>
<td>22.2%</td>
<td>26.7%</td>
<td>50%</td>
</tr>
<tr>
<td></td>
<td>AH</td>
<td>TGH</td>
<td>TH (Dube et al)</td>
<td>DGH (Dube et al)</td>
</tr>
<tr>
<td>----------------------</td>
<td>---------</td>
<td>---------</td>
<td>-----------------</td>
<td>------------------</td>
</tr>
<tr>
<td>Chole. Within 4 weeks</td>
<td>65.5%</td>
<td>84.3%</td>
<td>22.2%</td>
<td>20.0%</td>
</tr>
<tr>
<td>ES+ERCP</td>
<td>1</td>
<td>1</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>Re-admission</td>
<td>4</td>
<td>3</td>
<td>6</td>
<td>12</td>
</tr>
<tr>
<td>Complications</td>
<td>1</td>
<td>0</td>
<td>-</td>
<td>3</td>
</tr>
<tr>
<td>Mortality</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
</tbody>
</table>

**Table 4.5:** Definitive Treatment For Gallstone-related Acute Pancreatitis. Re-admission, complications, and mortality due to non-operated gallstone acute pancreatitis.
Chapter 5

“To have... or not to have...”

Should CT and U/S scan be implemented as a routine work-up for patients with suspected acute appendicitis in a regional hospital?

Abstract

Background

Appendicitis is a common diagnosis, but is by no means a simple one to establish. This retrospective study investigated the value of medical imaging (U/S and/or CT scan) for patients with suspected appendicitis. Negative appendicectomy rate and appendiceal perforation with or without medical imaging were used as end points for this investigation.

Methods and Materials

This study retrospectively reviewed all patients admitted in one district general hospital with suspected acute appendicitis. The patient cohort was identified from the Unit Registry and an International Classification of Diseases-based Review of medical records. The medical records were analysed, and the outcome of patients were followed up.

Results

Between 12/01/2004 to 27/05/2005, 168 patients’ medical records were audited. The negative appendicitis rate was 6.7% and appendiceal perforation rate was 3.2%.
Among them only twenty inpatients (12%) had medical imaging (U/S and/or CT scan) after clinical assessment for suspected acute appendicitis. Medical imaging had a 70% prediction rate for acute appendicitis, 20% false negative rate, and 10% false positive rate.

Overall, the prediction rate for appendicitis by clinical assessment supplemented by laboratory tests and medical imaging at clinician’s discretion was 93.2%.

**Conclusion**

Despite studies advocating routine use of medical imaging for patients with suspected acute appendicitis, this study showed that the clinical evaluation is still paramount to the management of patients with suspected acute appendicitis before considering medical imaging.

**Keywords:** Acute appendicitis, RIF, RLQ, District General Hospital, Clinical assessment, CT scan, US scan

**Introduction**

Surgery for pain in the right lower quadrant of the abdomen remains a clinical dilemma. Acute appendicitis is traditionally a clinical diagnosis, however not all patients present with the ‘classical’ symptoms and signs of acute appendicitis. Although patients with atypical symptoms and signs can be admitted to hospital for a period of observation, laboratory tests and medical imaging that may culminate in a diagnostic laparoscopy, this approach can be associated with its own morbidity and financial costs. Recent studies advocated medical imaging, mainly helical CT and U/S scans, for management of this condition [92-97].

The dilemma in the clinical diagnosis of acute appendicitis is to balance diagnostic accuracy with appendiceal perforation. Centres with the most accurate diagnosis (89%) have higher rate of appendiceal perforation (29%), and vice versa, presumably due to earlier operation [98, 99].
This retrospective study was designed to audit the experience of managing patients with suspected acute appendicitis by the conventional approach at a district general hospital. If the result was not satisfactory when compare to other centres, a protocol CT and/or U/S scan (as advocated by some) would be instituted and a prospective audit conducted.

**Patients and Methods**

This study was a retrospective audit of patients over 15 years of age who presented to the emergency department of Latrobe Regional Hospital (LRH), Australia, between 12th January 2004 and 2nd July 2005. LRH located at 150km east to Melbourne. The hospital consisted of 250 beds and specialties including general surgical, gynaecology, urology, orthopaedic surgery, general medical, paediatric and psychiatry. The clinical diagnosis was established by a senior general surgeon in all patients. Management, including discharge home, laboratory tests, medical imaging, admission for observation, and operation (laparotomy or laparoscopy) was based on the senior surgeons’ clinical assessment and discretion.

LRH is a district general hospital that received patients from both urban and rural communities, with a catchment of approximately 30,000 people. The clinical presentation was right iliac fossa (RIF) or right lower quadrant (RLQ) pain, where a diagnosis of acute appendicitis was considered. Occasionally, referrals from other units for suspected appendicitis, especially gynecology and pediatric, are included. Patients were initially assessed by the emergency department staff and referred to the general surgical units if acute appendicitis was suspected. Preoperative evaluation included documenting the medical history, physical examination and laboratory tests (including pregnancy tests if appropriate) all at the discretion of a surgeon at the on-call general surgical unit. Exclusion criteria were signs of acute bowel obstruction, contraindication to surgery, and contraindication to general anaesthesia. Signs of acute pancreatitis or acute aneurysm of the abdominal aorta or iliac arteries on laboratory tests and/or medical imaging were
considered to be stopping points. The patients having laboratory tests, medical imaging, referral to other units, an operation, admission for observation, or discharge home depended on the clinical assessment of the senior surgeons.

Patients with ‘classical’ clinical symptoms and signs of acute appendicitis might undergo appendicectomy without pre-operative laboratory tests or medical imaging. Patients with equivocal clinical findings and laboratory tests might subsequently undergo a helical CT and/or a U/S scan for further assessment at the surgeon’s discretion. The choice of imaging modality was made by the surgeon at the time of assessment. These imaging were reviewed by the attending radiologist.

Detailed information on each patient, including clinical findings, results of laboratory tests, preoperative US and/or CT scan, operative finding, and the histopathology report was recorded and analysed. The end points of the study included negative appendicectomy and appendiceal perforation.

All CT scans were performed with a helical CT scanner (10 multi-slide Phillip® MX8000), and no oral or rectal contrast was used. The primary criteria used to establish the diagnosis of appendicitis included an abnormal appendix, presence of an appendicolith, peri-appendiceal phlegmon or abscess and peri-appendiceal inflammatory changes, such as fat stranding of the mesoappendix or adjacent retroperitoneal fat. An abnormal appendix was defined as a distended fluid-filled, blind-ending tubular structure (‘double halo’ or ‘target sign’) with a thickened wall greater than 6mm in diameter. Peri-caecal inflammatory change were defined as fat clouding or stranding, local fascial thickening, local fluid collections or phlegmon, or abscess formation [93, 98-101].

U/S scan (Toshiba, Tochigi, Japan) was performed with high-frequency, Linear C5-2 or Linear array 12-5 MHz transducers depending on individual circumstances. Scanning was performed with the patient having a full bladder, to optimize imaging of the pelvic organs. The point of maximum tenderness in the right lower quadrant was identified, and gentle graded compression of the caecal pole was performed to displace bowel gas. The study was completed by examination of the pelvic organs. U/S scan diagnosis of appendicitis was based on visualization of a non-compressible,
tubular, non-peristaltic, blind-ending structure, 6 mm or greater in diameter; or the presence of an appendicolith with a normal sized appendix. The appendix had to be constant in position and shape on imaging. Other sonographic findings were considered to be non-diagnostic if seen in isolation. These included a disruption of the echogenic line of submucosa (indicating necrosis of the appendiceal wall), a peri-appendiceal mass, and localized or general free peritoneal fluid [101-104].

