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The impact of anaesthesia on the urinary bladder following delivery and retropubic incontinence surgery

By

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A thesis presented to the College of Medicine and Dental Sciences at the University of Birmingham
for a degree of Master of Philosophy (MPhil)

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Abstract

A systematic review looking at voiding function following various modes of vaginal deliveries using different analgesia showed a significantly higher risk of voiding dysfunction in women undergoing vaginal deliveries with epidural anaesthesia or instrumental deliveries.

In one of the three studies conducted, the median time for bladder sensation to return in women having vaginal deliveries without epidurals, with epidurals, and after elective Caesarean sections under spinal anaesthesia were 122 minutes (95% IQR 112-136), 234 minutes (95% IQR 202-291) and 374 minutes (95% IQR 311- 425) respectively. The median volumes were 144 ml (95% IQR 112 -192), 200 ml (95% IQR 136- 336) and 152.2 ml (95% IQR 125 – 270) respectively. Examination of the accuracy of ultrasound bladder measurements showed a good correlation between the volume of urine present in the bladder and the volume of urine measured using the ultrasound scan.

A double blind randomised controlled study assessed the effect of spinal and local anaesthesia on the bladder when used for incontinence surgery. The study showed that postoperatively patients having spinal anaesthesia had a first desire to void and a strong desire to void with smaller volumes of fluid in their bladder at 3 hours compared to 1 hour.

Dedication

I would like to dedicate this thesis to my wife Carol-Ann and thank her for all her patience.

I would also like to dedicate it to my parents who taught me the value of a good education.

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This project was based on the work done while I was a Clinical Research Fellow at the Birmingham Women's Foundation Trust, Birmingham between the period April 2006 to March 2008.

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Personal contribution

The study looking at the impact of anaesthesia on the urinary bladder following delivery

- Formulation of the Protocol
- Ethics approval
- Patient recruitment
- Analysis of data
- Writing up the thesis

The study looking at the impact of anaesthesia on the urinary bladder following incontinence surgery

- Ethics approval
- Patient recruitment
- Analysis of data
- Writing up the study

List of abbreviations

Confidence Interval - CI

Centimetres - cm

Electrocardiogram – E.C.G.

Four times daily - qds

Gauge - g

Grams - gms

Inter-quartile range – IQR

International Continence Society – ICS

International Urogynaecological Association - IUGA

Low dose spinal anaesthesia - LDS

Millilitres – mls.

Millimetres - mm

Micrograms – mg

National Institute of Clinical Excellence - NICE

Not significant – NS or ns

Patient controlled epidural analgesia – PCEA

Propofol target controlled sedation regime - TCI

Oral dose – po

Rectal dose - pr

Tension free vaginal tape – TVT

Ultrasound scan - USS

Visual analogue scale - VAS

PRESENTATIONS AND PUBLICATIONS FROM THIS THESIS

Publications

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Oral presentations

Foon R, Toozs–Hobson P**: Uncharted Territory: Anaesthesia and the Urinary bladder after delivery -** oral presentation at the International Continence Society meeting October 2008, Cairo, Egypt**.**

Foon R, Toozs–Hobson P**: The impact of anaesthesia and mode of delivery on the urinary bladder following delivery –**Oral presentation at the UKCS 2008**.**

Foon R, Toozs-Hobson P**: The impact of spinal anaesthesia on the urinary bladder following delivery -** oral presentation at the International Continence Society meeting August 2007, Rotterdam, Netherlands

Poster Presentations

Foon R, Toozs-Hobson P: **Retro pubic tape insertion: Spinal or sedation? A patient's perspective (A randomised control trial):** poster presentation at the International Continence Society meeting October 2008, Cairo, Egypt

Chapter one

Introduction

1.1 The Anatomy of the Urinary bladder

The urinary bladder has two functions firstly to store urine, which it does for 99% of the time and secondly to expel urine at the appropriate time. The urinary bladder can vary in shape, size, position and its relation to surrounding structures. Its size and shape depends on the volume of urine contained at any particular time; and in the gravid patient, the size of the uterus (Gray H 2003).

At birth, the bladder is located in the abdominal region rather than the pelvis. It extends about two-thirds towards the umbilicus and arrives in the adult position shortly after puberty (Sinnatamby C S 2004). The urinary bladder, when empty is tetrahedral in shape and is found in the lesser pelvis and, when full it is in the abdominal cavity. The urinary bladder has a fundus, neck, apex, a superior and two inferiolateral surfaces (Standring S 2006).

The base is triangular and posterior-inferior and is closely related to the anterior vaginal wall. The neck (not the base) forms the lowest part of the bladder. The neck of the bladder is fixed and lies 3-4 cm behind the lower part of the symphysis pubis which corresponds to a little above the plane of the inferior aperture of the lesser pelvis (Gray H 2003).

The apex faces towards the symphysis pubis with the median umbilical ligament (urachus) ascending behind the anterior abdominal wall to the umbilicus (Sinnatamby C S 2004). The peritoneum over the ligament forms the median umbilical fold.

The superior surface is triangular in shape and is bounded by the lateral borders from the apex to the ureteric entrances and the posterior borders joining them. The superior surface is covered with peritoneum and posteriorly the peritoneum is reflected to the uterus at the level

of the internal os thereby forming the vesico-uterine pouch (Sinnatamby C S 2004). The posterior part of the superior surface is devoid of peritoneum; is separated from the supravaginal cervix by fibro-areolar tissue (O'Rahilly 1986). Fascia is closely applied to the inferiolateral surface of the bladder and this fascia also covers the pelvic floor and pelvic walls (De Lancey J 2010).

When the bladder fills the superior surface moves cranially into the abdominal cavity and, it becomes ovoid in shape (Sinnatamby C S 2004). The anterior aspect displaces the parietal peritoneum from the suprapubic region of the abdominal wall and the surface become anterior and rests against it (O'Rahilly 1986). When slightly distended it is rounded in shape and in the pelvis. A distended bladder is ovoid in shape with a larger horizontal diameter than vertical diameter in the female. The relation to surrounding structures includes the small intestine, the uterus and the sigmoid flexure hence it adopts its optimal spherical shape (Gray H 2003). There is no intervening peritoneum for a distance above the symphysis pubis varying with the degree of distension and commonly about 5 cm (Gray H 2003). In cases of excessive distension, the bladder may reach the level of the umbilicus or beyond. A full bladder can therefore be approached surgically via the anterior abdominal wall above the symphysis pubis without traversing the peritoneum (Sinnatamby C S 2004) .When the bladder is full the apex points up and forwards.

1.2 The Vesical interior

The Vesical mucosa is attached only loosely to the subjacent muscle, they fold when the bladder empties and the folds are eliminated when the bladder fills (Gray H 2003). The mucosa is adherent to subjacent muscle layer and is always smooth over the trigone (Gray H 2003).

There are 3 orifices in the bladder which delineate the trigone of the bladder; the 2 ureteric orifices and the internal urethral meatus (De Lancey J 2010). Laterally this ridge extends beyond the ureteric openings as ureteric folds produced by the terminal parts of the ureters running obliquely through the bladder wall (Sinnatamby C S 2004).

The ureteric orifices found at the posteriolateral trigone angles are slit-like. The ureters run obliquely through the bladder wall for 1.5-2.0 cm and enter the bladder (De Lancey J 2010). In an empty bladder, the ureteric orifices are 2.5 cm apart and about the same from the internal urethral orifice (Gray H 2003). With a distended bladder, the distance between the two orifices can be doubled (Gray H 2003). The urethral orifice is at the trigone apex and, it forms the lowest part of the bladder and is usually crescent shaped (Gray H 2003).

The bladder capacity is approximately 500 ml and when it empties, leaves no residual urine under normal circumstances (Chapple C 2000). The sensation of pain is caused by tension in the wall, and it leads to a reflex contraction and urgent desire to micturate with nerves T11-L2, S2-4, supplying pain (Barret K 2010).

1.3 Bladder structure

The wall of the urinary bladder consists of three layers: the outer layer is an adventitial layer of connective tissue (Gray H 2003). The middle layer is a layer of non-striated muscle or detrusor muscle and the inner layer consists of a mucous membrane (Gray H 2003). When the urinary bladder is empty the mucosa is folded (except over the trigone) however, when the bladder is full the mucosa becomes smooth (De Lancey J 2010).The detrusor muscle layer consists of a number of interlacing bundles of non-striated muscle cells arranged in a complex mesh (Gray H 2003).

1.4 Blood supply to the bladder

The urinary bladder requires an abundant blood supply in order for tissue oxygenation, transport of nutrients and removal of metabolites (De Lancey J 2010).The main arterial supply to the bladder arises from the superior and inferior vesicle arteries, which are derived from the anterior branch of the internal iliac artery (Gray H 2003). The obturator, the inferior gluteal, the uterine and vaginal arteries also send small branches to the bladder (Sinnatamby C S 2004). Evidence would suggest that the base of the bladder is supplied by the vaginal artery while the base and the neck of the bladder are supplied by inferior Vesical artery (O'Rahilly 1986). With regards to the venous supply, there is a complex plexus on the inferiolateral surfaces that drain into the internal iliac vein (Gray H 2003).

1.5 Nerve supply to bladder

Afferent nerves travel via the hypogastric and pelvic splanchnic nerves and the urinary bladder is supplied by these afferent nerves (Vaughan C.W.and Satchell P.M. 1995). However there are no local afferent neurons within the bladder but instead the cell bodies are located in the dorsal root ganglia in the lumbosacral region. The sensory nerves that supply the urinary bladder are either unmyelinated fibres or thin myelinated A delta fibres that end as free nerve endings (Vaughan C.W.and Satchell P.M. 1995). Most A delta fibres are sensitive to mechanical stimuli such as stretch and distension while the C fibres respond to noxious, chemical and cooling stimuli (Griffiths DJ and Apostolidis A 2010). Some of the afferent nerves operate as slowly adapting tension receptors and as a result respond to a physiological distension in a graded style (De Lancey J 2010). These are mainly concerned with sensation, the transmission of pain and awareness of distension. Acute distension in

neurologically intact women stimulates the pain fibres and these fibres are predominantly parasympathetic fibres. The path for pain is in the anterolateral white columns (De Lancey J 2010).

Efferent fibres: Parasympathetic fibres originate at the second to the fourth sacral segments of the spinal cord: the sympathetic fibres are derived from the lower two thoracic and upper two lumbar segments of the spinal cord (De Lancey J 2010).

The motor cell bodies of the nerves in the anterior horn of the S_2-S_4 segment of the spinal cord are known as the Onuf's nucleus (Brading 1997). This supplies the urethral striated muscle and is critical in the process of micturition. The axons of the efferent parasympathetic nerves originate from the S_2-S_4 roots of the spinal cord. The S_2-S_4 roots have the preganglionic parasympathetic fibres that go to the ganglia in the pelvis and from there the postganglionic fibres originate and then innervate the detrusor muscle. At the point of innervation there is release of acetylcholine which attaches to the muscarinic receptors in the detrusor muscle and this causes a contraction (Yoshimura 1999). The acetylcholine acts on five subtypes of muscarinic receptors (M1-M_5) with the M_2 subtype being the most predominant type but the M_3 subtype being responsible for detrusor contractions (Abrams et al. 2006). The sympathetic neurons that originate from the intermediolateral cell column of T11 – L2 innervates the urethral smooth muscle and the base of the urinary bladder. Norepinephrine acts on the alpha-adrenoreceptors causing contraction of the bladder base and urethral smooth muscle thus aiding in storage of urine (Griffith DJ and Apostolidis A 2010). The purenergic pathway also accounts for fast and short acting detrusor contractions with the release of Adenosine triphosphate (Griffiths DJ and Apostolidis A 2010).

The beta-adrenoreceptor is classified into beta 1, beta2 and beta 3 with beta 3 found in the urinary bladder smooth muscle. The evidence suggests that beta 3 adrenoreceptor activation

results in detrusor muscle relaxation. As a result beta 3 agonists is used in therapy for the overactive bladder (Yamaguchi O 2007).

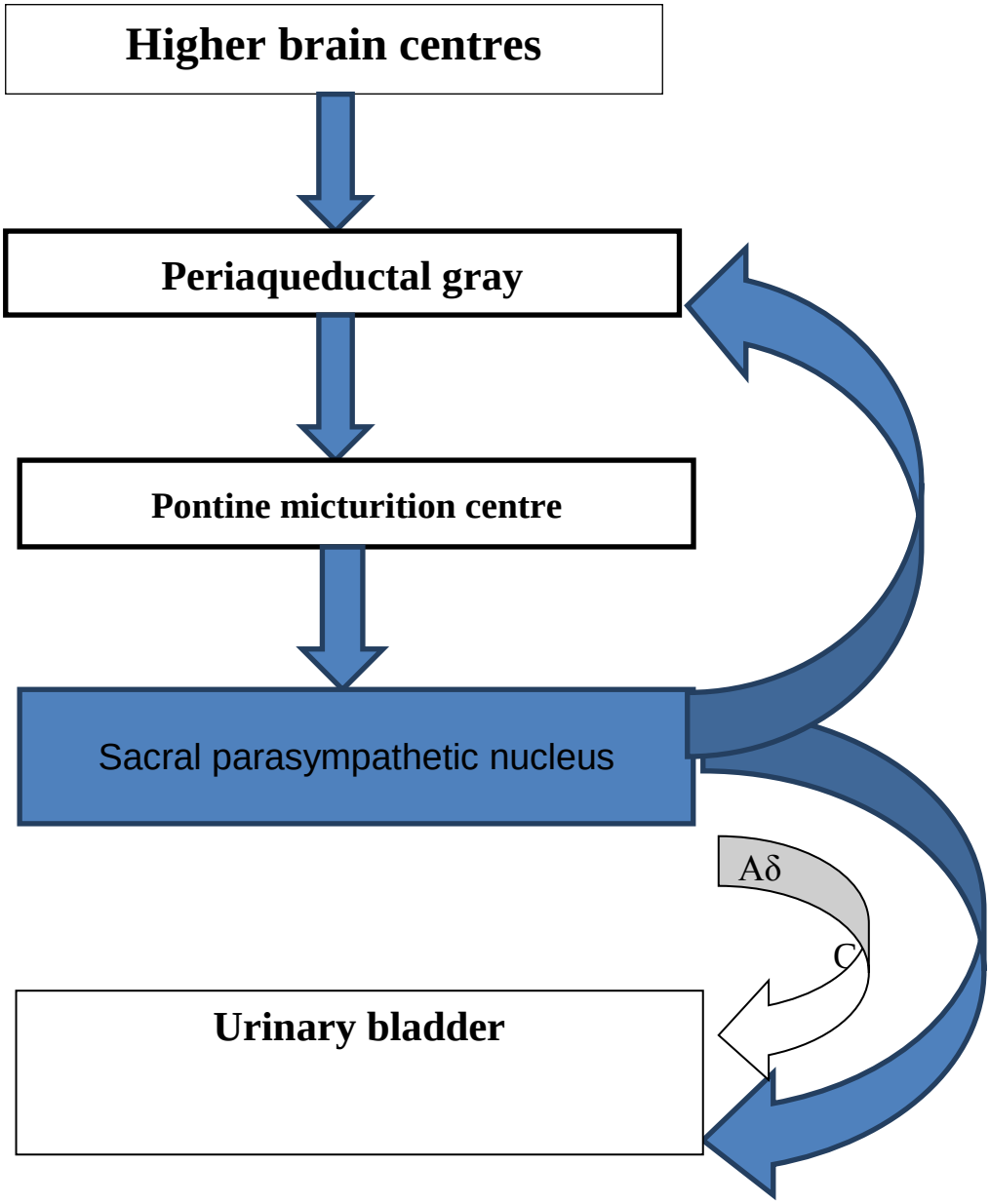


Figure 1.1: A simplified micturition pathway (Griffiths DJ and Apostolidis A 2010)

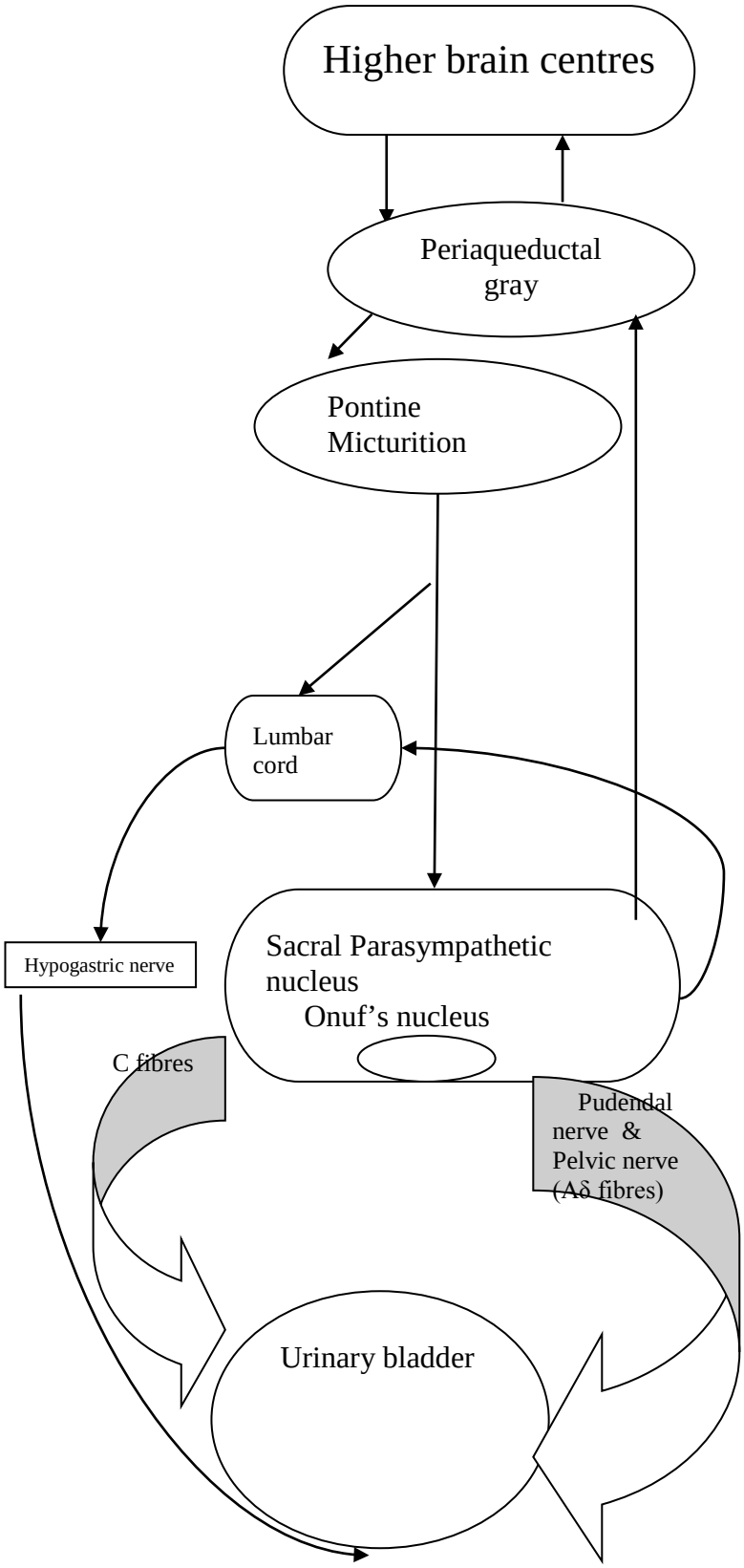


Figure 1.2: The voiding reflex pathway (Griffiths DJ and Apostolidis A 2010)

1.6 Functional anatomy of the lower urinary tract

The urinary bladder stores and expels urine from the body (Wyndaele 2010). In order to maintain continence of urine, the intraurethral pressure has to be greater than the bladder pressure. Within the walls of the urethra, there is the external urethral sphincter, which is the region where the maximum urethral closure pressures are recorded (Chapple C 2000). Micturition is a series of spinal reflexes which has a facilitatory area in the pons and an inhibitory centre in the midbrain which are subject to voluntary control and inhibition (Barret K 2010). The bladder is a compliant organ, which means that changes in volume tend not to have a dramatic effect on increasing pressure under normal circumstances. However when the normal volumes are exceeded the bladder smooth muscle has the property of plasticity thus maintaining a stable tension.