Follow-up of both operated on and non-operated on patients included completion of post-operative and post-discharge records one day, two days, one week and six weeks after discharge. Other data collected included operation note, hospital stay, pathological diagnosis, complications and change of diagnosis and treatment after discharge. The definitive diagnosis was made with operative findings and the histology report.

A general surgical trainee, an intern and general practitioner who were not directly working for the surgeons or the radiology department of LRH were involved in this project to limit bias and confounding factors while collecting the data.

Results

There were 168 consecutive patients presented to LRH who were included in this study; age ranging from 6 to 81 years (mean age, 20.4), 98 males and 70 females.

One hundred and thirty-two patients had an ‘immediate’ appendicectomy, of which were 46 open and 86 laparoscopic surgery. There were 10 negative appendicectomies (6.7%). All of them were diagnosed with ‘appendicitis’ on clinical grounds supplemented by laboratory tests if required, but they did not have any medical imaging before operation. Although five patients had normal appendices, they had other major abdominal or pelvic pathology that required surgery. One patient had torsion of a fallopian tube with very extensive hemorrhage, one had rupture of a large ovarian cyst with extensive hemorrhage, one had a ruptured Meckel’s diverticulum and one adenocarcinoma of the caecum. They all received appropriate operation and
no major complications had been recorded after six months of follow-up. Five patients had a normal appendix and no major abdominal or pelvic pathology was encountered. Therefore, the true negative appendicectomy rate was 3.2%.

Twenty patients with equivocal presentations had in-patient U/S and/or CT scans. Sixteen scans accurately diagnosed acute appendicitis or revealed normal appendix (consistent with clinical assessment). Hence the sensitivity of medical imaging was 70%. However, there were four false-negatives (three U/S scans and one CT scan; 20%). These patients were admitted for observation (based on clinical assessment) and were all eventually operated on to remove the appendix (two open and two laparoscopic). All four had appendicitis according to their histopathology report. There were two false-positives (one on U/S and one on CT scan; 10%), One patient had an U/S scan showing signs suggestive of possible appendicitis. He was unwell and had laparoscopic appendicectomy for a normal appendix on histopathology report. He subsequently improved after operation. The other patient had U/S scan and showed signs suggestive of a possible appendicitis. She was admitted for observation on the ward and improved clinically without surgery. She was discharged home, and followed up at outpatient clinic. There has been no documented complication to date.

Regarding appendiceal perforation, seven (3.2%) had appendiceal perforation, five of which had an appendicectomy immediately after review (no laboratory and/or medical imaging) and two of which had appendiceal perforations occurring during the operation. There was no appendiceal perforation due to delay for observation.

Thirty-six patients were admitted to hospital for observation. Six eventually had an appendicectomy; four had appendicitis with no perforation, while two had normal appendices (discussed in previous section). Seven patients were admitted for observation, and had further laboratory tests and medical imaging. The tests and medical imaging were all normal, and they improved clinically and were discharged without operation. Eighteen were admitted for observation on the ward. They clinically improved and were discharged home without the need for operation or medical imaging.
The study was ceased at this point. The preliminary result of this study has demonstrated that management of patients with suspected acute appendicitis by clinical assessment and performing laboratory tests and medical imaging as appropriate was satisfactory. With known cost, limitations and side effects of CT and U/S scans, the ethical committee of the hospital had decided not to proceed with the implementation of medical imaging (CT scan) for suspected appendicitis as routine work-up.

Discussion

In the western world, the lifetime risk of acute appendicitis is 6.7% for females and 8.6% for males. However, the lifetime chance of appendicectomy is higher as suggested by Berry and Malt who reported that the average negative appendicectomy rate can be as high as 20% [105, 106]. Hence the negative appendicectomy rate is high. Recent studies on advocating the CT scan with or without rectal contrast and US scan for diagnosis of appendicitis have appeared in the medical, paediatric, radiological, emergency and surgical literature which have had an enormous influence on the practice and claimed to be able to reduce negative appendicectomy and costs of admitting patients for observation without additional co-morbidity to the patients [92, 94, 96, 107]. In many centers, medical imaging has been included in the routine work-up for patients with suspected appendicitis.

However, studies advocating the use of medical imaging to diagnose appendicitis were mostly conducted at tertiary or specialist centers where professional and technical expertise in this field can be difficult to replicate in another centre [93, 108]. In addition, protocols for imaging patients with suspected acute appendicitis have not yet been standardized, so variable interpretation of the imaging and patients’ outcome may be expected as this study found as well [96, 101].

The quality of care in this study, using as indicators the rates of appendiceal perforation (7; 3.2%) and the rates of true negative appendectomy (5; 3.2%), was satisfactory when compared with other studies.
(including those that had medical imaging as their routine work-up) [92, 96, 107, 109, 110]. Five of 10 negative appendicectomies were found to have other major pathology, which would still need surgery anyway. Two of seven appendiceal perforations occurred during surgery. Hence there were only five appendiceal perforations, therefore making the true perforation rate 2.2%. It should also be noted that there was no delayed appendicectomy because of undue observation. A diagnostic strategy based on the clinical acumen of a general surgeon supplemented with laboratory tests at clinician discretions has shown to be satisfactory. This strategy may be generalized to a regional centre than at a tertiary referral centre where the protocols, technology, and technical expertise of radiologists and technicians might be unique.

In this study, only 20 equivocal cases had helical CT and/or U/S as inpatient. The sensitivity and specificity of the medical imaging were not as convincing as suggested by some. The result was obviously due to only 12% of cases having medical imaging in this series which was not statistically significant. Nevertheless, the medical imaging may only be needed for clinically equivocal presentations. For patients with ‘classical’ symptoms and signs of acute appendicitis or ‘acute abdomen’ requiring operation, the additional benefit from medical imaging is debatable [111].

Despite studies advocating CT and/or U/S scan for diagnosing appendicitis, these studies had false-negatives too [96, 112], which might lead to serious consequences if a clinician solely relied on medical imaging to diagnose appendicitis and make the clinical decision to operate or discharge a patient, especially in a rural area. In the situation of a patient with negative medical imaging, the clinician should always consider individual circumstances before discharging the patient. In this study, there were four equivocal cases where medical imaging did not show signs of appendicitis, but eventually received a laparoscopy and appendicectomy. They all had histopathologically proven appendicitis.

Because appendicitis is an evolving pathological process, and early appendicitis can be impossible to differentiate from other causes of abdominal pain, clinical re-evaluation after a period of observation and supportive care could be appropriate [113]. However, cost analysis may be biased towards rapid testing and medical imaging to make the diagnosis. If appendicitis can
be ruled out (by testing and/or medical imaging), the patient should be sent home from the emergency department or diverted to another specialty [114]. In an urban setting, this strategy may be successful, especially where patients don’t live far from the hospital. However, in a rural hospital, discharging a patient with a clinical suspicion of appendicitis and normal medical imaging might not be a safe option.

Benedeck et al reported using helical CT without oral or rectal contrast could achieve an acceptable accuracy rate of diagnosing appendicitis [95], which eliminates the discomfort and hassles of contrast administration, especially in children. However, the radiation from CT scans can still cause a increased lifetime risk of malignancy [115], which is particularly serious in paediatric patients and is harmful to pregnant patients. The benefits of imaging include eliminating inpatient observation and unnecessary surgery, as advocated by others [92, 107, 116] must be weighed against the malignancy risk from radiation, as well as financial costs.

Although an U/S scan is safe with pregnant women and free of radiation-induced malignancy, it has several limitations. These include the inability to visualize the appendix in individuals when abandon bowel gas or an empty urinary bladder, limited views in obese patients; the inability to compress the underlying bowel in cases with severe pain, and a decreased specificity associated with perforation. Ultimately, the sensitivity and reliability of scan is largely dependent on the experience of the technicians [96, 104, 107, 117].

In this study, only six in-patient scans were conducted after-hours, which certainly saved on the cost of re-call staff to perform scans and radiologists to interpret the imaging. Therefore, the cost of staff and running the machinery certainly need to be taken into consideration when conducting cost-effective analysis and comparison.

Improved technology does not always translate into improved diagnosis and patient outcomes. Weyant et al reported their experience of 625 patients with appendicitis but found no correlation between CT findings and pathologically proven appendiceal disease [118, 119]. A previous population-based study on this subject was conducted during the 12-year period from 1987 to 1998 when CT, U/S, and laparoscopy were improving and
advancing. Contrary to expectation, the incidence of negative appendectomies and perforation did not change with the availability of advanced diagnostic testing [120].

Although these medical imaging modalities might not be considered as a diagnostic routine for patients with suspected appendicitis, they still have roles in patients with right iliac fossa pain where other pathology is suspected. U/S scans can be useful to identify gynaecological pathology, such as ovarian cysts, which is helpful in explaining the cause of symptoms. Also, a CT scan can be useful when other causes of right iliac fossa are suspected, such as inflammatory bowel disease and ureteric calculi. In addition, both medical imaging modalities were found useful in demonstrating peritoneal fluid which might explain patient's symptoms and signs [92, 99, 107, 109, 110, 117]. Subsequently, the finding might lead to diagnostic laparoscopy with clinical co-relation. In addition, medical imaging has prevented ‘missed appendicitis’ in two equivocal presentations in this series. We believe that there is definitely a role for medical imaging, as long as its result is co-related to clinical assessment.

**Conclusion**

We found that clinical assessment supplemented with laboratory tests and medical imaging if appropriate for patients with suspected acute appendicitis was satisfactory. In this study, U/S and CT scans were only used in equivocal cases. We found that the scans must be interpreted within the clinical context. Protocols on the routine use of medical imaging may need to be further investigated and standardized before implementing it as a part of work-up for patients with suspected acute appendicitis.

**Acknowledgement**

The authors would like to acknowledge the contribution of Dr. K. Xu for collecting data at the initial period of the study.
Chapter 6

Laparoscopic inguinal hernia repair with totally extra-peritoneal approach, but without disposable instruments

“Cutting the cost”

Abstract

Introduction

One disadvantage of laparoscopic inguinal hernioplasty with the totally extra-peritoneal approach (TEP) is the cost associated with disposable instrumentation to establish and maintain the preperitoneal space. A prospective audit and cost-analysis on this approach with and without disposable instruments was conducted at the Royal Hobart Hospital, Australia.

Method and Material

Without the disposable balloon expanders, forty-seven consecutive cases were reported using digital dissection, supplemented by movements of a 30-degree laparoscope, and further dissection with laparoscopic forceps to establish the preperitoneal space during hernioplasty.

Detail information on the patient’s pre-, intra-, and post-operative finding has been audited for both laparoscopic inguinal hernioplasty techniques, with and without disposable instruments. In-hospital cost analysis was conducted for theatre time, cost of laparoscopic and disposable instruments for comparison.

Result

The overall cost saved by not using disposable instrumentation was around $AU 19,000 for 47 cases. The difference in theatre time used was essentially not significant.

Disposable balloon expanders were still required in three cases (8.2%) due to gas leakage, and one conversion to open procedure (2.6%) due to
profuse bleeding and two post-operative complications, including one seroma and one post-operative urinary retention.

**Conclusion**

Without the specially designed balloon expanders, the pre-peritoneal space was established and maintained in most cases. Therefore, this modification on the TEP approach could be considered safe and effective, and should be attempted initially. Nevertheless, in difficult cases, the disposable balloon expanders would still be required.

**Key words:** Inguinal hernia, Laparoscopic hernioplasty, Totally extraperitoneal approach (TEP), Disposable instrumentation, Balloon expanders

**Introduction**

With the advance of laparoscopic instruments and techniques, laparoscopic repair of inguinal herniae has been gaining popularity [121, 122]. Several authors have reported with the totally extraperitoneal (TEP) approach as being a safe and effective technique [123].

But laparoscopic inguinal hernia repair with the TEP approach involves disposable dissecting and structural balloons to establish and maintain the extra-peritoneal space during hernioplasty, and the cost associated with these disposable instruments is considerable [124].

We report our technique of establishing and maintaining the extra-peritoneal space for the hernial repair without using the specially designed disposable instruments at the Royal Hobart Hospital, Australia.

Cost-analysis was conducted to investigate the advantages by the laparoscopic inguinal hernia repair with and without the disposable instrumentation.

**Technique**

A transverse skin crease incision, 15-20mm long, was made alongside the umbilicus on the opposite side to the inguinal hernia. The underlying
rectus sheath was exposed and a transverse incision was made in the anterior rectus sheath, exposing the underlying rectus muscle.

Digital dissection was performed to separate the rectus muscle from the posterior rectus sheath. When the lower margin of the posterior rectus sheath was reached, further extraperitoneal dissection was done to facilitate the movement of the instruments. A stay suture (1/0 Vicryl) was placed in the anterior rectus sheath. All movements were performed under direct vision.

The 10mm Hasson cannula was threaded through a square foam (Figure 6.1). The rectus muscle was retracted anteriorly, and the Hasson’s cannula was placed into the pre-peritoneal space under direct vision. The cannula was advanced toward the pubic symphysis. The stay suture was tied around the foam to create a seal (Figure 6.2).

Figure 6.1 10 mm port through a square foam
To further establish the preperitoneal space, a 30-degree laparoscope was inserted and small vertical and horizontal movements performed to break down the soft adhesions between the peritoneum and the anterior abdominal wall to create a tunnel to the pubic symphysis (Figure 3). Two 5-mm working ports were then inserted under vision and with aid of illumination of the 30-degree scope through the abdominal wall to avoid perforation of vessels.
The extra-peritoneal space was expanded by blunt dissection with laparoscopic forceps via the two 5-mm ports. Insufflation of gas maintained the space (Figure 6.4). The sac was reduced and a 10*15cm polypropylene mesh placed. Four tackers were normally used for mesh fixation, but more may be used depending circumstances.

Figure 6.4 Laparoscopic view of an inguinal hernia without disposable balloons

Cost Analysis, Patients, and Methods

There were general surgeons performing laparoscopic inguinal hernia repair with TEP approach and disposable instruments for unilateral, bilateral, recurrent hernia in the Royal Hobart Hospital. Therefore the comparison between these two techniques was rather straightforward.

In-hospital cost analysis was conducted for laparoscopic inguinal hernia repair with TEP approach with and without disposable instrumentation (balloon expanders and cannulae) during this period of time. Cost of non-disposable laparoscopic instruments, disposable instruments, theatre time, recovery period, length of hospital stay, and analgesia requirement on the ward, outpatient review for both groups was collected and analysed by the medical record, theatre, pharmacy, and financial department.
Statistical Analysis

Statistical analyses were carried out using SPSS (Chicago, IL, USA), and Analyse-it (Microsoft, Redmond, WA, USA) for the time and cost for patients of the two different groups. $P$-values of $<0.05$ was considered to be statistically significant.