On initiation of micturition, there is relaxation of the pelvic floor muscles; this causes a caudal displacement to the detrusor muscle allowing the initiation of micturition (Barret K 2010). The perineal muscles and external sphincter can be contracted voluntary.

1.7 Physiology of micturition

The female bladder normally has a capacity of approximately 500 mls (Chapple C 2000). Urine enters the bladder via the ureters, which contain smooth muscle arranged in a spiral, longitudinal and circular bundles. Vermosis type contractions allow the urine to move from the renal pelvis to the bladder.

In order to facilitate voiding there must be coordination of relaxation of the urethral sphincter and contraction of the detrusor muscle (de Groat and Yoshimura 2010). This is synchronized by three groups of peripheral nerves: the somatic (pudendal) nerves, the thoracolumbar (hypogastric and sympathetic chain) nerves, and the sacral parasympathetic (pelvic nerves) (Fowler et al. 2008). Sacral afferents are more localised in the fundus and trigone while lumbar afferents are more common in the trigone of the bladder (Uemura et al. 1975).

1.8 Filling Phase

The urine produced by the kidneys enters the bladder via the ureters. As the filling occurs, this sends afferent impulses form the stretch receptors located in the walls of the bladder to the sacral roots S_{2-4} via the pelvic nerves (Barret K 2010). From the sacral roots, the impulses are transmitted to the spinal cord by means of the lateral spinothalamic tracts (Barret K 2010). The response to detrusor muscle is transmitted from the basal ganglia and these subconsciously inhibit the descending impulses from the basal ganglia.

When the bladder fills the afferent signals are sent to the cerebral cortex and under normal circumstances the first desire to void sensation occurs at 150 to 250 mls (Barret K 2010). At this point in time, the inhibition of the detrusor muscle activity is mediated by the cerebral cortex (Barret K 2010). As the bladder continues to fill these afferent impulses together with the desire to void, become even greater and as a result there is now a conscious inhibition of micturition (Barret K 2010). As the volume gets closer to the maximum bladder capacity there will also be a voluntary pelvic floor contraction to help with urethral closure.

1.9 Storage phase

In order for conscious bladder control to be feasible one needs to have a satisfactory sensory input. If there is no feeling of bladder sensation or delayed sensation, bladder function can be affected. However, in 65% of cases, a patient voids when it is convenient and this is used as a guiding factor rather than just afferent signals (De and Wyndaele 2003).During the storage phase, the bladder is dormant and the bladder outlet is closed. This allows a low intravesical pressure while allowing for a rise in bladder volume. The sensory nerves that supply the urinary bladder are either myelinated A-delta or unmyelinated C fibres. The afferents to the mucosa are unmyelinated fibres where as those in the detrusor muscle can be either myelinated A delta or unmyelinated C fibres (Fowler 2002;Wiseman et al. 2002). Afferent nerves do respond to distension of the bladder the pelvic myelinated A-delta fibres formulate the afferent arm of the micturition reflex.

There are some unmyelinated units called nociceptors that send signals when bladder over distension is to the extent causing pain (Morrison S 2002). Both A-delta and C-fibres respond to non-painful sensation during bladder filling (Wyndaele 2010). Continence is maintained by contraction of the muscles of the pelvic floor and urethral sphincter**.** Efferents that originate from the Onuf's nucleus release norepinephrine which then activate the receptors. This causes contractions of the pelvic muscles and urethral sphincter and maintains continence (Griffith DJ and Apostolidis A 2010).

1.10 Voiding phase

When the time and place are appropriate voiding can be initiated. There are three components of micturition: an awareness of the opening of the urethral sphincter, the feeling of urine passing through the urethra and a thermal sensation (Nathan 1952). Initially the pelvic floor relaxes and then there is an inhibition of the sympathetic activity that causes relaxation of the urethral smooth muscle and voluntary relaxation of the rhabdosphincter (Barret K 2010). Within seconds the reflex that results in the inhibition of voiding is removed and the detrusor muscles now under the control of the parasympathetic system start to contract (Barret K 2010).

On completion of voiding the cortical inhibition resumes, causing relaxation of the detrusor muscle; the pelvic floor is elevated and the rhabdosphincter contracts. It is believed that the perineal muscles and rhabdosphincter muscles can contract voluntarily thus preventing urine from being expelled or interrupting the flow once micturition has started (Barret K 2010;Wyndaele 2010). If micturition is postponed the patient starts to complain of vague suprapubic pain and the sensations of impending micturition are felt (George NJR 1986).

1.11 Pregnancy and the bladder

Urine production increases in pregnancy due to an increase in perfusion of the kidneys and rise in glomerular filtration rate to a peak of approximately 50% (Davison J 1996). Additionally the higher level of relaxin, the effect of the gravid uterus and increased bladder neck mobility, all impact on the urinary tract function in pregnancy. The higher levels of relaxin may have some protective effect in reducing stress incontinence in pregnancy while the gravid uterus can cause increased frequency of micturition(Kristiansson et al. 2001).

Pregnancy is also associated with a lower first sensation to void and a reduced bladder capacity (Chaliha et al. 2000).

1.12 Anaesthesia in Obstetrics

1.12.1 Epidurals/Spinal anaesthesia

In an ideal setting one would use an anaesthetic agent that can be easily administered, provide adequate pain relief and have no side effects on mother or fetus. Continuous infusion of local anaesthetic drugs into the epidural space for pain relief was first described in 1963 (Scott and Walker L 1963). In most Western countries the use of epidurals in labour has become the gold standard for analgesia (Holdcroft A 2000). The use of continuous infusions avoids the peaks and troughs in pain relief and hence reduces the risks of hypotension and total spinal block (Glosten B 2000). However it was not until the introduction of infusion pumps were they used in obstetric practice (Holdcroft A 2000).

An epidural involves an injection of a local anaesthetic drug such as lidocaine or bupivacaine and an opioid drug such as morphine or fentanyl into the epidural space of the lumbar spine (Hawkins 2010). The drugs move across the dura into the subarachnoid space and act on the spinal nerve roots and the paravertebral nerves (Hawkins 2010). Spinal anaesthesia is injected into the subarachnoid space and allows for a more rapid onset than the epidural anaesthesia (Glosten B 2000).

The pains during labour and delivery occur from two main sources. The first, the uterine contractions and dilatation of the cervix and the second from the stretching of the perineum (Hawkins 2010). In the case of the former the pain is transmitted via visceral afferent (sympathetic nerves) to the spinal cord (T10 to L4) (Hawkins 2010). The pain from the

stretching of the perineum is transmitted via the pudendal and sacral nerves (S2 to S4) (Hawkins 2010).

Insertion point of the epidural is at the lumbar vertebral space below the level of L1 (Glosten B 2000). Once the epidural is sited the local anaesthetic is combined with the local opioids (Glosten B 2000). Maintenance of analgesia is obtained by either continuous infusion of dilute local anaesthesia and opioids or a patient controlled administration (Hawkins 2010). An effective form of pain relief does in fact have other indirect benefits such as a reduction of hyperventilation and hence hypocarbia, reduction of catecholamine which can affect uterine activity and blood flow (Hawkins 2010). Epidurals however are known to increase the length of the second stage of labour and increase the risk of instrumental delivery (Hawkins 2010). Urinary retention can occur and it is thought that avoiding dense motor and sensory blocks can reduce urinary retention (Hawkins 2010).Dense paralysis however is not inevitable with the use of epidural analgesia. Other side effects include hypotension, high blocks leading to respiratory compromise, headaches and non-reassuring cardiotocographs after neuraxial analgesia (Glosten B 2000).

1.12.2 Opioids

A recent survey showed that 95.5 % of units in the United Kingdom use either intramuscular pethidine or diamorphine while 49% offered patient-controlled intravenous analgesia in labour (Saravanakumar et al. 2007).

The maternal side effects of intramuscular opioids include nausea, vomiting, delayed gastric emptying, amnesia and dysphonia (Tuckey et al. 2008). No opioids causes complete analgesia without causing some degree of respiratory depression (Tuckey et al 2008). There is however little in the medical literature that addresses the mechanism of action of opioids on the urinary bladder.

One of the main side effects of opioids is urinary retention. Opioids do decrease the tone and contractility of the detrusor muscle and this can have an impact on the urge to micturate and sensation of fullness of the bladder (Ramsin et al 2008). The incidence of urinary retention following the postoperative administration of opioids ranges from 3.8% to 18.1% (O'Riordan et al. 2000). Apart from the effect on detrusor contraction strength, it is believed that opioids inhibit sphincter relaxation hence adding to the cause of urinary retention (Rawal et al. 1983). Intrathecal administration of opioids inhibits the afferent and efferent arms of the reflex micturition arc. This therefore impairs detrusor contractility with the sensory portion returning to normal function before detrusor contraction strength (Kuipers et al. 2004).

1.13 Underlying problem of Anaesthesia in Obstetrics

Bladder distension and post partum bladder dysfunction have been reported since the use of epidural anaesthesia in the 1960's. Bladder complications exist despite the use of newer techniques and lower doses of epidural anaesthesia (Holdcroft A 2000). It can take up to eight hours for sensation to return after the last dosage of anaesthesia (Khullar V 1993).This is due to the blockade of the sacral root, which paralyses the parasympathetic nerve supply to the bladder (Torrens 1975). With regards to voiding function after regional anaesthesia the evidence is conflicting. One paper shows that there are higher post residual volumes 2-5 days after delivery in patients undergoing epidurals during labour (Tapp A 1993). More recent papers have shown that there is little difference in the risk of urinary retention (Wiseman et al 2002). This may be due to the different constituents of the drugs used for the regional anaesthesia (Gedney and Liu 1998). Pethidine was first used for pain relief in labour in 1940 and was licensed for use by midwives acting independently in 1950 in the United Kingdom (Tuckey, Prout, & Wee 2008). Pethidine is easy to administer and relatively cheap conversely diamorphine is associated with euphoria and less vomiting (Tuckey, Prout, & Wee 2008). There are other factors that occur during labour that can affect the bladder. Factors such as over distension of the bladder during labour or injury due to a difficult or a traumatic instrumental delivery (Andolf et al. 1994).

In order to prevent bladder distension routine catheterisation is performed.

1.14 Delivery and the Urinary bladder

Childbirth and pregnancy can affect the function of the lower urinary tract function in a variety of ways ranging from stress incontinence to loss of sensation of the bladder following delivery. As far as stress incontinence is concerned there are several risk factors including maternal age, vaginal delivery, birth weight, instrumental delivery, prolonged labour and in general pregnancy itself (Viktrup and Lose 2001;Wilson et al. 1996). Some of the risk factors to developing urinary retention include: instrumental deliveries, regional anaesthesia, fetal macrosomia, episiotomies and perineal lacerations (Carley et al. 2002).

Table 1.1: Risk factors for developing urinary retention.

Instrumental deliveries
Fetal Macrosomia
Perineal lacerations
Episiotomies
Regional anaesthesia

1.15 Current practises of bladder care post delivery and following incontinence surgery

Urinary retention following delivery can present as the inability to void or voiding small amounts of urine. Urinary retention when detected is treated in a variety of ways, but its initial treatment involves catheterization. A survey conducted on postpartum and intrapartum bladder care reported from 189 units in England and Wales showed a wide variety in practice (Zaki et al. 2004). There were large variations in both diagnosis and management of patients with urinary retention. There is limited data available with regards to good evidence based guidelines for bladder care in the postpartum period. The NICE guidelines suggest that if urine is not passed within six hours after delivery efforts should be made to help with micturition. If urine is not passed then the patient should be catheterised thus allowing measurement of the bladder volume (NICE 2006).

1.16 Aims and Objectives of this thesis:

This thesis looks at the impact of anaesthesia and mode of delivery on the urinary bladder following delivery. In addition it looks at the impact of anaesthesia used for the insertion of retropubic tapes and its effect on the urinary bladder. The aims of this thesis are as follows:

- To identify the time taken for sensation to return to the maternal urinary bladder following various modes of delivery and forms of regional anaesthesia.
- To assess the volume of urine present in the bladder when sensation returned to the bladder and compare it with the total volume of urine produced at that time.
- To measure the post-micturition residual volume of urine within 48 hours after delivery.
- To compare the effect of spinal versus sedation/local anaesthesia on the urinary bladder following the insertion of retropubic tapes.
- To assess the accuracy of measuring bladder volumes using ultrasound scanning in the postnatal patients

In order to achieve these objectives I conducted the following studies:

- A systematic review on the effect of various modes of delivery and anaesthesia on voiding function in the post delivery period
- A study to compare the accuracy of bladder volume measurements in patients following elective Caesarean Sections
- An observational study looking at the time taken for sensation to return to the urinary bladder for various modes of delivery and anaesthesia. The study would

also look at the volume present in the urinary bladder when sensation returned as well as voiding function post delivery. In this study 140 patients were recruited.

- A randomized controlled study of 38 patients undergoing insertion of retropubic tapes under spinal anaesthesia versus sedation/local anaesthesia.

CHAPTER TWO: FACTORS AFFECTING URINARY BLADDER FUNCTION AFTER DELIVERY – A SYSTEMATIC REVIEW

2.1 Introduction

Over distension of the urinary bladder can lead to permanent bladder dysfunction including voiding difficulties. There is evidence to suggest that a single episode of over distension of the urinary bladder can lead to permanent damage of the detrusor muscle and hence abnormal function (Hinman 1976). Patients in the immediate post delivery period are therefore susceptible to over-distension of the urinary bladder. This may be as a result of temporary nerve damage during childbirth or it could be as a result of the anaesthesia used during childbirth. Recently there have been newer techniques used in administering anaesthesia for childbirth. One such development is the use of patient controlled epidural analgesia (PCEA). This is a form of regional anaesthesia that allows the patients to control their own dosage of analgesia.

It is estimated that more than 150,000 women use epidural analgesia for pain relief every year in the United Kingdom (Khor et al. 2000). It is an effective form of pain relief in labour; however it may result in a dense paralysis of motor function that may perhaps affect the tone of the pelvic floor and thus the ability to push in labour (Buggy et al. 2001). One of the effects of regional anaesthesia on the bladder in the immediate post delivery period is urinary retention, which can have a profound long-term effect on the urinary bladder.

There is a large variation of the evidence on impact of anaesthesia and mode of delivery of the urinary bladder in the medical literature. Most of the published studies are small and in some cases underpowered. The aim of this systematic review was to look at the published

data on the effect of various forms of delivery (and anaesthesia) on the urinary bladder in terms of urinary retention or abnormal voiding function.

2.2 Methods

Participants: Participants in this review were patients who had a vaginal delivery and were 0 – 5 days advanced in the postnatal period.

Intervention: There were two interventions considered: epidural anaesthesia in labour or non-regional analgesia in labour and instrumental versus non-instrumental vaginal deliveries.

Outcome: Studies used the parameters of either abnormal voiding (defined as high post void residual volumes and/or low flow rates) or high post void residual volumes of urine.

Sources

Studies that describe voiding difficulties after various modes of delivery with or without regional anaesthesia were obtained. MEDLINE (1950 to January 2012) EMBASE (1980 to January 2012), CINAHL (1994 to January 2012), AMED (1985 to January 2012), PsycINFO (1967 to January 2012), CENTRAL (The Cochrane Library Issue 3, 2011), National Library of health were all searched. The following keywords were used for the search as text words or subject headings using OVID software: Anaesthesia or Analgesia AND Postpartum AND Bladder AND trials.

The first author was contacted for additional information. The bibliographies were hand searched looking for all relevant reviews and primary studies to identify articles not captured by electronic searches. In addition abstracts of the International Urogynaecological Association (IUGA) meetings and the International Continence Society (ICS) meetings of the past 12 years (1999-2011) were scrutinized.