Results

Forty-seven consecutive laparoscopic inguinal hernioplasties were performed without disposable instruments between October 2002 and September 2004 at the Royal Hobart Hospital, Australia. There were two female and 45 males with age ranging 34 to 77. Among them, 13 patients had recurrent inguinal hernia and 11 had bilateral herniae.

Forty hernioplasties were performed by the senior author (laparoscopic general surgeon) and seven performed by the two general surgical trainees under supervision of the senior author. One case (2.6%) was converted to open repair due to profuse bleeding that was unable to stop despite multiple attempts with laparoscopic instruments. The patient was an obese male with bilateral inguinal hernia. This case took 52 minutes to complete. In three patients (two primary unilateral and one recurrent), the pre-peritoneal space was difficult to maintain with this technique due to perforation of the peritoneum and consequent filling of the peritoneal cavity with gas and loss of the extra-peritoneal working space, and structural balloons were used to complete the repairs. The average time to complete these cases was 51 minutes.

Three patients had to stay in hospital overnight due to their social circumstances, and one patient developed post-operative urinary retention. One patient developed a post-operative seroma two weeks later that required aspiration for symptomatic relief.

For the group of repair without disposable instrumentation, the average time spent was 48 minutes for bilateral repair, 46 minutes for recurrent herniae and 38 minutes for unilateral primary repair. Three bilateral repairs performed by the general surgical trainees, the average time was 51 minutes.
Four unilateral repairs performed by the trainees, the average time was 41 minutes.

There were also 47 consecutive laparoscopic repairs with TEP approach with disposable instruments. Twelve were bilateral herniae, 12 recurrent herniae, and 23 unilateral primary herniae. The average time spent for unilateral primary hernia repair was 37 minutes, 44 minutes for recurrent herniae, and 48 minutes for bilateral herniae.

After statistical analysis, the difference in time spent for two different techniques (with and without disposable balloons) were not statistically significant ($p>0.05$).

After cost analysis by the financial department, the major difference between these two groups was the cost of the disposable instruments, especially the balloon expanders. The cost per case the group with disposable instruments was around $AU 1951$, whereas the average cost per case with non-disposable laparoscopic instruments was around $AU 1526$. The cost of disposable balloon expanders and cannulae for laparoscopic inguinal hernioplasty was quoted from Tyco®, Australia, was around $AU 430$ for one case. Despite three cases still required balloon expanders and one conversion to operation repair, the cost saved for 47 cases without disposable instruments at first attempt was around $AU 19,000$ ($p<0.05$).

The total number of tackers used for Group One was 248 and the Group two was 253. These numbers included wastage and some cases required more than four tackers at the surgeon’s discretion. The cost of the tackers in each group has been included in the cost analysis.

<table>
<thead>
<tr>
<th></th>
<th>Unilateral primary inguinal hernia (min)</th>
<th>Recurrent inguinal hernia (min)</th>
<th>Bilateral inguinal hernia (min)</th>
</tr>
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<tbody>
<tr>
<td>With disposable instrumentation</td>
<td>37</td>
<td>44</td>
<td>48</td>
</tr>
<tr>
<td>Without disposable instrumentation</td>
<td>38</td>
<td>46</td>
<td>48</td>
</tr>
</tbody>
</table>
Table 6.1 Theatre time for laparoscopic inguinal hernia repair (TEP), with and without balloon

<table>
<thead>
<tr>
<th></th>
<th>With disposable instrumentation</th>
<th>Without disposable instrumentation</th>
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<tr>
<td>Average cost per case</td>
<td>$ AU1,951</td>
<td>$AU 1,526</td>
</tr>
<tr>
<td>Total cost (47 cases)</td>
<td>$ AU 92,703</td>
<td>$AU 72,898</td>
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Table 6.2 Average cost per case for laparoscopic hernia repair (TEP) in Australian dollars

Generally, the post-operative follow-up of patients ranged from two weeks to six months, and this follow-up regime was the same for both groups.

Discussion

The cost saved by not using the disposable instruments was obviously substantial when the operation time and complication rate were not increased.

Optimal operative procedures for the repair of inguinal hernia are still matters for debate [125, 126]. Although the laparoscopic approach is gaining momentum and acceptance [126], some may still argue open technique over laparoscopic repair for first time unilateral inguinal hernia. However, the choice should belong to the patient after thorough discussion of advantages and disadvantages of different options [127].

The two most common laparoscopic techniques are the transabdominal (TAPP) and totally extraperitoneal approach (TEP). The TEP approach is essentially identical to the TAPP approach with the exception that the procedure is performed entirely in the preperitoneal space and with the advantage of not entering the peritoneum proper. Ramshaw and others compared different techniques of laparoscopic hernioplasty and showed that complications of intra-abdominal injuries and bowel obstruction caused by
adhesions at the site of peritoneal closure are more frequently associated with the TAPP approach than the TEP [122]. Although some may argue primary unilateral inguinal hernia should be repair with open technique, the choice should belong to the patients after thorough discussion of different options.

Although laparoscopic inguinal hernia repair has been criticised for its technical difficulty and long learning curve especially with TEP approach due to less familiar anatomy and limited working space [128], the two first-year general surgical trainees were able to perform this procedure within a reasonable operating time under the senior author’s supervision. Furthermore, Lal and others had reported their experience of establishing the learning curve with TEP approach laparoscopic repair and instituted a working protocol for educating a surgeon to perform this technique which could potentially eliminate the steep learning curve [126, 129].

Although there was no increased morbidity and recurrence associated with this approach (laparoscopic inguinal hernia without disposable balloon expanders) when comparing with other techniques [128], there were only limited number of cases and short-term follow-up in this study. Therefore, further studies should be recommended to investigate post-operative pain control and any long-term complications, such as recurrence and incisional hernia associated with this technique. Also, a comparative study of open mesh repair and this technique would be valuable and currently underway, since one of the disadvantages (when compare with open repair) associated with most laparoscopic inguinal hernia repair techniques was the cost. The data of the study may provide an insight of cost comparison of these two distinct techniques.

In cases of less familiar anatomy, poor laparoscopic vision, and gas leakage, the dissection and structural balloon expanders should be utilised to provide better visual field. In this study, the pre-peritoneal space was poorly maintained in three cases due to perforation of the peritoneum, and the disposable balloon expanders were used to complete the procedures. Also, due to individual preference of techniques, only two surgeons continued to perform laparoscopic inguinal hernia repair without disposable instruments at first attempts.
Conclusion

The TEP approach of laparoscopic inguinal hernial repair without disposable balloon expanders was safe and successful in nearly all cases. This technique should be attempted initially to establish and maintain the preperitoneal space during hernioplasty. The specially designed disposable instruments should be reserved for difficult cases.
Chapter 7

Guide-wire Assisted Urethral Dilatation for Urethral Strictures in Paediatric Urology
Abstract

Purpose:

To report the results of 32 cases of dilatation of urethral stricture using a guide-wire and sheath dilator technique, supplemented by clean intermittent catheterization if further stabilization of the urethral stricture was felt warranted.