Study Selection

All cohort studies assessing the effects of various forms of regional anaesthesia modes of delivery on the urinary bladder in the post-natal period were selected.

The author selected the studies for inclusion after using the previously described search strategy. There was a three-stage selection process. The first stage involved examining all the potential abstracts and titles. Manuscripts of potential studies were then obtained and examined. The second part of the selection process involved selecting relevant studies and looking at the references, looking at abstracts from meetings and contacting experts. The third stage involved looking at the studies isolated to ascertain whether data on voiding difficulties and delivery could be extracted. Studies without a comparative group were excluded.

The data included population studied, size of population studied, the various interventions and outcomes for all the included studies. The population consisted of postpartum patients in the period immediate following delivery. The intervention consisted of patients having had instrumental deliveries and/or regional anaesthesia versus patients with normal vaginal deliveries without regional anaesthesia. The outcomes measured were urinary retention following delivery or abnormal voiding parameters.

The quality of the papers was assessed using the Newcastle-Ottawa scale (GA Wells 2009). For each study a quality assessment was performed using the proforma in table 2.1 and the results are summarised in table 2.2.

Table 2.1: The quality assessment proforma used for the included studies (Newcastle-Ottawa scale)

Study (author and year)

Selection				Compare	Outcome	
Representativeness of the exposed group	**Selection of the non exposed group**	**Ascertainment of exposure**	**Demonstration that outcome was not present at the start of the study**	**Comparability of patients on the basis of the design or analysis**	**Assessment of outcome**	**Adequacy of follow up**
Truly representative of the average patient undergoing vaginal delivery *	Drawn from the same type of patients as the exposed group *	Secure record *	Demonstration that the outcome of interest was not present at the start	Most important factors of adjustment	Independent blind assessment *	Complete follow up – all patients accounted for *

Somewhat representative of the average patient undergoing vaginal delivery *	Drawn from a different group	Structured interview*	Yes	Any additional factor *	Record linkage *	Subjects lost to follow up <5% *
Selected group of patients	No description of the derivation of the non exposed group	Written self report	No		Self report (adverse effects)	Subjects lost to follow up >5%
No description of the derivation of patients		No			No description	No Statement

Selection **** maximum score Comparability ** maximum score Outcome ** maximum score

Table 2.2 A summary of the quality of the included studies

Study	Selection	Comparability	Outcome
Foon 2010/2008	***		*
Demaria 2008	***		*
Ismail 2008	***		*
Liang C 2002	***	*	*
Chien 1996	***	*	*
Chien 1994	***	*	*
Ramsay 1993	***	*	*
Tapp 1993	**		*
Weil 1983	**		*

For the purpose of this review adequate sampling of the population was considered to be satisfactory if recruitment was consecutive.

In cases where the data could have been combined for a meta-analysis, the Review Manager 5 software was used.

Table 2.3: The characteristics of the included studies

Study	Journal	Participants	Intervention	Outcomes
Foon et al	Int Journal of Obstetrics & Gynaecology 2010	76 women undergoing spontaneous vaginal delivery with or without epidural anaesthesia. In addition 44 women undergoing elective Caesarean section under spinal anaesthesia	Group 1 – Spontaneous vaginal delivery with no anaesthesia (n=50). Group 2 – Spontaneous vaginal delivery with epidural anaesthesia (n= 26) Group 3 - Elective Caesarean section under spinal anaesthesia (n = 44)	Post void residual volume (PVRV) > 150 mls post delivery Group 1: 1/50 Group 2: 1/26 Group 3: 1/44
Demaria et a1	Eur J Obstet Gynecol Reprod Biol 2008	Between January 2004 and May 2004.154 consecutive primiparous women who had singleton vaginal deliveries under epidural analgesia	154 primigravid women had received epidurals 33 had instrumental deliveries.3D Ultrasonography to determine the post-void residual volume 3 days after delivery	PVRV > 100 mls on day 3 Instrumental deliveries 7/33. Non- Instrumental deliveries 48/121
Foon et al	International Continence Society meeting 2008	Women with indwelling catheters had their catheters clamped following delivery	10 Women had instrumental deliveries with epidurals 10 Women had instrumental deliveries without epidurals The time taken for the women to regain their first desire to void was recorded	PVRV >100mls.Instrumental delivery (epidurals) 1/10. Instrumental delivery (no epidural) 0/10. Vaginal delivery (no epidural) 1/40,Vaginal delivery (epidural) 0/24

Ismail S & Emery	Journal of Obstetrics & Gynaecology July 2008	One hundred women had an ultrasound scan of the bladder within 48 hrs of delivery	60 women had normal vaginal deliveries (non-instrumental), 11 instrumental deliveries and 29 Caesarean sections 23 women had Epidural anaesthesia 14 had Spinal anaesthesia No woman had general anaesthesia * No data given on the number of women having Epidural or Spinal anaesthesia.	37% women had PVRV of > 150mls. 24/60 following normal vaginal deliveries (non-instrumental) 2/11 following instrumental deliveries .11/29 following Caesarean sections. *14/37 following regional anaesthesia. 23/63 following non- regional anaesthesia.
Liang C et al	Int J of Obstetric Anaesthesia 2002	Between December 1999 and September 2000 Women were recruited in both the epidural and non- epidural groups 9 control). Each had a vertex presentation and a vaginal delivery	110 primigravid women recruited into the epidural and 110 into the non-epidural groups. 4 and 10 were withdrawn or failed follow up in the respective groups	PVRV > 150 mls Epidural group 30/106 (16/84) -non-instrumental deliveries and 14/22 (instrumental). Comparative group 14/100, (10/92) having non-instrumental deliveries and 4/8 having instrumental

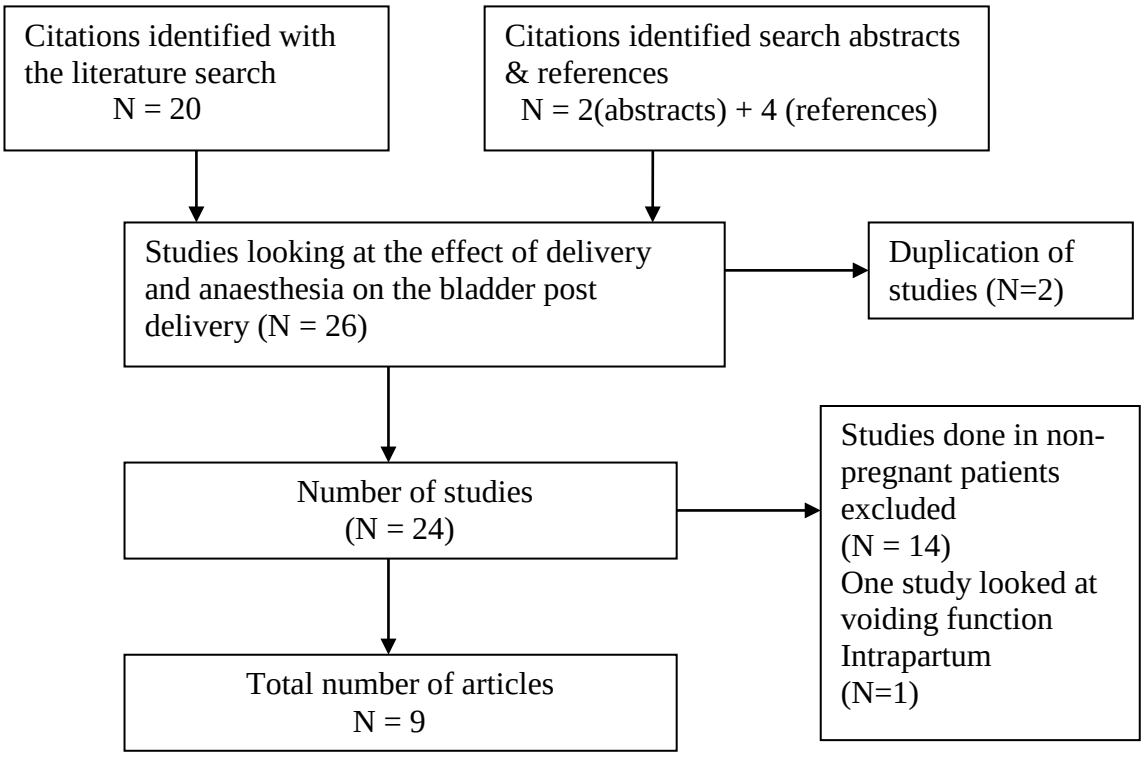
Chien P.et al	Journal of Obstetrics and Gynaecology 1996	A prospective, non-randomized, non-blinded observational study looking at residual volumes in 216 postpartum women with or without epidurals following spontaneous vertex delivery	102 received epidurals 114 received no or alternative analgesia	PVRV of >50 mls after first void 1-2 days post delivery Epidural 25/102 No epidural 14/11
Chien P & Agustsson	Journal of Obstetrics & Gynaecology 1994	72 women following a forceps delivery	Control group –52 women having normal deliveries with epidurals Group 1 Haig – Ferguson forceps with epidural (n=26) Group 2 Kielland's forceps with epidural and spinal (n=25) Group 3 Haig- Ferguson forceps with pudendal block (n=21)	The median residual bladder volume following Kielland's forceps was larger than the control. The median residual volumes in women having Haig Ferguson forceps delivery under epidurals did not differ from women having pudendal blocks.

Ramsey I &. Torbet T	Neurourol & Urodynamics 1993	184 patients had Uroflowmetry and post-micturition Ultrasonography in the immediate postpartum period	Uroflowmetry and post micturition ultrasound was done to assess voiding parameters	79 (43%) had an abnormal voiding parameter of which 37 (20%) had a PVRV > 100mls, 5% had low flow rates (< 10mls /sec) and 18% had both. Abnormal voiding; Non-instrumental vaginal delivery 53/149, (Epidurals 27/54, No epidurals 26/95) Forceps 26/35
Tapp A et al. (abstract)	Neurourol and Urodynamics 1987	33 consecutive women having different analgesia for vaginal/instrumental deliveries	Group 1(n=5)- Spontaneous vaginal deliveries with epidurals Group 2 (n=4) - Forceps delivery with Epidurals Group 3 (n=17) - Vaginal deliveries with other analgesia Group 4 (n=7) -Forceps delivery with other analgesia	PVRV >100mls on day 2 post delivery. Group 1 4/5 Group 2 4/4 Group 3 1/17 Group 4 2/7.Mean residual volume Group 1 163 mls Group 2 176 mls Group 3 15 mls Group 4 87 mls

Weil A	British Journal of Obstetrics & Gynaecology May 1983	27 women had Urodynamics studies done 2 to 5 days after delivery.	11 women delivered vaginally without epidural (group 1), 11 delivered vaginally with epidural (group 2) and 5 underwent Caesarean section under epidural (group 3) No separate data on instrumental delivery or types of anaesthesia used.	Post void Residual volume > 100 mls. Group 1 - 2/11 Group 2 - 2/11 Group 3 - 0/5 * 4 women in-group 2 had hypotonic bladders. However only 2 women had a PRV of > 100 mls.

Table 2.3 The characteristics of the included studies

Figure 2.1: A flow profile of the literature search



2.3 Results

A total of 26 citations were obtained from the literature search (Figure 2.1). After the first stage of the search only 9 articles were found to be relevant. There was a tenth study which consisted of unpublished and also duplication of data from one of the nine included studies (Foon R 2008;Foon et al. 2010). The characteristics of the nine included studies are outlined in Table 2.3. The nine studies had 1011 participants and looked at the effect of anaesthesia and the urinary bladder post delivery. The studies were conducted in the United Kingdom (Chien P et al 1996;Chien P.F.W 1994;Foon, Toozs-Hobson, Millns, & Kilby 2010;Ismail and Emery 2008;Ramsay and Torbet 1993;Tapp A 1993) (6), Switzerland (Weil et al. 1983) (1), Taiwan (Liang et al. 2002) (1) and in France (Demaria et al. 2008) (1). Three studies compared instrumental deliveries with normal spontaneous vaginal deliveries; three looked at epidurals versus no epidurals while the other three looked at a combination of instrumental deliveries and regional anaesthesia. The median age of the participants was 24 with a range of 22 to 30.1years. There was a median follow up period of 2 days post delivery (range of 1 day to 5 days).

The quality of the studies showed that they were lacking in their comparability but in most (n=5) studies patient selection was appropriate. The follow up was good due to short study period.

For the purpose of the meta-analysis the instrumental and normal vaginal deliveries were combined and a comparison of patients with and without epidurals was performed. In studies where the odds ratio is greater than 1, it means that the risk of abnormal voiding is higher in the intervention group (e.g. epidurals). Figure 2.2a shows there is a higher risk of raised post void residuals in the group having epidurals (OR = 3.03, 95% CI 1.64 to 5.61, $p<0.05$).

When comparing patients undergoing normal vaginal deliveries with and without epidural; the patients having epidurals had a significantly higher incidence abnormal voiding (OR = 2.49, 95% CI 1.52 to 4.09, $p<0.05$) as shown in figure 2.2b. There is a higher incidence of abnormal voiding after instrumental versus normal vaginal deliveries (regardless of anaesthesia) (OR = 2.00, 95% CI 1.35 to 2.95, $p<0.05$) as shown in figure 2.2d. There is a higher incidence of abnormal voiding after instrumental versus normal vaginal deliveries without epidural (OR= 7.61, 95% CI 2.19 to 26.46, $p<0.05$) with a wide confidence interval as shown in figure 2.2e. There is also a higher incidence of abnormal voiding in patients undergoing instrumental versus normal deliveries with epidurals (OR = 6.88, 95% CI 2.66 to 17.75, $p<0.05$) as shown in figure 2.2f. There is however no significant difference in voiding when comparing patients having instrumental deliveries with or without epidurals (OR = 3.25, 95% CI 0.93 to 11.37, $p<0.05$) as shown in figure 2.2 c.

Figure 2.2 a: A meta-analysis of abnormal voiding after patients undergoing vaginal deliveries (instrumental and normal vaginal) with and without epidurals

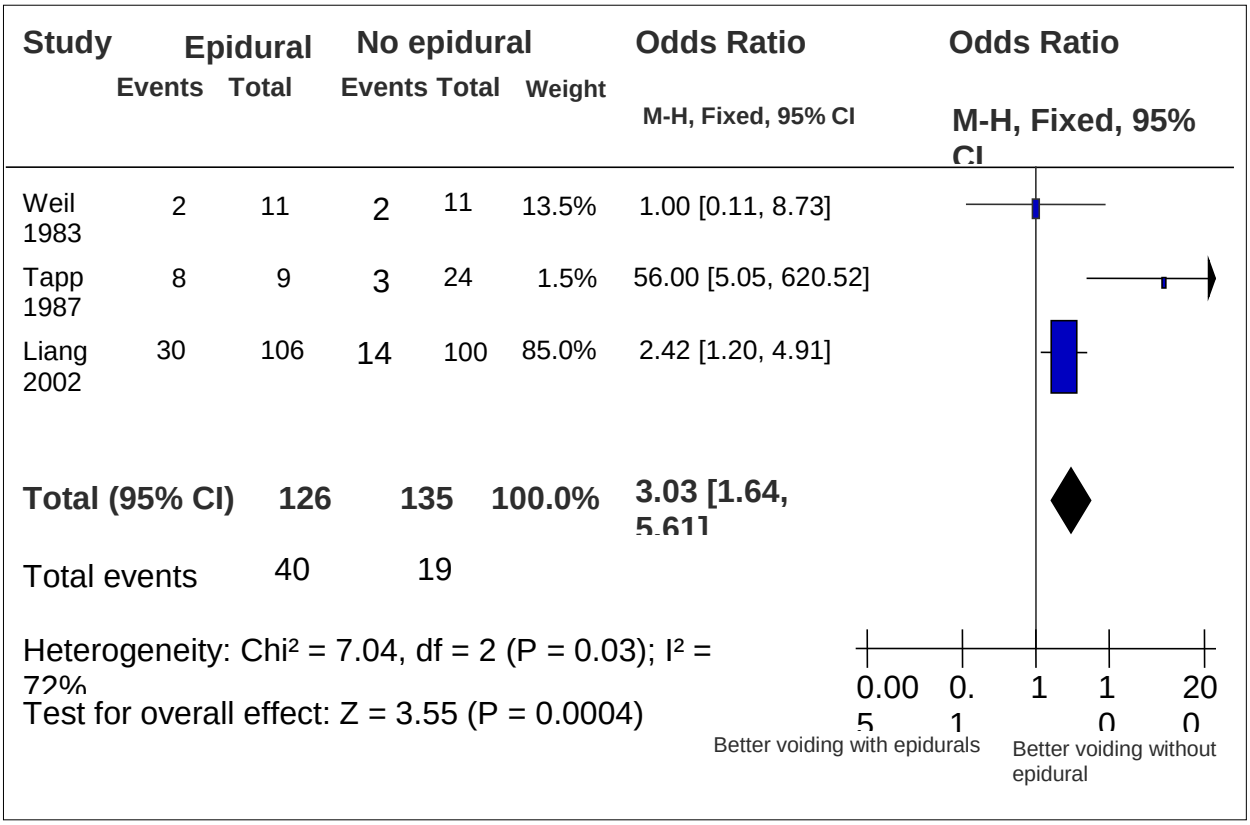


Figure 2.2 b: A meta-analysis of abnormal voiding after patients undergoing normal vaginal deliveries with and without epidurals