Materials and methods:

The procedure involves insertion of a straight flexi-tip lubricated guide-wire through the urethral stricture under cystoscopic guidance, followed by insertion of a series of sheath dilators. Dilatation was followed by insertion of a Foley catheter, which was left in situ for 1 to 3 days. Patients underwent repeat cystoscopy to evaluate the urethra for recurrent stricture and those with a recalcitrant stricture were commenced on clean intermittent catheterization (CIC) to stabilize the narrowing.

Results:

Thirty-two patients were included. They have been followed for up to two and half years after their last cystoscopy (mean = 16 months). Thirteen of 32 patients had more than four dilatations under anesthesia. Twelve patients had undergone CIC post-operatively. Complications included a urinary tract infection in three boys and bladder spasms in one. No false passage or sepsis occurred with this approach.

Conclusions:

Guide-wire assisted urethral dilatation avoids risks associated with blind dilatation techniques and appears to be a safe and simple alternative for management of urethral strictures in pediatric urology.

Key Words: guide-wire assisted, urethral stricture, dilatation, urinary tract
Introduction

In many ways, management of urethral stricture disease in children parallels that in adults, however technical demands made by the small size of the stricture and delicacy of tissue involved provide more of a challenge [130]. Visual urethrotomy and urethroplasty yield promising results in management of a scarred urethra [131, 132]. Nevertheless, surgical correction does require hospitalization, a major surgical procedure (or multiple procedures), and is usually reserved for complicated cases [133, 134].

Although urethral dilatation with a conventional “blind” approach does occasionally cure stricture disease, most strictures recur and gradually worsen, especially in pediatrics, with a risk of the development of a false passage [132, 135].

We report our experience with guide-wire assisted urethral dilatation of urethral strictures.

Materials and Methods

From 1999 to 2002, 32 children were referred to the senior author for management of urethral strictures.

Patients were admitted to the day surgical unit. Under caudal and general anesthesia and the patient in the lithotomy position and analgesic jelly in the urethra, a cystoscope was introduced and advanced to visualize the stricture. A straight flexi-tip guide wire, Cook Urology®, was inserted through the stricture via a cystoscope (Fig 1). This wire was then used to guide the dilatation after withdrawal of the cystoscope. Each stricture was serially dilated with well-lubricated sheath dilators until the largest appropriate size (according to age/size of the patient) was passed. The cystoscope was then re-introduced to ensure sufficient urethral dilatation had been achieved, and allow assessment of the degree of trauma. A Foley catheter was left in situ for one to three days to stabilize the dilatation, as shown in Fig 2-1,2. Foley catheter insertion was achieved by threading with a 22 gauge intravenous catheter retrograde through the tip of the catheter and out through the eye of the catheter. The needle was removed leaving the plastic cannula in situ,
through which the guide-wire was passed. The Foley catheter was then advanced over the guide-wire and into the bladder. Patients received a standard dose of antibiotic cover in the theater as for routine urological procedures.

**Follow-up**

Patients were followed in the out-patient clinic and assessed cystoscopically. When urethral strictures recur over a short period of time at follow-up cystoscopy, patients would require CIC with appropriately sized Foley catheters for stabilization of the urethral dilatation. Nevertheless, age of the patient, cause of urethral stricture, level of difficulty when passing the dilators previously, and social situation of the patient would all be taken into consideration when prescribing CIC.

**Results**

Thirty-two patients with urethral stricture were included in this study. The patients’ ages ranged from 1-18 years, with a mean of 5.6 years. The etiology of the urethral stricture included post-hypospadias repair in 26 children, Cobb’s Collar in three patients, congenital obstructive posterior urethral membrane (COPUM)* [136, 137] in two, and idiopathic urethritis in one. Among the 26 patients with a urethral stricture after hypospadias repair, ten patients had distal and 16 had proximal hypospadias disease initially.

Clinical presentations included a decreased stream in 16 patients, difficulty voiding in seven, dysuria in three, urinary retention in five, and bladder spasm in one patient.

Under direct vision, urethral strictures were seen to be close to the meatus in 11 patients, at the proximal glans in six, and in the penile urethra in 15 patients.

Guide-wire assisted urethral dilatation was performed 108 times among 32 children. Nineteen patients had one to three procedures, ten had four to seven dilatations and three problematic cases required eight, nine and eleven dilatations, respectively.

* COPUM is a term recently coined as a reclassification of posterior urethral valves.
Twelve of the 32 patients went on to have CIC. The causes of urethral stricture in this subgroup included a congenital obstructive urethral membrane in one patient, idiopathic urethritis in one, distal hypospadias in two, and proximal hypospadias in eight patients. Four of the 12 have completed the course of CIC and are free from stricture recurrence. One patient did not continue with CIC because of increasing difficulty of catheterization, resulting in optical urethrotomy as the definitive treatment.

Follow-up of this guide-wire assisted urethral dilatation ranged from seven to 30 months, with mean follow up of 16 months. With this technique, 27 patients (84.3%) had a satisfactory result with respect to the urinary stream and the subsequent cystoscopic findings.

Five patients (15.7%) required further surgical interventions. Three patients underwent urethrotomy, one had a meatotomy, and one had an open urethroplasty.

Bladder spasm developed in one patient and urinary infections in three. No urethral injury or false passage was induced by this technique.

**Discussion**

Conventional ‘blind’ dilatation techniques with bougies and followers for urethral stricture commonly traumatize the urothelium, leaving a bleeding raw area that will heal by scarring and lead to further stricture formation [138-140]. Other complications associated with conventional dilatation techniques are creation of a false passage, impotence, incontinence, and rupture of the rectum and other neighboring organs. These complications are common when a narrow tunnel is located eccentrically in the urethral cross section and the urethra does not taper gradually onto the stricture. [134, 140]. In contrast, if a guide-wire is placed through the stricture endoscopically the dilatation is subsequently directed appropriately, allowing precise and safe dilation. Our results in 32 patients are encouraging, as no false passages have occurred with this procedure.

Insertion of a Foley catheter, following dilation, is used to hold the newly opened tissue apart to prevent potential urethral adhesion and
recurrence of stricture. Although the indications for and period of insertion of the catheter after urethral dilatation in paediatric cases is not yet universal, the clinical outcome using a Foley catheter after urethral dilatation with inflatable balloon and urethrotomy in adult urology has shown initial and sustained improvement [134, 141, 142]. To add safety and simplicity for insertion of the Foley catheter, the guide-wire is used to assist the advancement of the catheter into the bladder. So far, we have not encountered major technical difficulty or urethral trauma with this method.

Previous studies [143, 144] suggest that clean intermittent catheterization (CIC) with an appropriately sized catheter in selected adult patients after urethral dilatation can prevent recurrence of the stricture and avoid regular dilatation in the hospital. In this study, 12 (age ranges from 3 to 15 years) patients had their “in-theater” dilatation supplemented with CIC. Four of the patients have ceased CIC and are free from stricture recurrence. Two of the patients could not continue with their course of CIC; one didn’t have sufficient parental supervision and the other patient could not tolerate CIC well. In both, the urethral stricture recurred within two months. One required further dilatation and the other required optical urethrotomy. It seems that supplementing urethral dilatation with CIC in children is acceptable.

Guide-wire assisted urethral dilatation is shown to be a safe and simple alternative in management of urethral strictures in paediatric cases. Insertion of a Foley catheter at the end of the procedure and using clean intermittent catheterization in selected patients may reduce the number of patients requiring regular definitive surgery.
Figure 7.1 A and B: An intravenous cannula (size 22) was threaded retrogradely through the tip of a Foley catheter, and out through the eye of the catheter. The needle was removed leaving the plastic cannula in-situ.
Figure 7. 1 C and D: Through the plastic cannula, the guide-wire was passed. The Foley catheter was then advanced over the guide-wire and into the bladder.
Chapter 8

Guide-wire assisted urethral dilatation in paediatric urology

– Experience of a single surgeon

Abstract

Purpose

A simple and safe technique to dilate urethral stricture using guide-wire and sheath dilator in paediatric urology has been described. The purpose of this study is to report the long-term outcome of children who had this procedure.

Methods and Material

From 1999-2004, 52 children with documented urethral strictures were managed using this technique. Information on cause of urethral stricture, operation note, post-operative recovery, follow-up cystoscopic appearance, and patient’s outcome were audited and analysed.

Results

The follow-up study with this guide-wire assisted urethral dilatation has been for six and half years (mean 4½ years). Five minor urinary tract infections and three patients with bladder spasm have been reported after this procedure. No false passage or sepsis was encountered with this approach!

22 patients did not require any further surgical treatments. However, urethral stricture in 13 patients had progressed significantly.
Conclusion

Guide-wire assisted urethral dilatation avoids the risks associated with blind dilatation techniques, and continues to be a safe alternative for urethral strictures in selected cases.

However, only 42% of patients became ‘recurrence-free’ after two dilatations and 25% with strictures had progressed significantly, and definitive surgical interventions were required.

Introduction

The management of urethral stricture in children is similar to adults in some ways, nevertheless due to the small size of the urethra and delicacy of paediatric tissue, the tasks can be technically challenging [130]. Although some urethral strictures can be treated with conventional dilatation, the “blind” approach can cause false passages and other significant complications [132, 135]. Although optical urethrotomy and urethroplasty can produce promising results in management of a scarred urethra [145], surgical correction requires hospitalization, a major surgical procedure (or multiple procedures), and is usually reserved for complicated strictures [146].

A technique for safe urethral dilatation in paediatric cases has been described, and a short-term patient’s outcome reported. The technique basically involved a guide-wire placed through the stricture under cystoscopic guidance, and the dilatation was subsequently directed appropriately, allowing precise and safe dilatation. The short-term outcome of this technique was impressive, with 84.3% of patients had a satisfactory result, in terms of the urinary stream and the subsequent cystoscopic findings [147]. However, the long-term outcome of this technique and effectiveness of urethral dilatation remained unknown. This retrospective study aims to investigate the long-term safety and efficacy of this technique on children with urethral stricture based on the experience of a single surgeon.
Methods and Materials

The medical records (from 1999-2004) of patients referred to the senior author for management of urethral stricture were retrospectively reviewed. All children were evaluated preoperatively with a complete history and physical examination, urine culture, cystoscopy (and urethrogram if clinically indicated, especially when delineation of anterior urethra was required). Boys with proven urethral strictures were managed by urethrocystoscopy and guide-wire assisted urethral dilation under general and caudal anaesthesia [147]. The only exclusion criteria was a complete occlusion of the urethra on urethrography. The cystoscopy could be used for diagnosis only, but more often the dilatation was performed during the same session. If there was a different diagnosis found during cystoscopy or not feasible to perform a urethral dilatation, the children would be managed otherwise.

All procedures were performed under prophylactic antibiotic cover using intravenous injection of 80 mg of gentamicin, unless contraindication and other antibiotics would be used. Patients were under general and caudal anaesthesia, and procedures were only performed by the senior author. Lignocaine jelly was first instilled into the urethra at the commencement of the procedure.

The patients were followed at three, six, nine months, one, two, three, four, and five years after the initial procedure. Patients were followed up in the out-patient clinic, and assessed cystoscopically or radiologically if suggested by symptoms of recurrence. When urethral strictures recur over a short period of time at follow-up cystoscopy, urethral dilatation would be repeated, and clean intermittent catheterization (CIC) might be recommended with appropriately sized Foley catheters for stabilization of the urethral dilatation if circumstances permitted. Age of the patient, cause of urethral stricture, level of difficulty when passing the dilators previously, and social situation of the patient were taken into consideration when prescribing CIC.
Result

Fifty-two consecutive patients with urethral strictures were managed with this technique and included in this study. The patient’s age ranged from 2-18 years, with a mean of 5.6 years (±2.3 years). Two hundred and thirty-five guide-wire assisted urethral dilatations were performed by the same surgeon. The children had been followed for up to 3.8 to 6.5 years with mean of 4.5 years (±2.4 years). Four patients had lost for follow up. Table 1 showed the patient’s demography and causes of stricture.

Twenty-two patients had one or two dilatations with no recurrence (suggested by symptoms and endoscopic appearance in selected cases) after two years and considered recurrence free (42%). Thirteen had progressed significantly based on symptoms, cystoscopy, and/or urethrographic appearance. Four patients eventually had urethrotomy, and nine required urethroplasty.

Eighteen patients required three dilatations and 12 more than three. But no patient had more than two dilatations in any 12 month period.

The complications of the procedures included three patients who developed cystitis and two had bladder spasms. All patients settled on appropriate treatment. The dilatation was unsuccessful in 11 occasions (5%) because of tight structuring or bleeding. There were five occasions in which bleeding had precluded the attempts of dilatations. In two, the cystoscopic vision was not optimal from urethral bleeding. The urethral lumen was not visualized. We had to insert suprapubic catheters with ultrasound guidance, and urethral bleeding had settled spontaneously. In three, and we didn’t perform urethral dilation, but we were still able to see the urethral lumen and insert glide-wires, then pass small urinary catheter over the wires. Again, the urethral bleeding settled without further intervention. Although bleeding had precluded the dilatations, bleeding settled on the ward, and patients didn’t require transfusion of any blood products. No patient developed a false passage or significant sepsis.

| Location of | N=52 |
Table 8.1: Location of Stricture

<table>
<thead>
<tr>
<th>Cause of urethral stricture</th>
<th>N =</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post-Traumatic</td>
<td>2</td>
</tr>
<tr>
<td>Urethritis</td>
<td>2</td>
</tr>
<tr>
<td>Idiopathic</td>
<td>4</td>
</tr>
<tr>
<td>Cobb’s Collar</td>
<td>4</td>
</tr>
<tr>
<td>Post-urethral Membrane</td>
<td>2</td>
</tr>
<tr>
<td>Post-operative – Hypospadias repair</td>
<td>38</td>
</tr>
</tbody>
</table>

Table 8.2: Cause of stricture

Table 8.3: Complications Associated With This Technique

<table>
<thead>
<tr>
<th>Complications</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cystitis</td>
<td>3</td>
</tr>
<tr>
<td>Bladder spasm</td>
<td>2</td>
</tr>
<tr>
<td>False passage</td>
<td>0</td>
</tr>
<tr>
<td>Significant sepsis</td>
<td>0</td>
</tr>
<tr>
<td>Aborted attempt to dilate urethra</td>
<td>11</td>
</tr>
<tr>
<td>Tight stricture</td>
<td>6</td>
</tr>
<tr>
<td>Haemorrhage</td>
<td>5</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Patients</th>
<th>N= 52</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recurrence-free</td>
<td>22 (42%)</td>
<td></td>
</tr>
<tr>
<td>After 1 dilatation</td>
<td>20 (38.4%)</td>
<td></td>
</tr>
</tbody>
</table>
After 2 dilatations | 2 (3.8%)  
---|---
Requiring CIC | 13 (25%)  
Unable to complete CIC | 4 (7.7%)  
Requiring other surgical alternatives |  
Urethrotomy | 4 (7.7%)  
Urethroplasty | 9 (17.3%)  

Table 8.4: Patient Outcome

Discussion

The management of the paediatric urethral stricture is controversial and there is considerable debate regarding to the long-term outcome of all approaches. While urethroplasty offers the best long-term outcome, the procedure should be performed by experienced paediatric urologists with expertise in reconstructive urology [145, 146]. However, even in the experienced hands, the post-operative complications are not minor [148]. This paper reported a safe and minimally invasive procedure that offered 42% of patients with ‘recurrence-free’ after one or two dilatations.