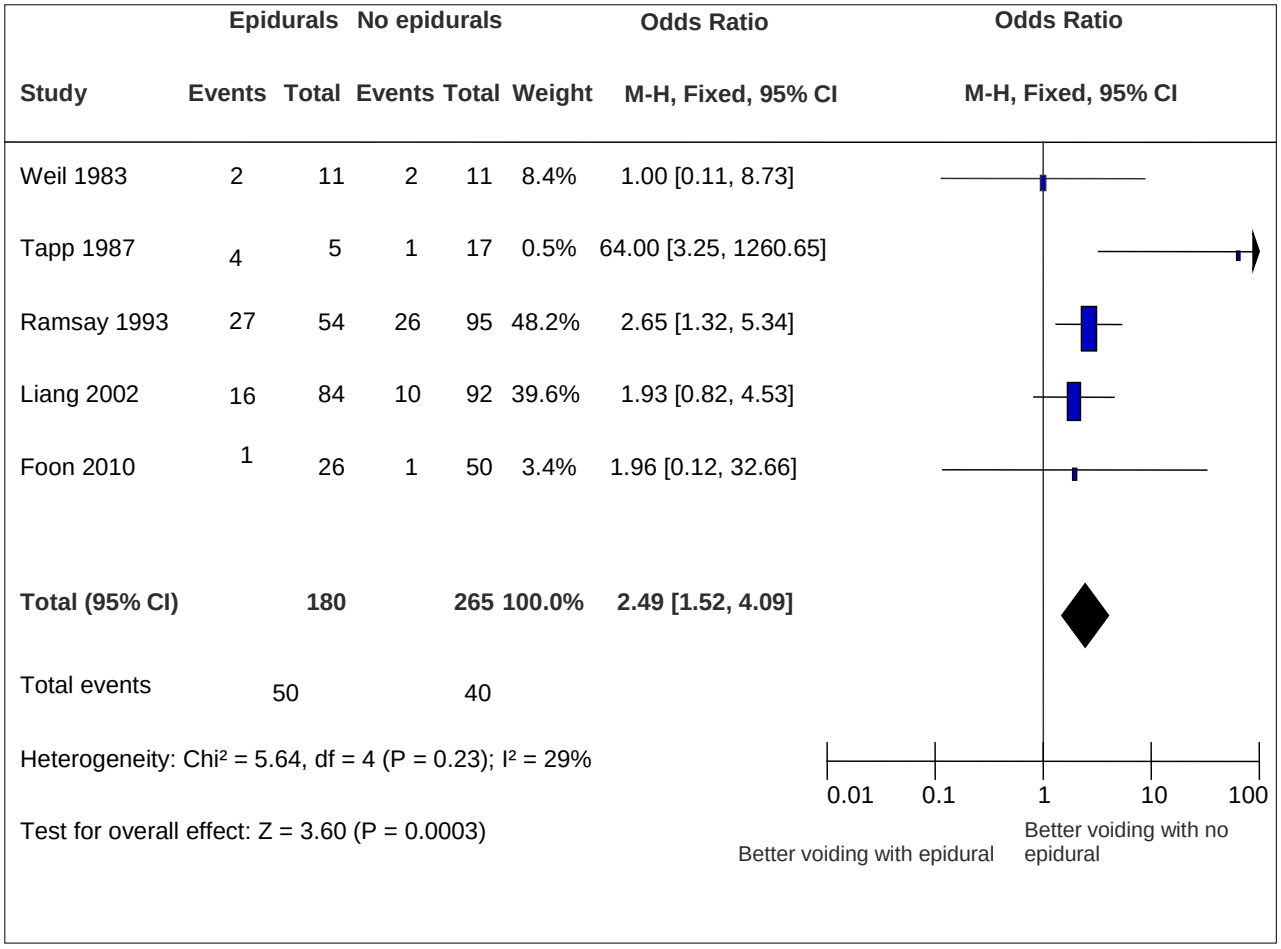


Figure 2.2 c: A meta-analysis of abnormal voiding after patients undergoing instrumental deliveries with and without epidurals

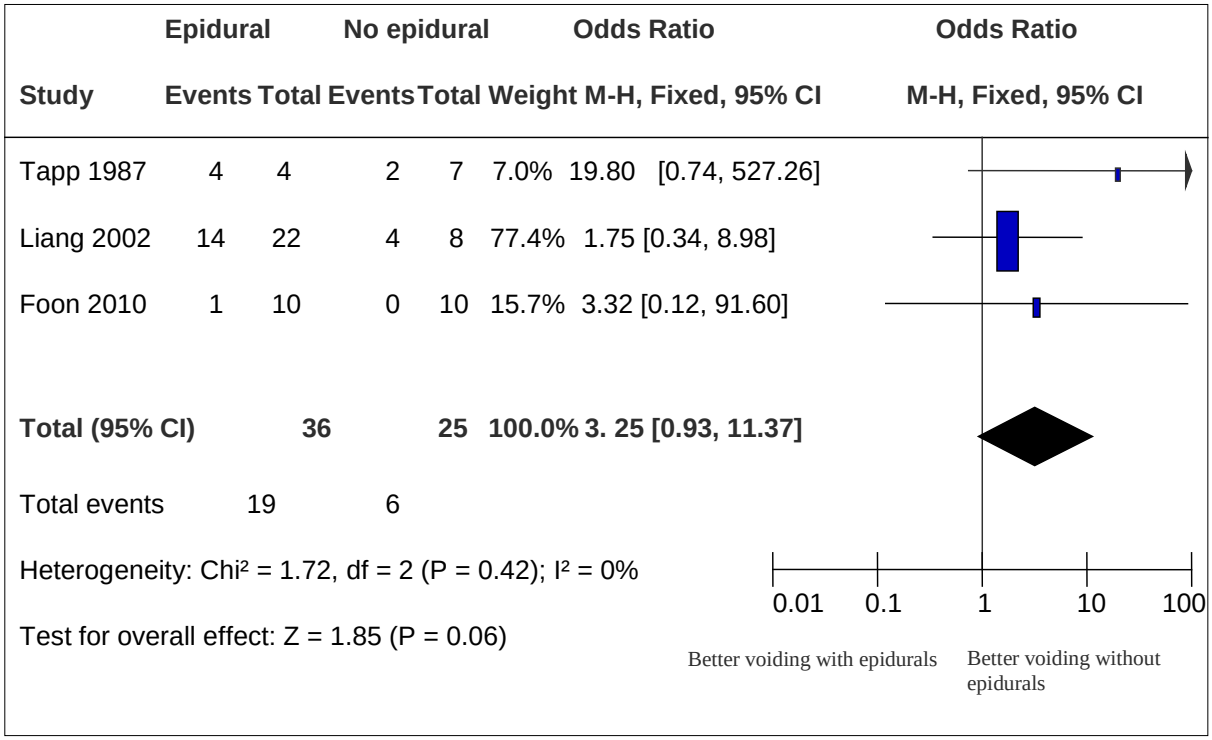


Figure 2.2 d: A meta-analysis of abnormal voiding after patients undergoing instrumental versus non-instrumental vaginal deliveries (regardless of anaesthesia)

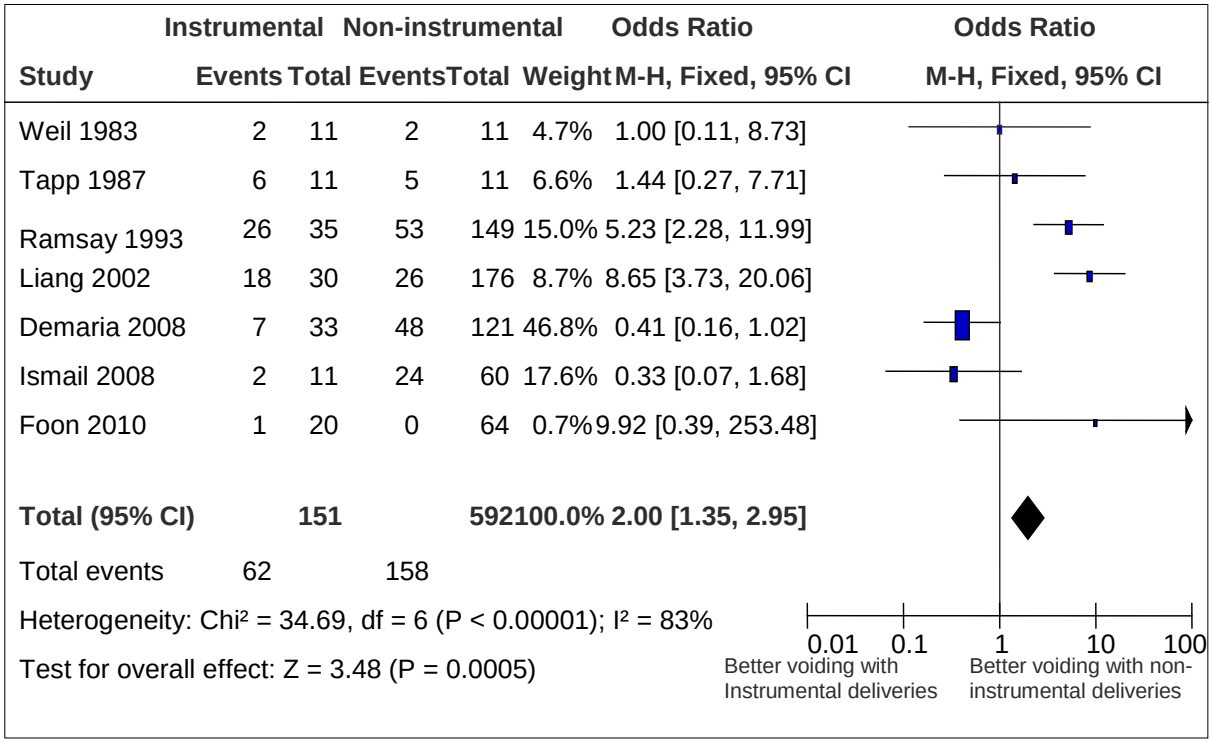


Figure 2.2 e: A meta-analysis of abnormal voiding after patients undergoing instrumental versus normal vaginal deliveries without epidurals

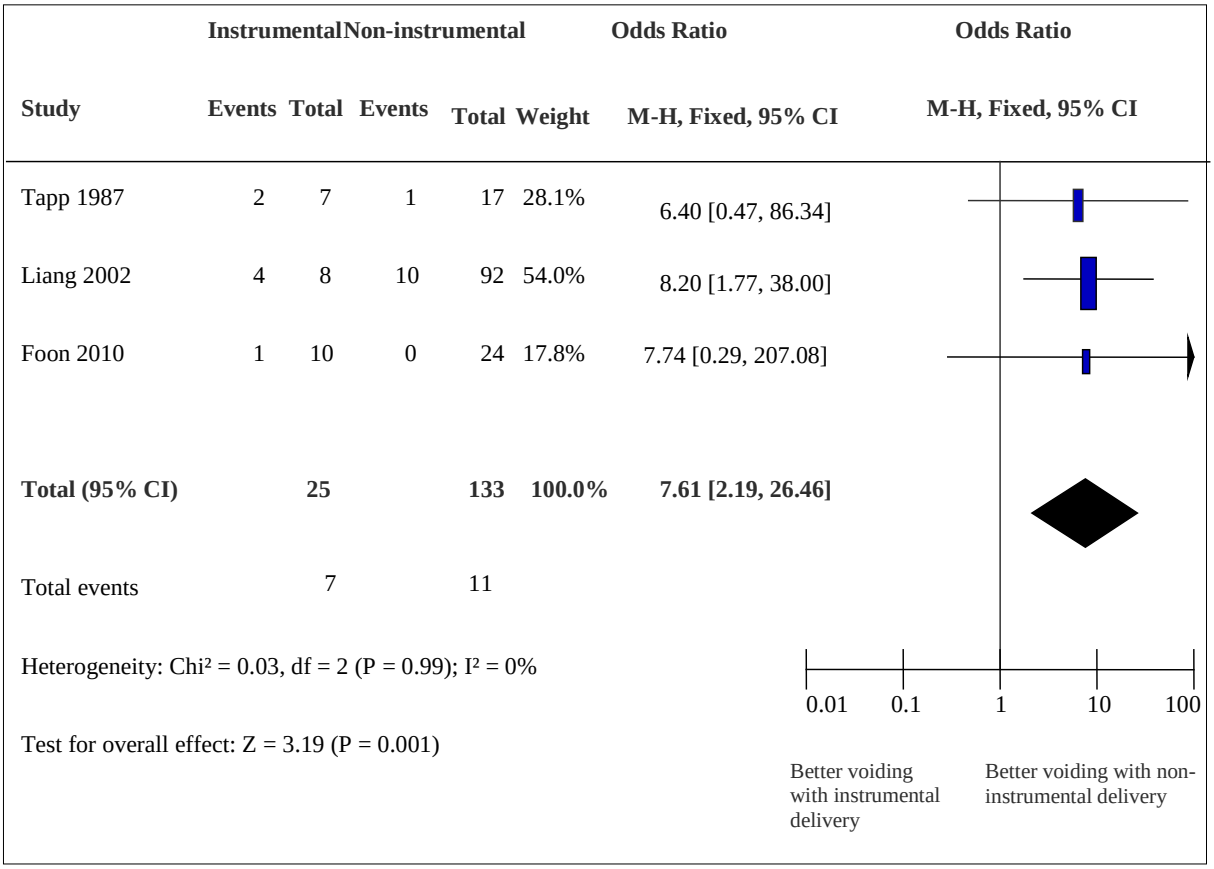
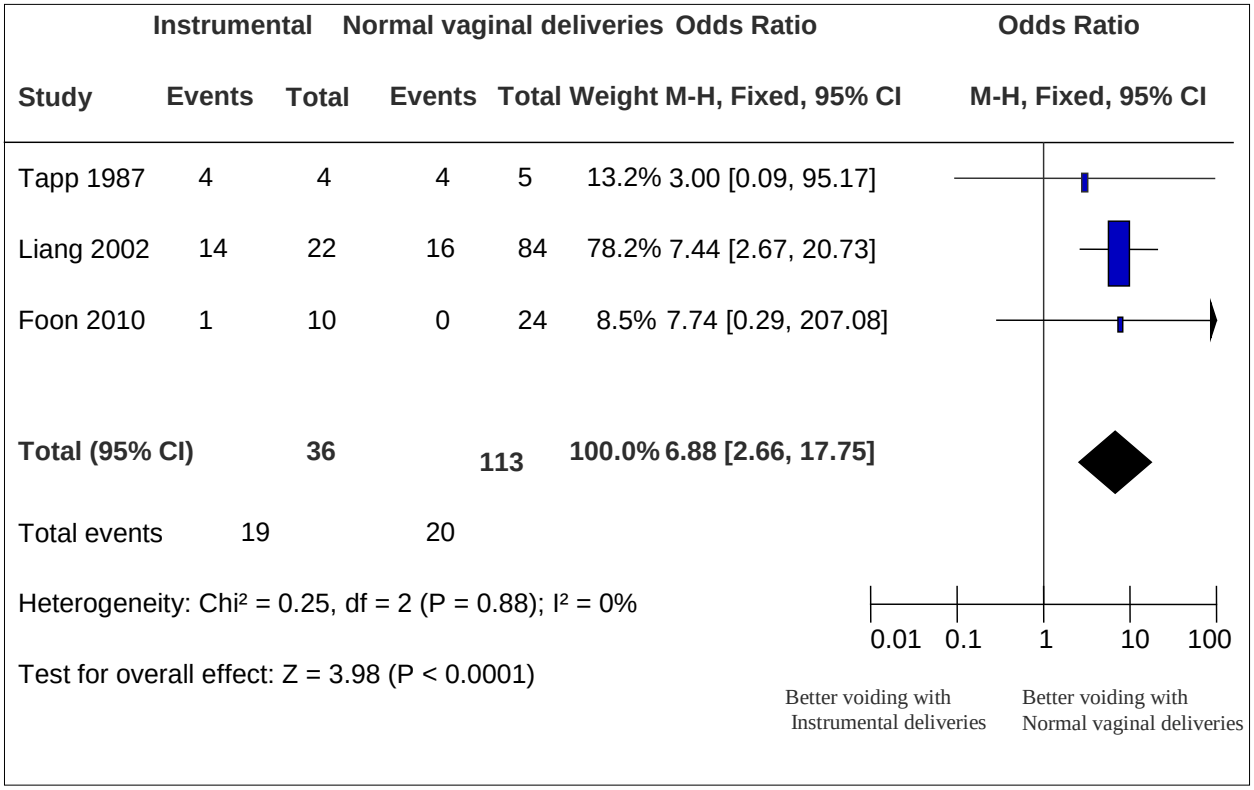


Figure 2.2 f: A meta-analysis of abnormal voiding after patients undergoing instrumental versus normal vaginal deliveries with epidurals



2.4 Discussion

This review demonstrates patients having vaginal deliveries and epidurals do have a risk of abnormal voiding following delivery. Patients who have significantly higher risk of abnormal voiding following delivery include patients having vaginal deliveries with epidural and patients having instrumental deliveries. However there was no significant difference in the risk of abnormal voiding associated with patients undergoing instrumental deliveries with epidurals versus those without epidural anaesthesia. That is to say that the combination of instrumental delivery and epidural does not significantly increase the risk of abnormal voiding when compared to patients having instrumental deliveries without epidural anaesthesia. It should be noted that the quality of the studies in the review was poor to moderate.

Anaesthesia affects the detrusor contractions by a neuraxial blockade hence causing urinary retention. Spinal anaesthesia with bupivacaine can produce a dysfunction of the detrusor muscle longer than blockage of the sensory and peripheral motor function thus causing urinary retention (Mulroy et al. 2002). Epidurals are not only associated with a higher incidence of motor blockade but also a longer second stage (Anim-Somuah et al. 2011). Both of these factors can contribute to the urinary retention following delivery (Viktrup & Lose 2001;Wilson, Herbison, & Herbison 1996). Another variable that needs to be taken into consideration is the fact that epidurals are usually requested in women having prolonged and in some cases obstructed labour. These women go on to have instrumental deliveries not only as a result of the obstructed labour but also as a result of epidural. It therefore means that the women with epidurals requiring instrumental delivery for a prolonged second stage have an added variable of a prolonged labour and this can have an added impact on the urinary bladder.

For the purpose of the meta-analysis we looked at the group of patients having vaginal deliveries, which included instrumental as well as non-instrumental vaginal deliveries as a separate comparison. One of the factors causing heterogeneity is the variation in anaesthesia given over the time span this review covers and the variations from different countries. In the most recent study included in the systematic review, patient controlled anaesthesia was given and this might have had a different impact on the bladder than the epidurals given 15 years ago.

There are some other limitations of this review that should be considered. The quality of the included studies was poor as most studies were deficient in the category of comparability. Publication bias is another factor that has to be taken into account with cohort studies. The likelihood of a cohort study being published is higher if the result is a positive one.

To my knowledge this systematic review is the first that looks at the effect of epidurals and delivery on voiding in the immediate post delivery period. There are several strengths of this systematic review. The search was systematic and thorough with no language restrictions. Attempts were made to contact the authors where data clarification was required. The review also addresses clear and concise questions and gives a summary of all the studies on the topic.

One of the solutions to the prevention of urinary retention during labour and immediately post delivery would be to keep an indwelling catheter or to perform intermittent catheterisation. A randomised controlled study comparing the two showed that there was no difference in the frequency of both urinary retention or urinary tract infections in the postpartum period (Evron et al. 2008). A study looking at various methods of epidural anaesthesia (high dose bupivacaine, combined spinal epidural and low-dose infusion), mobile epidural techniques allowed better maintenance of ability to void urine (Wilson MJ 2009).

The studies included in this systematic review were observational studies and in an ideal setting randomised controlled trials would be desirable but not feasible or ethical. But the sample size would have to be very large making it impractical.

There is evidence to suggest that the mobile epidurals methods decreases the risk of urinary retention, hence the need for catheterisation, when compared to the conventional high-dose epidural (Wilson 2009). With the advent of newer techniques for epidurals (e.g.: PCEA) the need for further robust prospective studies on the impact of anaesthesia on the bladder are required. There is some data based on a randomised controlled trial that have looked at patient satisfaction, control and pain relief but not on the impact of anaesthesia on the urinary bladder (Cooper et al. 2010).

CHAPTER THREE: ACCURACY OF TRANSABDOMINAL ULTRASOUND IN ESTIMATION OF BLADDER VOLUME IN THE POSTNATAL PERIOD

3.1 Introduction

Post residual bladder volume is defined as the volume of urine left in the bladder after completion of micturition (Haylen et al. 2012). As demonstrated in the previous chapter there is a paucity of data on post partum bladder function and perhaps because of this there is also a lack of data on the accuracy of measuring postpartum urinary bladder volumes. Data relating to voiding after surgery does exist. Some of the factors identified for voiding dysfunction include: previous history of urinary retention, anaesthesia for more than 2 hours, patients given anaesthesia with barbiturates or muscle relaxants, spinal anaesthesia, alpha-adrenergic drugs, postoperative opiates and more than 1000 mls intravenous fluid (Ringdal et al. 2003). Women undergoing elective Caesarean under spinal anaesthesia would potentially be at risk for developing urinary retention postoperatively. Long acting spinal anaesthesia with bupivacaine can delay return of bladder function long after the sensation has returned hence predisposing the patient to urinary retention (Axelsson et al. 1985).There are several methods of measuring residual volume ranging from the most invasive techniques such as catheterisation to less invasive methods such as radioisotopes, radiography and ultrasound (Yip et al. 1997). Catheterisation has the risk of introducing infection and also the invasive nature can lead to traumatisation of the urethra. The use of radioisotopes is also an invasive method that is complex and somewhat inaccurate. Ultrasound has no contraindication and is a method whereby one can easily assess the bladder volume. However despite this fact, ultrasound scanning not gained popularity. One of the possible reasons could be that the

incidence of reported urinary retention is very variable post delivery. It is estimated that the prevalence of urinary retention ranges from 1.7% to 17.9% (Saultz et al. 1991).

Ultrasound will give an estimate of bladder volume based on a series of assumptions about the shape of the bladder. Any estimation, by definition has an associated error and therefore assessment of accuracy of the technique is important to confirm that the results of the study are valid. There are several formulae to calculate the post residual volumes. Most formulae have been extrapolated using non-female or non-pregnant patients where there is usually more space in the pelvis for the bladder as the uterus is usually smaller than the immediately post partum uterus. There is also the difficulty in scanning the patient with the added oedema and in some cases the presence of an abdominal incision. I looked at patients undergoing elective caesarean sections and the accuracy of measuring the urinary bladder by ultrasound scanning. The null hypothesis was ultrasound scanning is not an accurate method of measuring bladder volume in patients following a caesarean section.

3.2 Methods

A prospective observational study was conducted for the period of January 2007 to March 2008 in which 44 patients undergoing elective Caesarean sections were recruited. These patients were the same group of patients who had elective Caesarean sections in Chapter 4 (demographics shown in Table 4.1).

Following delivery, the patients with the indwelling catheters had their catheters clamped (Foley 14Fr catheter as per hospital policy). Patients had their urinary bladders scanned when sensation to their bladders returned. After estimating the bladder volume using the ultrasound scan, the clamp of the catheter was released and the volume of urine expelled from the

bladder was measured. All patients had their catheter clamp released within 5 minutes of the ultrasound scan.

One individual measured the dimensions of the bladders as follows:

The subject was placed in the supine position with the ultrasound probe placed on to the lower abdomen thus enabling visualization of the longitudinal section of the bladder. The height of the bladder (the cephalocaudal diameter) was measured as well as the depth of the bladder (anterioposterior diameter) in the longitudinal section. With the same contact point maintained, the ultrasound probe was turned ninety degrees to identify the transverse diameter of the bladder. The width of the bladder corresponds to the widest diameter in the transverse scan. All measurements, height (H), width (W), and depth (D) were quantified in centimetres. The bladder volume was calculated using the formula:

Bladder volume = (H x W x D x π/6) – 10 mls.

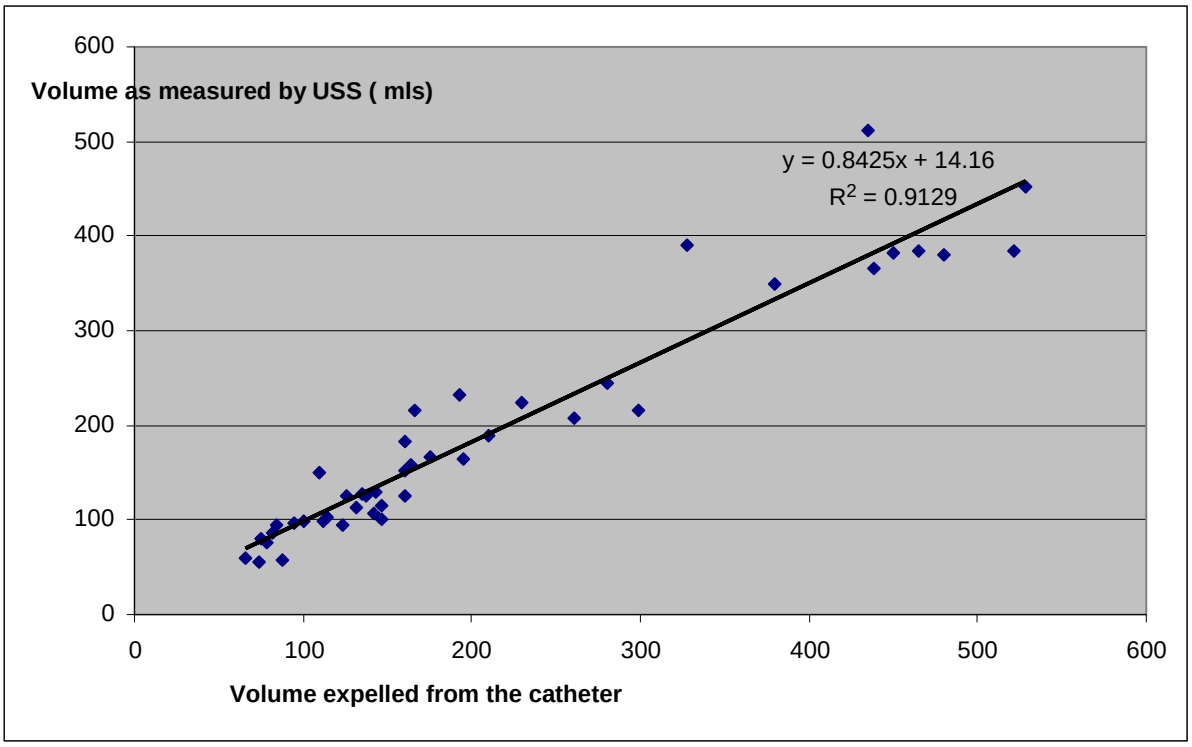
This formula has been validated based on previous work done on post partum bladder studies (Yip, Brieger, Hin, & Chung 1997;Yip et al. 2003). A value of 10 mls was subtracted to compensate for the volume of water in the balloon of the catheter.

For the purpose of this study actual volume was defined as the volume of urine expelled from the catheter when the clamp on the catheter was released (drainage time = 10 minutes).

The upper limit of normal post void residual done by ultrasound immediately after voiding was 30 mls while studies measuring the post residual volumes with catheterisation show an upper limit of 100mls (Haylen et al. 2008) . The difference could be because of the delay in catheterisation with the use of the catheter.

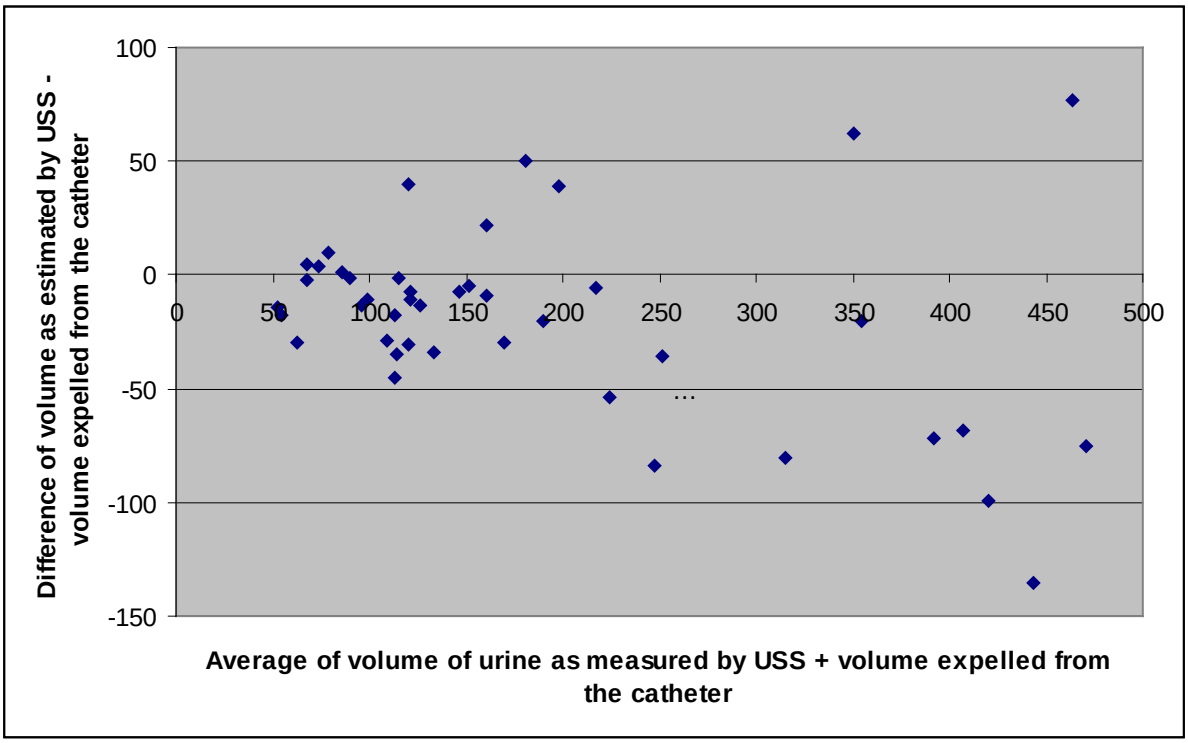
3.3 Results

Figure 3.1: Volume in the bladder as estimated by ultrasound vs. Volume of urine in the bladder (expelled from the catheter)



There is good correlation between the volume of urine measured by ultrasound and the volume of urine expelled from the bladder when the clamp on the catheter was released. A Bland Altman plot comparing the calculated volumes on ultrasound and volume of urine expelled from the urinary bladder. The mean difference was 5.1 mls with a standard deviation of 41.1 and a range of –135 to 77 mls.

Figure 3.2: Bland Altman plot comparing the calculated volumes on ultrasound and volume of urine expelled from the urinary bladder



3.4 Discussion

The study confirms good correlation between the volume of urine present in the bladder and the volume of urine measured using the ultrasound scan (Toshiba Nemio 10 ultrasound machine) in the immediate post partum period. The Bland Altman plot showed that using the ultrasound scanning one was more likely to underestimate the volume of urine than overestimate. It also showed that the likelihood was higher for larger volumes of urine. The degree of accuracy can be due to maintaining the ellipsoid shape of the bladder and using the formula: Bladder volume = H x W x D x π/6.This could also suggest that the urinary bladder

maintains an ellipsoid shape in the immediate postpartum period. However the effect of a postpartum uterus impacting on the wall of the urinary bladder can sometimes influence the shape of the bladder. This may well account for the underestimation in the measurement of the urinary bladder and the reason for the inaccuracy in measurement in the larger bladders. The post residual volume is defined as the volume of urine left in the bladder at completion of micturition (Haylen et al. 2010). The renal output can range from 1- 14 mls/min which added to the volume in the urinary bladder in the immediate post void period and measurement by ultrasound can reduce this error if done immediately after voiding (Haylen and Lee 2008) (Haylen et al 2008). It is estimated that 1.7 to 17.9% of patients do have retention of urine in the immediate postpartum period (Burkhart et al. 1965). The residual volume does predispose the patient to urinary tract infections and in cases of significant volumes, can lead to permanent bladder damage. In a survey conducted on post operative patients who developed urinary retention these patient were 2 times more likely to develop a urinary tract infection, five times more likely to suffer a catheter-related complication and hence required additional hospital care (Wu 2012). The use of the Foley catheter might have some implications with regards to the accuracy of the volume of the urine in the bladder measured and the volume expelled upon releasing of the clamp.

Studies have looked at the use of the ultrasound bladder scanners as a postoperative tool in determining whether a patient is in retention before catheterising and hence preventing unnecessary catheterisation. The portable ultrasound scanner (Bladder Scan, Diagnostic Ultrasound model BVI 3000) gives a quick but an inaccurate estimate of the bladder volume in the postpartum period (Mathew et al. 2007). Another study showed the mean difference between ultrasound measurements and catheter urine volume of 21.5 mls (95% CI –147 to 104mls) (Roseland L 2002). However this study did not look at post partum patients and the

former involve the use of more than one operator hence the data could be operator dependent. While the accuracy of an ultrasound bladder scanner has not been looked at in many studies done on postpartum patients immediately following delivery, the concept of doing an ultrasound scan to prevent unnecessary catheterisation is something worth considering. The accuracy of ultrasound scanning with a mean difference in volume of 5.1 mls would be a suitable method for diagnosing urinary retention. However this does require the resources of having trained staff to perform ultrasound scanning on a regular basis. In addition it does require adequate resources in having the equipment available. Nevertheless it can be a useful tool in performing an ultrasound scan on patients who are at risk of urinary retention prior to discharge. There was a discrepancy of ultrasound estimates of bladder volume by 17.6%. This may be due to a larger range of volume of urine in the bladder in the group of patients. One of the factors this study did not take into consideration was the time between the actual release of the clamp on the catheter and the ultrasound scanning of the urinary bladder. All patients had the catheter clamps released within 5 minutes of being scanned. However it is unknown as to the exact time it takes for the urinary bladder to completely empty after the catheter clamp is released. It can therefore be concluded that the volume of urine in the bladder in the postpartum patient can be accurately measured using the formula: Bladder volume = H x W x D x $\pi/6$ – (volume of water in the catheter balloon). It has a higher accuracy when measuring lower volumes in the bladder and therefore can be a useful tool in determining patient with residuals greater than 150mls. This is of particular benefit in the postpartum patient.

Chapter Four: THE EFFECT OF ANAESTHESIA AND MODE OF DELIVERY ON THE URINARY BLADDER FOLLOWING DELIVERY

4.1 Introduction

It has been stated or reported that a one episode of over-distension injury of the urinary bladder can result in permanent damage of the detrusor muscle resulting in abnormal bladder function (Hinman 1976). Women in the immediate post-delivery period, are vulnerable to bladder over-distension through both regional anaesthesia used during childbirth and temporary nerve damage during childbirth (Smith A.R.B 1989). The afferent sensory impulses from the bladder may be blocked by epidural analgesia thus suppressing the reflex mechanism for micturition (Katz and Aidinis 1980). Women with normal vaginal deliveries show evidence of denervation of the pelvic nerves which has been confirmed by neurophysiological studies (Smith A.R.B 1989).

When conducting the literature search for chapter two, only one abstract was identified looking at patients undergoing epidural anaesthesia and the time taken for sensation to return to the urinary bladder after vaginal delivery (Khullar V 1993). The study was conducted in a small cohort (n =18) with the authors reporting a mean time of 402 minutes (0 – 480 minutes) for voiding sensation to return. Another limitation of this study was that the bladder was filled in a retrograde manner, which is not in keeping with normal physiological filling (Khullar V 1993). In view of the dearth of data relating to the risks associated with bladder anaesthesia in the postnatal period we decided to undertake this study.

The aims of the study were to:

1. Identify the time taken for sensation to return to the maternal urinary bladder following various forms of regional anaesthesia and modes of delivery.

2. Record the volume of urine in the bladder when sensation returned to the bladder and compare it with the total volume of urine produced at that time.