Complications associated with conventional ‘blind’ dilatation techniques are common, including recurrence with scarring tissue, creation of a false passage, impotence, incontinence, and rupture of the rectum and other neighboring organs. These complications can be made worse when a narrow tunnel is located eccentrically in the urethral cross section and the urethra does not taper gradually onto the stricture [134, 138, 140]. Therefore, if a guide-wire is placed through the stricture endoscopically the dilatation is subsequently directed appropriately, allowing precise and safe dilation. After 235 urethral dilatations were performed with this approach, there were no false passage or significant sepsis occurred.

To some urologists, dilation is not a cure. Bleeding from the urethra during dilatation means that the scar was torn and further mucosal and
spongy injury had occurred. The stricture will soon recur and result in worsened stricture length and density. In this study, thirteen patients (25%) with urethral stricture had multiple recurrences, with worsened cystoscopic and/or radiological appearance. These patients eventually required more definitive surgical alternatives, such as urethrotomy and urethroplasty. Although urethrotomy overall yields more definitive ‘recurrence free’ rate than urethral dilatation [149], the recurrence rate and associated morbidity should not be under-estimated [146, 150]. Even with insertion of a Foley catheter after dilatation and supplement with intermittent catheterization (CIC) in selective cases to prevent urethral adhesion and recurrence, this approach were only proven effective in some patients. Criticism has arisen from the patient selection for urethral dilatation and other surgical options. Certainly, the strictures that had recurred early after two dilatations, definitive surgical options should be considered [146]. However, the decision to perform ‘one-stop’ urethroplasty is a complex and challenging one, especially when considering long-term major morbidities in young children, such as erectile dysfunction and urinary incontinence[148].

Although the initial short-term audit reported 84.3% of patients had a satisfactory result with respect to the urinary stream and the subsequent cystoscopic findings [147], this long-term audit showed that the majority of patients (58%) required multiple dilatations, clean intermittent self-catheterization, or definitive surgery, such as urethrotomy and urethroplasty. We believe that this approach certainly was not for all urethral strictures, nevertheless this technique can be useful in settings, such as an alternative to suprapubic catheter, management of ‘simple’ strictures, and patients (or parents) refusing or waiting for urethroplasty.

Other minimal invasive techniques, laser urethrotomy and balloon dilatation, in management of urethral stricture in paediatric urology have been described. The initial results from those studies have been promising, and certainly would have their roles in the management of this condition in the future [151, 152]. The issues with those techniques were availability of the equipments, hospital accreditation to operate those equipments, and surgeons’ preference. Further studies to compare those modern techniques with the ‘current’ dilation should be encouraged.
**Conclusion**

Guide-wire assisted urethral dilatation avoids the risks associated with blind dilatation techniques, and continues to be a safe alternative for urethral strictures in paediatric urology. This technique had been performed 235 times in 52 children without a major complication.

However, only 42% of patients were considered ‘recurrence-free’ after two dilatations and 25% with strictures had progressed significantly, and definitive surgical interventions were required. Urethral dilatation should only be considered in selected cases and emergency settings.
Chapter Nine: **Conclusions**

**Summary of Key Findings**

“In God we trust. All others must keep data.”

-Anonymous

This statement summarized the most important finding of the thesis. Deming and Juran, in early 1950s, stated the ‘successful industry’ adopted modern quality oriented methodology to replace empiricism. Facts or data replaced guesswork, and often we found that the truth was different from the impression [153-156]. By conducting audits with targeted issues, audits were useful in current surgical practice.

Surgical audits ensure the quality of patient care. Chapter Three, *Audit improves acute gallstone pancreatitis*, analyzed the performance of a local hospital in the management of gallstone acute pancreatitis. This was a classical example how audits identified the deficiency in the management of acute gallstone pancreatitis and poor patient outcome. By modifying the practice and performing timely gallstone removal treatment (an evidence-based guideline), the rate of re-presentation to the hospital with severe pancreatitis was remarkably reduced and overall patients outcome was improved.

In the paper, *Comparative study on acute pancreatitis*, both the tertiary referral centre and regional hospital were found to comply closely with published BSG guidelines [54, 157] and the recommended standard of patient’s care was achieved. The guidelines, including a specific assigned unit (e.g. hepatopancreatobiliary surgery) in a hospital, ICU/HDU for severe pancreatitis, and dynamic CT scanning, were complied well in both centers. The recommendation for definitive treatment of patients with gallstone-related pancreatitis within four weeks of presentation was also complied well in both hospitals, and the outcome was compatible with the recommendation[157]. Although the evidence was from ‘elsewhere’, this study has shown the international guideline was found to be relevant to local surgical practice.

Although compliance with the guidelines on investigation for severity
stratification of acute pancreatitis was low, the lack of formal severity
assessment did not appear to delayed management for patients with severe
pancreatitis. Perhaps the data suggested that this particular recommendation
may not necessary apply locally.

Despite some studies advocating the use of medical imaging as part of
a routine assessment for patients with suspected acute appendicitis, the
retrospective audit study, 'To Have or Not To Have; How Does Medical
Imaging Assist Management of Patients With Acute Appendicitis?', didn't
support the belief. Medical imaging was not effective to exclude or confirm
acute appendicitis in a rural center. In fact, a thorough clinical evaluation of
patient is still paramount to the management of patients with suspected acute
appendicitis before considering medical imaging. Perhaps this was another
example of what was considered to be the EBM or standard of care
‗elsewhere‘ might not apply to another clinical setting. Regular audits on the
local practice become paramount to ensure the relevance of applying EBM
(from elsewhere) in a clinical setting.

The paper on ‘Save the costs: Laparoscopic inguinal hernia repair with
TEP approach but with no disposable instrumentation’ has demonstrated that
without the specially designed balloon expanders, the pre-peritoneal space
was established and maintained in most cases without disposable
instrumentation and no significant extra theatre time was required and no
further morbidity with this approach, comparing with other methods. This is
an audit used ‘outside-of-box' with cost-effective analysis to compare different
surgical techniques. We concluded that, this modification on the TEP
approach could be considered safe and effective, and should be attempted
initially to save the cost, although in difficult cases, the disposable balloon
expanders would still be required. This study is a rare paper published in
medical literature (at to our knowledge) with an emphasis of cost-effective
utilization of hospital resource.

The two chapters on the new surgical technique for management of
paediatric urethral strictures intended to describe a new surgical technique
and validate its use with long-term audits. Although this technique continued
to be a safe alternative in paediatric urology, the long-term follow-up study
failed to show its effectiveness, because the majority of patients (58%) still
required multiple dilatations, clean intermittent self-catheterization, or definitive surgery, such as urethrotomy and urethroplasty. We believe that this new technique certainly was not for all urethral strictures, it can be useful in specific circumstances, as reported in the study. The important lesson to learn was that long-term audits should be conducted. Although an initial study was favorable, as long-term audits could report findings which might not manifest at the early stage.