3. Assess the post-micturition residual volume of urine within 48 hours after delivery.

4.2 Method

This study was registered with the Birmingham Women's Foundation Trust Research & Development Committee (Hereford and Worcester Local Research Ethics Committee - 06/Q2801/60). The women were recruited from the preoperative clerking clinic and the antenatal clinic. The period of time between recruiting patients and enrolling the patient into the trial ranged from 24 hours to 1 week.

Women having vaginal delivery (both instrumental and non-instrumental) with or without regional epidural analgesia and women undergoing elective caesarean section under regional spinal anaesthetic were recruited. All women having an epidural had patient-controlled epidural anaesthesia (PCEA).

The inclusion criteria:

- Term pregnancies (37 completed weeks until 42 weeks)
- Patient's age of more than 16.

Exclusion criteria:

- Women with pre-existing renal anomalies
- Symptoms of a urinary tract infection.
- Any contraindication to clamping the catheter, (e.g. post partum haemorrhage or suspected bladder trauma).

Table 4.1 shows the demographic details of the patient population. In keeping with hospital policy, women had indwelling catheters following epidurals, instrumental and Caesarean sections. In order to allow filling of the bladder under physiological conditions women with indwelling Foley catheters had their catheters clamped. The time taken for first subjective sensation to void was recorded. An ultrasound scan of the urinary bladder was performed prior to releasing the clamp on the catheter. This was used to estimate the volume of urine in the bladder as part of the ultrasound validation study (Chapter 3). The clamp on the catheter was then released and the volume of urine expelled via the catheter was measured. This allowed the volume of urine present in the urinary bladder when sensation occurred to be recorded. The volume of urine expelled from the catheter was compared with the estimated volume of urine using the ultrasound scans as indicated in chapter three. The methodology of estimating the volume of the urinary bladder has been mentioned in chapter three.

An ultrasound scan was done at regular intervals (every 1-1 ½ h) in order to detect over-distension of the urinary bladder while the clamp was applied. The clamp on the catheter was released if the estimated volume of urine present in the bladder was greater than 450 ml. The volume of urine expelled from the catheter was measured on every occasion that the catheter clamp was released. Patients were asked to indicate when they felt their first desire to void and for the purpose of the study this was taken as the return of bladder sensation. When the patient indicated that sensation to the bladder returned, the volume present in the bladder was added to the volume of urine previously expelled from the bladder giving the total volume of urine produced while awaiting the return of bladder sensation.

Women without regional anaesthesia did not routinely have indwelling catheters and so had their bladders emptied during the second stage of labour using an “in and out “catheter. The catheter was inserted using aseptic technique as per normal management of labour in the unit.

When sensation returned to the bladder the time taken was noted and the volume present in the bladder estimated using an ultrasound scan (Toshiba Nemio 10 ultrasound machine). Following vaginal delivery patients received as range of analgesia: diclofenac sodium (100mg pr stat), paracetamol (1g po qds) or codeine (30 -60 mg tds).

The women having elective Caesarean Section under spinal anaesthesia were given fentanyl (15 – 25 micrograms) and 0.5 % bupivacaine (2.2 – 2.7 ml). As part of the postoperative pain relief these women were given a combination of a 1g paracetamol suppository and/or a diclofenac sodium 100 mg suppository and up to 2 doses of morphine (10 – 15 mg). Women were excluded if they required more analgesia before sensation returned to the bladder. None of the patients had conversions to general anaesthesia.

Post-micturition residual volumes were estimated by ultrasound scan within 48 hours of delivery.

All the data from this study was analysed using the MedCal software. Intergroup comparisons for continuous variables with a non-parametric distribution were made using the Mann-Whitney U test to determine significant differences between the data sets. For such data, median values and interquartile ranges are described. Categorical data were analysed using Fisher's exact test and odds ratios and 95% confidence intervals.

4.3 Results

A total of 153 pregnant women were recruited in the study during the period January 2007 – March 2008 (nulliparous patients 39.1%). Four women were withdrawn because of post partum haemorrhage, two women required extra morphine injections post delivery, two had significant haematuria suggesting possible bladder trauma at Caesarean section and 5 withdrew consent. Thus 140 women completed the study (91.5%).

Table 4.1: Demographic details of the patients completing the study.

	Spontaneous Vaginal delivery without PCEA (n = 50)	Elective Caesarean Section under spinal anaesthesia (n = 44)	Spontaneous Vaginal with PCEA (n = 26)
Age (yrs.)	28.9 (20 – 40)	32.1 (24 – 41)	27 (17 – 41)
Infant birth weight (kgs)	3.2 (2.3 – 4.3)	3.3 (2.4 – 4.84)	3.4 (2.1 – 4.5)
Parity	1.2 (0 – 6)	1.4 (0 – 3)	0.7 (0 – 4)
BMI	25.8 (16.3 – 45)	28.1 (20.5 – 41.4)	25.2 (19.4 – 35.3)
Duration of second stage (min)	24 (1-217)	N/A	103 (17 – 248)*
Perineal tears	30 (50%)	N/A	10 (38.6%)*
Previous Caesarean Sections	7(14%)	28 (63.6%)*	3(11.5%)*

* P value <0.05 versus patients having spontaneous vaginal delivery without PCEA

Table 4.2: The time taken and volume of urine in the bladder when sensation returns to the bladder

	Vaginal deliveries with no regional anaesthesia (n= 50)	Vaginal delivery with PCEA (n=26)	Caesarean Section with Spinal anaesthesia (n= 44)
Median time for bladder sensation to return (minutes) IQR for median	122 (46– 397) 112 – 136	234 (95 – 382) 202 – 291	374 (172 –692) 311 – 425
Median Vol. of urine at first sensation (mls) IQR for median	144 (42 – 631) 112 – 192	200 (74 – 600) 136 – 336	152.5 (56 – 518) 125 – 270
Total vol. of urine at first sensation (mls) median IQR for median	144 (42 – 631) 112 – 192	461 (74 – 1500) 343 – 650	415 (115 – 2755) 314 – 601
Residual volume (mls) – median	17 (5 – 161)	16 (2 – 92)	32(5 – 163)
Number with residual vol. > 150mls	1	1	1

Table 4.3: The time taken and volume of urine in the bladder when sensation returns to the bladder following instrumental deliveries

	Instrumental delivery without PCEA (n= 10)	Instrumental with PCEA (n=10)	P value
Median time for bladder sensation to return (minutes) IQR for median	134 min (113 – 181) min	278 min (151 – 376) min	> 0.05
Median Vol. of urine at first sensation (mls) IQR for median	202 (78 – 542	152 (74 – 1011)	> 0.05
Total vol. of urine at first sensation (mls) – median IQR for median	202 (78 – 542)	395 (150 – 1011)	> 0.05
Residual volume (mls) – median	41 (6- 64)	78 (4 – 165)	> 0.05
Number with residual vol. > 150mls	0	1	

Fifty women (41.7%) had spontaneous vaginal deliveries without regional analgesia while forty-four women (36.7%) had elective Caesarean section under spinal anaesthesia and twenty-six (21.7%) had vaginal deliveries with PCEA. The time taken for sensation to return and the volume of urine present in the bladder when sensation returned are shown in table 4.2 & 4.3. The total volume of urine produced before sensation returned is shown in table 4.2 & 4.3.

Ultrasound estimates of bladder volume prior to releasing the catheter were within 17.6% of the measured volume of urine expelled from the bladder (r=. 92 p<0.0001, 95% CI 0.86 to 0.96). There was a slightly higher tendency to underestimate (52%) than to overestimate the volumes on ultrasound scan using the formula as described in chapter three (Yip, Brieger, Hin, & Chung 1997). The incidence of post -residual volumes greater than 150 mls was 2/76 (2.6%) for all vaginal deliveries and 1/44 (2.3%) for elective caesarean sections under spinal anaesthesia.

4.4 Discussion

To my knowledge this study is the first attempt to identify the effects of PCEA on the urinary bladder immediately post delivery. The study also looked at the effect of both vaginal delivery and spinal anaesthesia following elective Caesarean section on the urinary bladder sensation.

The median time for bladder sensation to return was 122 minutes following vaginal deliveries without regional analgesia, following Caesarean section under spinal anaesthesia was 374 minutes and over 234 minutes following vaginal deliveries after PCEA. The incidence of post-micturition volumes greater than 150 ml at 48 hours was 2.3% following elective

Caesarean section under spinal anaesthesia and 2.6% for all vaginal deliveries (with and without epidurals). The median volumes present when sensation returned ranged from 144 – 200 ml for modes of delivery included in this study.

The limitations of the methodology of this study are as follows: the majority of women undergoing vaginal delivery without regional anaesthesia had their bladder volumes estimated by ultrasound as they did not have indwelling catheters. However, as outlined in chapter three patients with a catheter were used to establish an absolute error of the estimated volumes. Women with indwelling catheters had their catheters clamped until first desire to void returned. We ensured that over distension of the urinary bladder did not occur by releasing the catheter when the ultrasound estimation measured a bladder volume greater than 450 ml. This therefore meant the bladder needed more time to refill. If the main factor that determined resumption of bladder sensation was time and not volume then this methodology can result in lower bladder volumes when sensation returns. However this factor may have only affected the 8 (5.7%) patients whose catheters were release for fear of over distension.

We considered the pertinent anaesthesia method used to be satisfactory if it achieved the required mode of delivery. For example if a local anaesthesia worked well enough to achieve an instrumental delivery then these patients were included in this category. However some in the case of regional anaesthetics some would have been more effective than others.

There are a number of other variables that can affect sensation to the bladder and post-delivery voiding especially in patients undergoing vaginal delivery without regional anaesthesia. These include lacerations to the vagina and other methods of analgesia used intrapartum such as Entonox, Pethidine and the use of TENS. The use of Opiods especially if utilized in conjunction with epidural anaesthesia has previously been shown to be associated with voiding difficulties (Panicker J 2009). There was a wide range of analgesia given post-

delivery, which included diclofenac paracetamol and codeine all of which may have an additional impact on bladder sensation. Poor voiding secondary to fear, oedema, detrusor hypotonia and bruising may also exist (Ramsay & Torbet 1993).

In this study nothing was known about the women's antecedent voiding function and bladder sensitivity. Patients were recruited for this study in the third trimester therefore their bladder could not be assessed preconception. Women were recruited based on the assumption that they had no pre-existing factors that could have affected bladder function after delivery. Similarly factors like birth weight, age, parity and length of the second stage might have some impact on the urinary bladder but there is nothing in the medical literature that addresses this issue for patients in the reproductive age group and as such they could be viewed as "normal" or typical women not reporting antecedent problems (Foon, Toozs-Hobson, Millns, & Kilby 2010).

In this study postpartum retention of urine was defined as a post-micturition residual bladder volume of greater than 150 ml on ultrasound scan estimation (Andolf, Iosif, Jorgensen, & Rydhstrom 1994). From the literature the incidence of asymptomatic postpartum post-micturition retention ranges from 1.5% to 9.7% following vaginal delivery (Andolf, Iosif, Jorgensen, & Rydhstrom 1994;Yip, Brieger, Hin, & Chung 1997). This study showed comparable results with an incidence of 2.3% following elective Caesarean section under spinal anaesthesia and 2.6% for all vaginal deliveries (with and without epidurals). The incidence of retention might seem low. However given the fact that all of these women were unaware of retention it could mean a significant number of patients being discharged with an underlying voiding problem if strict bladder care is not practised following delivery.

As mentioned previously, the methodology involved clamping the catheter until first sensation to void returned. This however may have accounted for lower bladder volumes at

the time of first sensation to void when contrasted to the only other studies that explored this phenomenon (Weil, Reyes, Rottenberg, Beguin, & Herrmann 1983). The median time taken for sensation to return to the bladder following delivery in groups with epidurals was slightly shorter than a previous study (234 minutes v 402 minutes) (Khullar V 1993). This could be partially due to the fact that in this study patients had patient controlled epidural anaesthesia. In addition that study used retrograde filling of the bladder and then proceeded to determine first sensation to void. This method is firstly artificial (but in keeping with other lower urinary tract investigations) and is based on the premise of a linear return of sensation rather than a stepwise response. The importance of this is that anaesthesia works in an 'all or none' approach, there cannot be a partial depolarisation of a neurone. The question of intensity is a factor of rate of depolarisation. By allowing the bladder to fill under physiological conditions it is estimated that this would give a more accurate and realistic estimation of time and volume of urine present at first sensation. Animal studies support the fact that diuresis cystometry approximates physiologic bladder filling more accurately than retrograde filling. The studies also show that the threshold volumes and compliance are significantly higher with diuresis cystometry (Hamaide et al. 2003). There is also the risk of introducing infection with retrograde filling as opposed to antegrade filling. However the investigations that look at the lower urinary tract function, such as urodynamics, do involve retrograde filling.

This study shows bladder sensation may take over eleven hours to return following Caesarean section under spinal anaesthesia, and between six to seven hours following vaginal deliveries with PCEA. This is not in keeping with a common misconception that spinal anaesthesia lasts approximately two hours. Bladder sensation is controlled by the small unmyelinated fibres, which are the last to revert to normal after regional anaesthesia (Axelsson, Mollefors, Olsson, Lingardh, & Widman 1985). The volume of urine produced before sensation returned in this

study was 2.7 litres in the caesarean spinal group. The volume of urine produced can be affected by excessive use of intravenous fluid. In the anaesthetised postnatal patient, the effect is exaggerated due to the vascular effects of anaesthetic being reversed and vascular tone regained producing an iatrogenic diuresis. This can potentially lead to a higher risk of bladder distension injury. One therefore has to question the optimum time to remove catheters following delivery.

There was a weak correlation between time taken for return of sensation in the bladder and volume of urine in the bladder after vaginal delivery. The same could be said for women having Caesarean section with spinal anaesthesia and vaginal delivery with PCEA. The negative correlation between volume present in the bladder and time for sensation to return in patients having PCEA may be as a result of the urine concentration. Animal studies have shown that a hyperosmolar concentration of saline can induce bladder motor activity similar to that seen in an overactive bladder (Juszczak et al. 2010). If this can be extrapolated to humans then it would mean that a high urine concentration can affect that sensation to void.

Overall the study was unable to demonstrate a reliable correlation between time and bladder sensation. It is suggested that return of sensation is a function of time rather than volume. This might imply that anaesthetic effects reverse in a stepwise fashion dependant on fibre type rather than by a gradual return as suggested by the return of sensation to the skin (which has a denser innervation). This suggests that the effects of anaesthetic on the bladder are potentially more profound than on other organs such as skin. We would suggest that return of sensation of light touch on the lower limbs cannot therefore be taken as reassurance of immediate and concurrent return of adequate bladder sensation (Foon, Toozs-Hobson, Millns, & Kilby 2010).

Chapter five

Anaesthesia for incontinence surgery: A randomized controlled trial using spinal versus local anaesthesia

5.1 Introduction

Mid-urethral retro pubic sling insertions were initially introduced as an ambulatory day case procedure. Today they have become a well-established surgical treatment for urodynamic stress incontinence. Ulmsten et al in 1995 first published this procedure and it was performed under local anaesthesia (with sedation) (Ulmsten et al. 1996;Ulmsten et al. 1998). Initially it was thought since it avoids paralysis of the abdominal and pelvic floor muscles the procedure should be undertaken under local anaesthesia. This also allows the patient to cough during the procedure to try and optimise tape placement. There have been studies that have compared epidurals versus local anaesthesia (Wang and Chen 2001). Currently the procedure is performed under general, spinal or epidural anaesthesia as well as under local anaesthesia with sedation. There is evidence suggesting no difference in the intraoperative and postoperative complications when insertion of the tape is done under spinal anaesthesia versus general anaesthesia (Ghezzi et al. 2005).

Pain during the operation is an unpleasant experience and is an important complaint of patients. There have been concerns with regards to providing adequate analgesia during the procedure without general or regional anaesthesia.

Because of this fear of pain or discomfort during the operation local anaesthesia is sometimes avoided. It is therefore important to assess the patient's perceptions of the various forms of anaesthesia. To date there are no randomised controlled studies looking at the patient's perception of pain, feeling of control nor has there been the surgeon's assessment on the patient's cooperation when comparing various forms of anaesthesia used for the insertion of

retropubic tapes. In addition there is little in the literature looking at the effect of both forms of anaesthesia on the bladder in the immediate postoperative period.

The aim of this study was to compare the efficacy of using spinal anaesthesia to sedation/local anaesthesia for the insertion of retropubic tapes from both the patient and surgeon's perspective. The study looked at the effect of both forms of anaesthesia on the bladder sensation post operatively. The clinical application for this would be to better inform patients in their choice of anaesthesia and also formulating a policy for bladder care immediately post operatively.

5.2 Null Hypothesis

There is no difference in bladder sensation when local/sedation is used compared to spinal anaesthesia in patients undergoing mid-urethral retropubic tape insertion.

5.3 Method

Forty patients were recruited with thirty-eight patients completing the study with 19 patients being assigned in each group. All patients included in the study had confirmed urodynamic stress incontinence requiring a Retropubic tape to be inserted as a primary procedure. Urodynamics failed to show any evidence of voiding difficulties.

The exclusion criteria were as follows:

Contraindication to spinal anaesthesia

Unable/unwilling to give consent

Significant respiratory/cardiovascular disease/ epilepsy

Allergy to propofol, Opiods, local anaesthetics

Previous pelvic floor repair or incontinence surgery

The patients were approached, given the information when seen in the clinic and consented prior to surgery on the admission ward. Randomization by an opaque envelope to low dose spinal anaesthesia (LDS) or to propofol target controlled sedation regime (TCI) took place in the anaesthetic room using an envelope containing a computer generated randomisation code which had been placed in an opaque envelope. The anaesthetist in the anaesthetic room, prior to administering the anaesthetic, opened the envelope. The study looking at the effect on the bladder was carried out with the intention to treat. Surgeons were not allowed into the anaesthetic room, thus blinding them to the type of anaesthesia. Patients were given either a spinal anaesthesia or 'sham' spinal anaesthesia hence blinding the patients.

Technique

A 14-16 g venous cannula was inserted.

Full monitoring was applied: continuous pulse oximetry, non-invasive blood pressure and continuous ECG.

500mls intravenous preload of 0.9% saline was given to both groups.

2 mls of lignocaine 1% was injected into the skin of back of all patients at a suitable lumbar vertebral interspace. Diprifusor infusion pump containing a syringe with 1% propofol was connected to all study volunteers.

In the group having spinal anaesthesia, using an aseptic technique, spinal anaesthesia was given via a 25-gauge Whitacre pencil point needle, at a suitable lumbar interspace, with 2.5mg-5.0mg hypobaric bupivacaine and 25mcg fentanyl (total volume 1.5mls-2.5mls). Discomfort during surgery in the spinal anaesthesia group was treated with the sedation group protocol.

The technique used to insert the mid urethral retropubic tape was as follows: the patient was placed in the lithotomy position. In both groups, local anaesthetic (Prilocaine) was

administered by infiltration to the operative field using a standard regimen of 100 mls normal saline, 50 mls Prilocaine and 1 ml of 1:1000 Adrenaline by the surgeon. Two retropubic infiltrations were made using 60 mls of the solution at each site. The points of infiltration were approximately 2cm from the midline at the level of 1 cm above the pubic symphysis. Suburethral and bilateral vaginal infiltrations were performed using the remaining 30mls of the infiltrate solution. A suburethral incision was made approximately 1 – 1.5 cm from the urethral orifice. Using a pair of McIndoe scissors a tunnel was made bilaterally inferior to the pubic rami. A rigid introducer was inserted into a 14 Fr catheter and the patient was catheterised. The urethra was deflected accordingly and a midurethral retropubic tape (Gynaecare device) was inserted as described by Ulmsten (Ulmsten 1995). Patients in both groups were asked to cough and the tape adjusted until there was no leakage.

In the local anaesthetic group additional sedation with propofol was commenced to a target concentration of 1mcg/ml of propofol. The target concentration was adjusted to achieve a sedation level of 2-3. If discomfort or pain occurred, incremental doses of 100 mcg of alfentanil were administered.

Heart rate, non-invasive blood pressure, oxygen saturation, respiratory rate, airway maintenance, sedation level were assessed at 5-minute intervals and surgical stimulus at the time of observation.

The target concentration of propofol and dose of alfentanil administered was recorded at the same time intervals of 5 minutes. The total dose of propofol and alfentanil given during the entire procedure at the end of surgery was documented.

Every patient received supplemental oxygen at 2 litres per minute via nasal cannulae.

Both groups of patients had an infiltration of local anaesthesia at the planned sites of entry and exit of the needles of the Retropubic tapes. A volume of 300 mls of Normal saline was used to fill the urinary bladder and Cystoscopy was performed.

Four hours post operatively a 100 mm visual analogue score was used to estimate the perception of the pain and feeling of being in control. The surgeons were also asked to rate the patient's cooperation using a 100mm visual analogue score. In the immediate postoperative period the patients had indwelling catheters. The patient's bladders were filled at one, two and three hours post operatively with normal saline. The volumes of urine present to elicit first desire and strong desire to void in both groups were recorded. For the purpose of the study the first desire to void was defined as the first feeling the patient has to void urine while the strong desire was defined as the persistent desire to void. Patients were asked about this at 1,2 and 3 hours following their surgery.

The sample size was calculated using power analysis based on a difference of a score of 20mm on the VAS between the 2 groups. Assuming a withdrawal rate of 10%, 40 patients had to be randomized leaving 18 patients in each group. The analysis is based on a 5% type 1 error with 80 % power. The null hypothesis was that there is no difference in the return to bladder sensation in the group having local versus spinal anaesthesia.

All data are reported as range and mean or median if appropriate. Comparisons between both groups were done using the Fisher's exact test, Mann-Whitney, Wilcoxon Signed rank test or the Student's t –test. The analysis was done using the MedCal software (MedCal Software bvba, Belgium). A p value of 0.05 was considered as statistically significant confidence intervals. Significance was taken as $P<0.05$ unless otherwise stated. The patients were grouped as intention to treat.

5.4 Results

Patients were recruited between January 2003 and March 2008. Fifty patients were approached to take part in the study but 10 declined. Forty patients were identified who had urodynamic stress incontinence in the absence of pelvic prolapse had a Retropubic tape insertion and were willing to be randomised. Of the 40 patients 19 patients were randomised into the group having sedation and 19 into the spinal anaesthesia. One patient in each group had to be withdrawn since one patient had to return to theatre for bleeding (spinal group) and another patient withdrew from the study (sedation group). As a result of this we do not have any data on the bladder sensation after surgery for these two patients. Both groups of patients were similar in age, parity and body mass index (table 7.1).

Table 5.1: Demographic features of the patients

Parameter	Tapes inserted under sedation	Tapes inserted under spinal anaesthesia	P value
Age (mean + SD)	54.4(SD 11.2)	53.5 (SD 11.6)	NS
Body Mass index (mean +SD)	27.3 (SD 5.3)	27.9 (SD 5.8)	NS

No significant difference between the means of both groups = NS

Table 5.2: The mean VAS (visual analogue scores) for sedation and spinal anaesthesia

	Mean VAS scores (sedation) N= 19	Mean VAS scores (spinal) N = 19	P value
Surgeon's assessment			
Patient's cooperation	69.4 (SD 27.26)	93.6 (SD 13.7)	0.0014
Patient's cooperation (Surgeon- Consultant)	68.2(SD 28.2)	92.3 (SD 14.68)	0.0015
Patient's cooperation (Surgeon – trainee)	70.2 (SD 4.21)	95.8 (SD 3.06)	0.0017
Patient's satisfaction			
Pain	34.6(SD 28.9)	13(SD12.4)	0.005
Feeling of in control	71.06 (SD 37.38)	92.36(SD20.37)	0.036

Table 5.3: Return of bladder sensation following sedation/local anaesthesia and spinal anaesthesia following retrograde filling of the urinary bladder

	Patients having sedation/local Anaesthesia Volume (ml) Mean (SD)	Patients having spinal Anaesthesia Volume (ml) Mean (SD)	P value
First desire to void at 1 hour	225.9(111.7)	283.7(119.3)	NS
Strong desire to void at 1 hour	364.1(92.2)	462(92.9)	0.0024
First desire to void at 2 hours	215.3(90.4)	224.7(97.7)	NS
Strong desire to void at 2 hours	331.8(88.7)	403.3(132.3)	NS
First desire to void at 3 hour	218.8(110.9)	192(88.8)	NS
Strong desire to void at 3 hours	328.8(113.5)	381.8(88.5)	NS

Table 5.4: First desire to void following sedation/local anaesthesia and spinal anaesthesia

	Patients having sedation/local Anaesthesia Volume (ml) Mean (SD)	Patients having spinal Anaesthesia Volume (ml) Mean (SD)
First desire to void at 1 hour	225.9(111.7)	283.7(119.3)
First desire to void at 3 hrs.	218.8(110.9)	192(88.8)
P value	NS	0.0108

Table 5.5: Strong desire to void following sedation/local anaesthesia and spinal anaesthesia

	Patients having sedation/local Anaesthesia Volume (ml) Mean (SD)	Patients having spinal Anaesthesia Volume (ml) Mean (SD)
Strong desire to void at 1 hour	364.1(92.2)	462 (92.9)
Strong desire to void at 3 hrs.	328.8(113.5)	381.8 (88.5)
P value	NS	.0099

For the purpose of this study we used 20% difference in the visual analogue scale (VAS) (which represented a 20 mm difference on a 10 cm line) or more as being clinically relevant (Koopman et al. 2009).

The difference in mean scores in the surgeon's assessment of patient cooperation was 24.2, 95% CI 9.6 – 38.8 p=0.002 while for pain the difference in the mean scores was -21.6, 95% CI -36.6 to -6.5, p=0.006 thus showing a significant difference of the mean with a wide confidence interval. The difference in the mean scores for the feeling of being in control was 21.4, 95% CI 0.85 to 41.63, p=0.004.

When looking at bladder sensation and the volume of urine present in the bladder post operatively, the only significant difference in volume of urine present in the bladder occurred when comparing strong desire to void at one-hour post operatively (Diff 97.9 95% CI 37 to 158.8 p = 0.0024). There was no significant difference in the first desire or strong desire in both groups at 2 and 3 hours post operatively (see table 5.3).

The data within each group suggested that there was no significant difference in the mean volume of urine present at 1,2 and 3 hours in the group having sedation/local anaesthesia (see table 5.3). In the group having spinal anaesthesia there was a significant difference in the volume of urine present in the bladder at 1 and 3 hours in first desire to void group (diff 91.7 95% CI 22.5 to 160.9 p = 0.0108) and at 1 and 3 hours in the strong desire to void group (diff 80.2 95% CI 20.5 to 139.89 p = 0.0099) (see tables 5.4 & 5.5).

5.4 Discussion

This study suggests that there may be a difference in the patient's perception of 'pain' and the 'feeling of being in control'. Likewise there might be a preference for spinal anaesthesia amongst the surgeons when looking at patient cooperation.

For the purpose of this study we used a difference in the VAS of 20mm as being clinically significant based on a previous study on chronic nonspecific back pain (Koopman, Vrinten, & van Wijck 2009). It is interesting to note that the mean visual analogue score for pain in the group of patients having sedation/local anaesthesia was 34.6mm (SD 28.9) with 0 being no pain and 100 being worst. In the literature it is recommend that a new dose of analgesia is used for values greater than 30mm (Rawal 1999;Rawal and Berggren 1994). This could imply that for future studies one may have to look at the dose of sedation and local anaesthesia used.

As far as bladder sensation following the procedure is concerned it would appear that the return of sensation was equal in both groups from 2 hours post operatively. The difference in the volume at which first sensation returns at 1 versus 3 hours post operatively under spinal anaesthesia may be consistent with the bladder sensation returning to normal. Consequently

as time progresses the bladder sensation normalises and hence first and strong desire occurs with a lower volume of urine in the bladder. This study can be helpful when formulating bladder care protocols for procedures done under spinal anaesthesia and sedation.

The bladder sensation following incontinence surgery returns to normal within 3 hours, which is a shorter time than following vaginal delivery or Caesarean section. This may well be partly because the urinary bladders were filled retrograde following incontinence surgery and antegrade following vaginal deliveries. Filling the urinary bladder with 500mls of normal saline (at room temperature) over a short period might induce a sensation of the bladder quicker than if the bladder filled over a longer period in an antegrade and physiological manner. In both cases the women were asked to identify when they noticed sensation in the bladder. However in the case of the postnatal patient these patients were left on their own and there are more distractions such as the presence of a newborn baby. In the patient who had incontinence surgery researcher was at the patient's bedside awaiting a response from the patient. Patients having spinal anaesthesia for Caesarean sections received other analgesia (e.g. morphine) which has a longer duration of action when compared to fentanyl used in women having incontinence surgery. The estimated half-life of morphine is 120 minutes and that of fentanyl is 10 - 20 minutes (Jenkins 2009).

Chapter Six:Conclusion and Recommendations

The effect of anaesthesia on the urinary bladder can have an impact in determining the bladder care in the postoperative period. In the case of pregnancy the effect of method of delivery is an additional factor to consider in bladder care in the immediate post partum period. Unfortunately there is not a lot of data in the literature that addresses these issues and hence bladder care policies vary amongst various institutions.

This thesis looked at the effect of anaesthesia and mode of delivery on the urinary bladder in the immediate post delivery period following normal vaginal deliveries with or without anaesthesia. A subgroup of these patients was looked at to assess the accuracy in the measurement of the volume of urine in the bladder in the postpartum period. The presence of an enlarged postnatal uterus and the increased fluid within the abdomen following a Caesarean section can potentially affect the accuracy of the measurement of the bladder volume if a bladder scanner is used. This thesis also looked at the effect of anaesthesia on the urinary bladder following incontinence surgery.

The systematic review in chapter two revealed only nine studies addressing the effect of delivery and anaesthesia on the bladder following delivery with all the published studies being observational studies. From the systematic review it would seem that both epidural anaesthesia and instrumental deliveries have an impact on voiding following delivery. In the limited data available instrumental deliveries appeared to have more of an impact on voiding in the postpartum period. Women who had a significantly higher risk of abnormal voiding following delivery also included women having vaginal deliveries with an epidural. The combination of instrumental delivery and epidural however, does not significantly increase the risk of abnormal voiding when compared to patients having instrumental deliveries without epidural anaesthesia. If one were to take this into consideration when formulating a

bladder care policy there would be no need to set up a separate guideline for women who had both an epidural and instrumental delivery.

In chapter three the accuracy of measuring the volume of urine in bladder using an ultrasound scan was examined. There is limited data that looks at the accuracy of ultrasound measurement of bladder volume in the immediate postpartum period and most of the data has been extrapolated from bladder measurements on patients who were not pregnant. The conclusion from the study conducted in chapter three showed that bladder measurements tend to be underestimated rather than overestimated when using the formula: Bladder volume = H x W x D x $\pi/6$. This assumes the bladder adopts an elliptical shape however one can question this assumption in the pregnant and postpartum patient due to the presence of an enlarged uterus. The results from chapter three shows that the accuracy of the measurement decreased with higher bladder volume. However given the fact that one would implement this method of measurement for detecting urinary retention and not bladder pathology, ultrasound scanning of the bladder would be a suitable option. That is to say that in such circumstances one would be only interested in seeing if the residual volumes were high and not identifying the actual volume of urine in the bladder. It would be less invasive than insertions of a urethral catheter while at the same time being accurate in detecting urinary retention. That is to say one might only need to know whether a patient is retaining volumes in excess of 150-200mls as opposed to knowing the exact volume of urine in the bladder. One of the areas worthy of future research would be to identify a method or even a formula to calculate large volumes of urine in the bladder in the immediate postpartum period.

Chapter four looked at the median time for sensation to return to the bladder in patients having vaginal deliveries without epidurals, with epidural, and after elective Caesarean sections under spinal anaesthesia these were 122 minutes (95% IQR 112-136), 234 minutes

(95% IQR 202-291) and 374 minutes (95% IQR 311- 425) respectively. The median volumes were 144 ml (95% IQR 112 -192), 200 ml (95% IQR 136- 336) and 152.2 ml (95% IQR 125 – 270) respectively. It would appear that strict monitoring of urinary output should be in place for all modes of delivery. Hospital policies should have a low threshold for catheterising patients if they do not void within 4-6 hours of a vaginal delivery (without regional anaesthesia). In patients having a normal vaginal delivery with epidural or an instrumental delivery one has to consider catheterising if the patients are unable to void 6-8 hours after delivery. As outlined in chapter three of this thesis, the use of ultrasound in the measurement of bladder volume in the post delivery period is an accurate assessment. Therefore another option would be to consider performing an ultrasound scan on the woman should they decline catheterisation.

The recommendations for bladder care (based on this thesis) in the immediate postpartum period are as follows:

In women who had vaginal deliveries (non-instrumental) one should consider catheterisation if the woman is unable to void 4 hrs after delivery or at least measure the bladder volume using an ultrasound scan. If the bladder volume confirms urinary retention then the woman should be catheterised.

In women who had vaginal deliveries (includes instrumental and non-instrumental deliveries) with epidural one should consider keeping in an indwelling catheter for 6-8 hrs following delivery. This duration should allow sensation to return to the bladder.

Women undergoing elective Caesarean section under spinal anaesthesia one should consider keeping an indwelling catheter for 8-12 hrs following delivery.

More research is needed on the subject and one suggestion is a randomised controlled trial to determine the optimum time for catheterisation following various modes of delivery.

If the facilities are available (both equipment and trained staff) one should employ the use of an ultrasound scan to measure the bladder volume in patients suspected of having urinary retention in the immediate postpartum period.

With regards to anaesthesia for insertion of retropubic tapes, the study confirmed that patients and surgeons favour the use of spinal anaesthesia for the insertion of retropubic tapes. In addition larger size samples are required to establish whether there is a difference in bladder sensation following insertion of a retropubic tape under spinal anaesthesia versus sedation/local anaesthesia.

There seems to be a difference in the volume of urine required to elicit a strong desire to void one hour post operatively with the patients having local/sedation having a lower volume of urine in the bladder .However there is no difference in the volume of urine required to elicit a first desire to void at 1,2 and 3 hours and strong desire to void at 2 and 3 hours.It would seem therefore that one would have to been more vigilant in bladder care for the first hour postoperatively in patients having spinal anaesthesia for the insertion of retropubic tapes.However beyond that time frame a similar bladder care policy could be adopted for both spinal and local/sedation anaesthesia. This should be taken into consideration when formulating bladder care protocols. More research is also required to determine at what volumes of urine retained in the bladder does one need to catheterise a post partum patient and also the optimal duration of catheterisation. With the need for ‘enhanced recovery‘ one can look to implementing a policy of ultrasound scanning in postnatal patients prior to discharge. This would reassure clinicians that the patients are voiding adequately prior to discharge. Furthermore if the patient has not voided 4 hours after a normal vaginal delivery or 6 hours after a forceps delivery or vaginal delivery with an epidural one should consider performing an ultrasound of the bladder to rule out retention.

I have identified three things from this thesis that can be applied in clinical practise.

The first is the bladder formula used (Bladder volume = H x W x D x π/6) is reliable in estimating bladder volume, or at least determining urinary retention, in the postpartum period.

The second is that bladder sensation was slower to return than motor function and one should not be guided by return to motor function when determining bladder sensation and catheter care post delivery.

The third was forceps and analgesia as separate factors in determining risks for urinary retention and is not addictive.

In the final analysis, the impact of anaesthesia and different modes of delivery on the urinary bladder still remains an enigma. Hopefully with more research on the topic can allow us to further understand and deal with voiding problems after delivery.