More Lessons Learned From This Project

Furthermore, I have learnt to integrate EBM in surgical practice; from formulating of a question with clinical relevance, research the current medical literature, conducting audits, critical analysis of data, essence of peer review, modification of current practice (if needed), and finally reporting and publishing data. I have realized that the attitude of conducting an audit was extremely important. We are at the modern era of practicing EBM. Audits critically evaluate the outcome of a clinical practice, and continue to provide current evidence supporting the practice or a ‘bash of honesty’ urging modifications to the practice. If an audit aims to answer a clinical question, we should not be afraid to challenge the ‘so-called’ guidelines or recommendations, because the limitations of research and data derived from studies conducted elsewhere might not be applicable to the local practice.

Audit should not be viewed as merely a ‘number-counting exercise’, but providing evidence for the clinical efficacy of current practice. Audit monitors and maintains the quality of care. In particular, the surgeons must take part in, and respond to the results of regular and systemic clinical audit, especially any short-coming. A national audit of surgical mortality and morbidity can be seen as the final step in what has been termed the ‘journey of care’ for both the individual patient and for the population as a whole. It may seem impossible. However, as studies by Stonebridge, Gillies, and McArthur, showed that Scottish Audit of Surgical Mortality (SASM) was able to conduct national audits on surgical mortality [158-160]. I believe that it is up to the responsible individuals and supervising body (such as Royal Australasian
College of Surgeons) to re-enforce the process that is taking place. Surgical Audit Taskforce in the RACS has been formed since 2002. Its role is to ensure that effective surgical audit has been taking place, provide education, and facilitate support for Australian and New Zealand surgeons [68].

Apart from learning experience for surgeons, audit provides opportunity to identify problems and deficiencies in “systems”, which bring the attention of hospital authorities to address the issues and provide opportunity for surgeons to understand and practice risk management. Publishing data from adverse events should be encouraged. It is as valuable (if not more) to report and publish a ‘less-than-perfect’ study, since other surgeons could share and learn from the experience. The studies on Audit improves acute gallstone pancreatitis and guide-wire urethral dilatation in paediatric urology, have done exactly that. I believe that ‘No blame environment and attitude’, honesty, and clinical accountability are the essence.

It is relatively easy to prove that an audit may affect the patient management in short term, but it is difficult to prove that audit can prove patients’ outcomes particular in medium and long terms due to limited resource and compliance [38, 39, 161]. Nevertheless in this project, two studies with long-term audits were conducted and completed. The first project (with a mean follow-up of four and a half year) on management of patients with gallstone pancreatitis was conducted and demonstrated that deficiencies in management of patients were identified, which were followed by institution and re-enforcement of changes, and finally improved outcomes of patients resulted. The second project was to investigate the safety and efficacy of a surgical technique managing urethral stricture in paediatric urology. The long-term audit (with a mean follow-up of six years) depicted the high recurrence rate stricture after dilatation with this technique, which was missed in the initial audit study. These two projects certainly highlight the important role of long-term audits in surgical practice.
Limitations of the Study

There were few specific areas in surgical practice being investigated in this project. The conclusions drawn from this project may not be applied universally. Nevertheless, the aim of this study was to investigate the experience of conducting audits in surgical practice.

Although EBM has gained prominence in current medical practice and research, it should be practiced with precaution. For example, how do clinicians reconcile discordant results of randomized trials or how they apply results of randomized trials to individual patients? Clearly, the EBM within a philosophical framework of science has been challenged and questions to be answered. According to the theory proposed by Karl Popper and David Miller, data from a study could be merely observations. As a research and clinician, we should be aware of the deficiencies and limitations of research data. The question still existing was whether EBM truly the answer to clinical practice. According to Karl Popper, although truth is the aim of science, it is impossible to justify the truth hypothesis. Blinding and randomization can only be regarded as valuable for the purpose of refuting universal hypotheses [162, 163]. Probabilities are propensities (or tendencies) for the production of certain outcomes, or certain frequencies of outcomes, by experimental arrangements [164]. It has been pointed out in the literature that the propensity view suffers from the reference-class problem since the probability to be attached to the experimental conditions of a single event depends on the characterization of the conditions [165, 166]. In other words, it is important to realize the limitations of research and be aware of its interpretation and clinical application. All projects were conducted locally. The conclusions drawn may not be applied elsewhere.

Surgical Risk Scale (SRS) has been proven to be effective and simple to apply in comparative studies, when sufficient data is available [167]. I believe that a comparative study in management of acute pancreatitis could include SRS to further improve the clinical significance of the paper. However it requires risk-adjusted analysis to make its data more meaningful,
Future Directions

It is obvious that application of EBM in surgery is important in this modern era, however its application in surgical practice can be difficult, due to the large amount and complexity of published research and the lack of user-friendly tools and necessary skills required for the use of research results. As Antes et al suggested [24], there were only 77 Cochrane reviews address surgical procedures. Although some of the difficulties were due to the intrinsic nature of surgery comparing to medicine (such as difficulty in conducting double-blinding and randomized trials for surgical operations), much work remains to be done to enlarge the number of high-quality and relevant reviews in surgery. Similarly, wherever possible, the number and quality of randomized controlled trials need to be increased in all surgical specialties.

Although the benefit and essence of practicing audits were apparent, Compliance of conducting surgical audits was an issue [67, 168]. As Bohnen suggested why surgeons not comply with the “best practice” was that surgeon’s behavior may be complex, more knowledge is required to influence the compliance and practice pattern. Nevertheless the task was not impossible [160, 169]. Recognition of the importance of audit and providing support to our surgical colleagues can be helpful. During the time of data collection and presentation, we did encounter clerical and technical difficulties which were resolved eventually. We believed that a governing body is not only to re-enforce the process of conducting surgical audit but also to provide educational courses and technical support for the surgeons and trainees [25, 170, 171]. In Australia, the Royal Australasian College of Surgeons (RACS) has taken up the role of the governing body, whose vision is to provide the highest possible standard of surgical care to patients, guidance to individual surgeons and hospital surgical units, and encourage hospital administrations to provide resources for these important activities. Conducting regular surgical audit is now an essential part of Continuing Professional
Development (CPD) for surgeons in Australia and New Zealand [68]. To further re-enforce the effectiveness, there should be continuous communication between these individuals who excise these activities and the governing body. As Veen et al pointed out, emphasis should be placed on training surgeons to document complications and provide feedback. The reporting process should be focusing on adequate and uniform classifying the events with major significance [172]. Education and support from the senior staff to junior is essential. As McCarthy suggested that the majority of junior surgical staff recognized the importance of surgical audit, however lack of support from their senior staff and commitment to other duty prevented them from attending or presenting in audit meetings [173].

During completion of the thesis, one common difficulty in all six studies was the completeness and accuracy of documentation in patients’ case notes. As Gillies, Ruckley, and Nixon pointed out in their study in fatal pulmonary embolism after surgical procedures, the quality of documentation, especially emergency cases, was very poor. Collecting data from the large numbers of patients necessary to formulate a contingency plan was essentially impossible [174]. It has become apparent to me that protocols, clinical pathways, and progress note need to be carefully documented. Without details and clear documentation, it is not only impossible to realize the events, the data and quality of the audit would be compromised, and subsequently unable to formulate a plan to prevent further recurrence, which is obvious the purpose of audits. Therefore, the education and support to the junior doctors and training surgeons on the essence of comprehensive medico-legal documentation is imperative.
Reference


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Chiang, David Ting-Wei

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Date:
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