APPENDIX ONE: LITERATURE SEARCH

SEARCH STRATEGY

No.	Database	Search term	Info added since	Results
1	EMBASE – 1980 to 2010	Anaesthesia	Unrestricted	14771
2	EMBASE – 1980 to 2010	Analgesia	Unrestricted	13760
3	EMBASE – 1980 to 2010	Postpartum	Unrestricted	7237
4	EMBASE – 1980 to 2010	Bladder	Unrestricted	28782
5	EMBASE – 1980 to 2010	1 or 2 AND 3 AND 4	Unrestricted	20

No.	Database	Search term	Info added since	Results
1	MEDLINE – 1950 to 2010	Anaesthesia	Unrestricted	10410
2	MEDLINE – 1950 to 2010	Analgesia	Unrestricted	9621
3	MEDLINE – 1950 to 2010	Postpartum	Unrestricted	8006
4	MEDLINE – 1950 to 2010	Bladder	Unrestricted	10132
5	MEDLINE – 1950 to 2010	1 or 2 AND 3 AND 4	Unrestricted	17

No.	Database	Search term	Info added since	Results
1	PsycINFO – 1967 to 2010	Anaesthesia	Unrestricted	4604
2	PsycINFO– 1967 to 2010	Analgesia	Unrestricted	8687
3	PsycINFO – 1967 to 2010	Postpartum	Unrestricted	5804
4	PsycINFO – 1967 to 2010	Bladder	Unrestricted	975
5	PsycINFO – 1967 to 2010	1 or 2 AND 3 AND 4	Unrestricted	10

No.	Database	Search term	Info added since	Results
1	AMED – 1985 to 2010	Anaesthesia	Unrestricted	832
2	AMED – 1985 to 2010	Analgesia	Unrestricted	3496
3	AMED – 1985 to 2010	Postpartum	Unrestricted	150
4	AMED – 1985 to 2010	Bladder	Unrestricted	600
5	AMED – 1985 to 2010	1 or 2 AND 3 AND 4	Unrestricted	0

No.	Database	Search term	Info added since	Results
1	CINAHL – 1994 to 2010	Anaesthesia	Unrestricted	604
2	CINAHL – 1994 to 2010	Analgesia	Unrestricted	1593
3	CINAHL – 1994 to 2010	Postpartum	Unrestricted	506
4	CINAHL – 1994 to 2010	Bladder	Unrestricted	331
5	CINAHL – 1994 to 2010	1 or 2 AND 3 AND 4	Unrestricted	1

APPENDIX TWO: STUDY PROTOCOL (Chapter 4)

PROJECT PROPOSAL

Title:

The Impact of Anaesthesia and Mode of Delivery on the Urinary Bladder Sensation following Delivery and following the insertion of a tension free vaginal tape.

Summary

The purpose of the study is to better understand the effect of various forms of anaesthesia on bladder sensation following delivery and following incontinence surgery namely the insertion of a tension free vaginal tape. In addition to this we also aim to understand the effect of regional anaesthesia on the urinary bladder following various modes of delivery.

This is a prospective study and the data would be collected over a one-year period. Patients would be recruited from the antenatal clinics, labour ward and Urogynaecology clinics at the Birmingham Women's Hospital. The aim is to recruit a total of 180 patients. In the case of the antenatal patients, they would be followed up to assess the time for bladder sensation to return after delivery as well as voiding up to 48 hours after delivery. The primary outcome will show when bladder sensation returns following delivery in patients receiving no regional anaesthesia, epidurals and spinal anaesthesia. The secondary outcomes will determine whether mode of delivery in patients having regional anaesthesia affects sensation.

A second arm of the study would look at the effect of bladder sensation following tension free vaginal tape insertion using local anaesthesia/sedation and spinal anaesthesia. For this arm of the study we aim to recruit 40 patients.

Patients would have their bladder sensations assessed 1, 2 and 3 hours following their operations. We would also attempt to assess both patient's and surgeon's satisfaction with the anaesthesia.

Principal Investigator:

Dr. Richard Foon, Research Fellow, Birmingham Women's Hospital

Contact details: 6 Rowntree Gardens
Harley Warren,
Worcester
WR4 0SB
E-mail: r.p.foon@talk21.com

Background and Rationale:

There is evidence that one episode of over distension of the bladder can cause irreversible damage to the bladder (Hinman 1976). One of the complications of epidural analgesia is retention of urine, which can lead to distension of the bladder. In addition little is known about the time before sensation of the bladder resumes, or of the effect of different modes of delivery on the bladder sensation.

Currently the practise of bladder care following delivery after anaesthesia (e.g.: epidural) varies. Our current practise involves removal of the catheter when the patient is fully mobile. The only study done previously - Bladder sensation after epidural analgesia - showed that the sensation of the bladder returned on an average of 6.7 hours with a range of 0 – 8 hours (Khullar V 1993). However this was a small study (18 participants) and was done over 13 years ago.

Other studies showed that up to 43% of patients had abnormalities emptying their bladder following epidurals after delivery (Ramsay & Torbet 1993). Our study would address the effect of not only epidurals but also the effect of other forms of anaesthesia (e.g.: spinal and general anaesthesia) as well as the effects of different forms of delivery.

The study is of importance since it would improve bladder care following epidurals by setting out an evidence-based framework for bladder care following delivery. We aim to further our understanding of the time it takes for normal bladder sensation to return. This may help us to determine the time needed to keep the indwelling catheter in after delivery or whether one is needed at all following delivery.

Also questions may be answered regarding various forms of Anaesthesia and the effect they have on the bladder, thus helping clinicians to be able to inform/advise patients about the effect of various types of anaesthesia on the bladder.
The tension free vaginal tape procedure has been introduced since 1995 for the management of urodynamic stress incontinence ((Ulmsten, Henriksson, Johnson, & Varhos 1996)). For better adjustment of the tape the patient would ideally need to be awake therefore the procedure can be done under local or regional anaesthesia. Very little is known about the time for sensation to return to the bladder following insertion of a tension free vaginal tape insertion under various forms anaesthesia.

Hypothesis:

The sensation in the urinary bladder following delivery after having an epidural in labour can take an average of 6 hours to return. Secondly time taken for sensation to return is dependent on the mode of delivery and the type of anaesthesia received.

Objectives:

- To determine the effect of epidurals on the sensation of the urinary bladder following delivery.
- To determine the effect of various modes of delivery on the bladder sensation following delivery in patients who have had regional anaesthesia.
- To compare the effect of sedation/local anaesthesia and spinal anaesthesia on bladder sensation following tension free vaginal tape insertion.

Design and Methodology:

This is a prospective study in which patients requiring various forms of regional anaesthetic in labour would be recruited.

From the statistical calculations one would be require a sample of 35 and 47 patients in each mode of delivery in order to determine a difference of one-hour time for return of sensation with a power of 80% and 90% respectively.

If the data (possibly transformed) turn out to be normally distributed, they will be suitable for (parametric) analysis of Variance, using anaesthetic and delivery method as factors, and post-hoc analysis to determine which pairs differ significantly. If the data isn't suitable, Kruskal-Wallis one-factor non-parametric analysis of variance on the anaesthetics and methods of delivery separately will be used.

These patients routinely would require having an indwelling catheter. Following delivery the patients would then have their catheters clamped to allow for filling of the bladder.

In order to avoid over distension of the bladder the patient's urinary bladder would be scanned to assess bladder volume on an hourly basis. If the patient does not feel the desire to void after 3 hours or if the bladder has filled to an estimated volume of 450 millilitres within the 3-hour period the catheter would be released. If after 3 hours the bladder sensation does not return then the catheter would be clamped again and the process repeated. For the purpose of this study we are taking the first sensation to void as the first sensation of the bladder.

When the clamp is released the volumes of urine expelled would be measured and compared with the volume of urine estimated on ultrasound.

After the catheter is removed the patient would be asked to empty her bladder and the bladder would be scanned to assess the residual volumes left in the bladder.

The inclusion criteria would include:

- Patients in the age group over16 years
- Patients in labour requesting an epidural for pain relief.
- Patients who require any other forms of anaesthesia for delivery.

Exclusion criteria:

- Patients < 16 years of age.
- Patients with suspected urinary tract infections.
- Patients having failed instrumental deliveries converted to caesarean sections would be excluded as well as patients who needed a change of anaesthesia. The rationale being that it would be difficult to assess which form of anaesthesia or mode of delivery resulted in their bladder sensation.

The patients would be recruited from the various Antenatal clinics as well as patients booked for induction of labour and those presenting to the delivery suite who are not in established labour who might consider requesting an epidural in labour. The patients would be counselled about the nature of the study and provided with the information leaflet on the study. Given sufficient time (twenty four hours) to read the leaflet and discuss the study, the patients would then give consent or decline to take part in the study.

In previous studies the urinary bladder was filled by retrograde filling; however allowing the urinary bladder to fill spontaneously by clamping the catheter is less invasive and is more accurate in imitating normal filling of the bladder and best represents normal physiology.

The results would be collected and tabulated as follows:

Table 1

Mode of delivery (with epidural)	Time for sensation To return	Volume at which sensation returned	Residual. volume
Vaginal delivery			
Vaginal delivery (Without epidural)			
Instrumental delivery			
Caesarean section (under spinal anaesthesia)			

Based on the results one would be able to conclude the difference in epidural sensation following various modes of delivery together with the return of sensation in the bladder following various forms of anaesthesia.
As far as the second arm of this study looking at the effect of anaesthesia on the urinary bladder after incontinence surgery the protocol is as follows:

Eligibility Criteria: patients undergoing elective first operative procedure for stress incontinence

Exclusion criteria: contraindication to spinal anaesthesia
Unable/unwilling to give consent
Significant respiratory/cardiovascular disease/epilepsy
allergy to propofol, opioids, local anaesthetics

The patient will be approached for information and consent prior to surgery in the clinic.

Randomisation by envelope to low dose spinal anaesthesia (LDS) or to propofol target controlled sedation regime (TCI) will occur in the anaesthetic room.

A 14-16 g venous cannula will be inserted.

Full monitoring will be applied: continuous pulse oximetry, non-invasive blood pressure and continuous ECG.

500mls intravenous preload of 0.9% saline will be given to both groups.

2 mls of lignocaine 1% will be injected into skin of back of all patients at a suitable lumbar vertebral interspace.

A Diprifusor infusion pump containing a syringe with 1% propofol will be connected to all study volunteers.

Drug Protocols

Sedation group (TCI):

10 mg of lignocaine will be injected into cannula to reduce discomfort of propofol administration. Sedation with propofol will commence to a target concentration of 1mcg/ml of propofol. The target concentration will be adjusted to achieve a sedation level of 2-3. If discomfort or pain occurs incremental doses of 100 mcg of alfentanil will be administered.

Spinal anaesthesia group:

Using aseptic technique, spinal anaesthesia will be established via a 25-gauge Whitacre pencil point needle, at a suitable lumbar interspace, with 2.5mg-5.0mg isobaric bupivacaine and 25mcg fentanyl (total volume 1.5mls-2.5mls). Discomfort during surgery in the spinal anaesthesia group will be treated with the sedation group protocol.

Both groups:

Local anaesthetic (Prilocaine) will be administered by infiltration to the operative field by the surgeon.

Every 5 minutes the following will be recorded: heart rate, non-invasive blood pressure, oxygen saturation, respiratory rate, airway maintenance, sedation level and surgical stimulus at the time of observation.

Post operatively:

We will ask the patient and operating surgeon to fill in a confidential questionnaire about satisfaction and comfort indices.

All patients are routinely fitted with an indwelling Foley catheter and return of bladder sensation will be quantified by bladder distension with a maximum amount of 500 ml of saline at 1, 2 and 3 hours post operatively. The volume of ‘first urge’ and ‘strong urge’ to void will be recorded.

Ethical Considerations:

Clamping the catheter can lead to overdistention of the bladder. In order to prevent this we propose to perform an ultrasound scan on an hourly basis and if the estimated bladder volume is in excess of 450 millilitres the clamp would be released. It is not anticipated that this would be a problem in the group having incontinence surgery since the bladder is filled in a retrograde manner to a maximum volume of 500 mls.

APPENDIX THREE: CONSENT FORM(S)

Consent forms

CONSENT FORM (version 7.0)

Title of Project: **the impact of anaesthesia and mode of delivery on the urinary bladder sensation following delivery**

Name of Researcher: Dr.Richard Foon Patient's ID number:

Please initial box

1. I confirm that I have read and understand the information sheet (version 7.0) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐

3. I understand that relevant sections of any of my medical notes and data collected during the study, may be looked at by responsible individuals from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐

4. I agree to my GP being informed of my participation in the study. ☐

5. I agree to take part in the above study. ☐

_____	_____	_____
Name of Patient	Date	Signature
_____	_____	_____
Name of Person taking consent (if different from researcher)	Date	Signature
_____	_____	_____
Researcher	Date	Signature

When completed, 1 for patient; 1 for researcher site file; 1 (original) to be kept in medical notes

Anaesthesia for Incontinence Surgery (Chapter 5)

Investigators: Dr Richard Foon, Mr P Toozs-Hobson

PATIENT CONSENT FORM

We are undertaking a study to see which is the best way of keeping patients comfortable during their surgery.

Sedation is usually given during the operation by an anaesthetist. The operation can also be done with a spinal anaesthetic. This study is to find out which technique patients prefer. If you choose to take part, you will be given one of these methods of anaesthesia. A doctor will monitor you closely during your operation for the effects of sedation and note the time when your bladder feeling becomes 'normal'.

We will ask you to complete a questionnaire before you leave hospital, asking you to give your opinion on the anaesthetic you received.

Your treatment will not differ in any other way from patients not taking part in the study.

You are under no obligation to participate. If you prefer not to be involved you will receive the standard method of sedation, this will not affect your care or your relationship with your doctor

There is a patient information leaflet telling you all about the study and there will be doctor on hand to answer any questions you have.

I fully understand what is involved in taking part in this study. Any questions I have about this study, or my participation in it have been answered to my satisfaction. I understand that I can withdraw from the study at any time and that it would not affect my treatment.

Patient's signature……

Doctor 's signature……

Date……

APPENDIX FOUR: LETTER TO GP

Birmingham Women's Health Care NHS
NHS Trust

GP's name
GP's address

Date:

Re: Participant's name D.O.B

Dear Sir/ Madam,

We are writing you to advise you that the above named patient has agreed to participate in a clinical trial at the Birmingham Women's hospital.
The patient has given us permission to inform you.
The study is entitled "
The impact of anaesthesia and mode of delivery on the bladder following delivery"

The study would be looking at the effect of epidurals on urinary bladder sensation following anaesthesia, especially epidurals.
The trial involved clamping the indwelling catheter following delivery for a period of 3 hour interval or until first sensation of needing to void returns (which ever was shorter).
The patient's bladder was scanned prior to unclamping the catheter as well as used to measure the residual volumes on day 1 post delivery.

We are hoping to compile the results of this study and inform both patient and General Practitioner about the findings.
If you have any questions about this research please contact me.

With kind regards,

Yours sincerely

……

RICHARD FOON MRCOG

APPENDIX FIVE: LETTER TO THE PATIENT

Birmingham Women's Health Care NHS
NHS Trust

Date:

Participant's name D.O.B

Dear Madam,

Re: Invitation to participate in clinical research

I would like to invite you to consider taking part in some clinical research that I am conduction at the Birmingham Women's hospital.
Please find the enclosed information sheet telling you more about why we want to do the study and what it would involve from you.
If you think you are interested in taking part in the study please contact me at *Contact name and telephone number*.
Please remember that the standard of medical care you receive would be the same regardless whether you take part or not and you are free to change your mind at any time.
Thank you for taking the time to read this letter and the information leaflet.

With kind regards,

Yours sincerely

……

RICHARD FOON MRCOG

(Research Fellow to Mr. P. Toozs- Hobson)

APPENDIX SIX: PATIENT INFORMATION LEAFLET(S)

Patient information leaflets – Chapter 4

Birmingham Women's Health Care NHS
NHS Trust

Patient Information leaflet
(Version 7.0 – 11th July 2007)

"THE IMPACT OF ANAESTHESIA AND MODE OF DELIVERY ON THE URINARY BLADDER SENSATION FOLLOWING DELIVERY"

You are being invited to take part in a research study which is being used for an educational qualification. It is important to understand why the research is being done and what it will involve. We therefore ask that you read carefully the following information. Please feel free to ask any questions if you so wish.

What is the purpose of the study?

Epidurals are a common and effective form of pain relief in labour. However little is known about the effects of epidurals on the sensation of the bladder after delivery.

This research will aim to determine the time it takes for sensation of the bladder to return following anaesthesia (including epidurals) and allow us to manage and improve bladder care after delivery.

We would be looking at the effect of different forms of anaesthetic on bladder function. This includes the time taken for sensation of the bladder to return and whether patients who have different forms of anaesthetic are more prone to developing retention of urine (incomplete emptying of their bladder).

Why have I been chosen?

You have been invited to take part as you may have received an epidural/spinal or general anaesthetic in labour. Some patients who do not receive either epidural or other forms of anaesthesia would also be asked to take part if they need to be catheterized for any reason during labour or after delivery.

Do I have to take part?

Your participation in this study is completely voluntary .The treatment you receive will not be affected by your decision.

What will happen if I take part?

If you do decide to have an epidural in labour or any other forms of pain relief, a catheter (small tube) might be placed in your bladder to aid in emptying your bladder. Normally after delivery your catheter would be removed when you are fully mobile. In this study after delivery your catheter outflow would be closed and this would allow your bladder to fill up as normal until sensation resumes. As soon as you feel the sensation to empty your bladder, we would then perform an

ultrasound scan to estimate the amount of urine in your bladder, open the outlet of the catheter and measure the amount of urine passed.
If after 3 hours of having your catheter outlet closed if you do not feel any sensation in your bladder, we would carry out an ultrasound scan, open the outflow of the catheter and repeat the process. We will be scanning your bladder on an hourly basis until you regain sensation in your bladder.
In addition, on the day after delivery or the day you are discharged you would be asked to empty your bladder **on a special toilet that is designed to measure the rate of flow of urine** and have a final scan to make sure that your bladder is emptying properly.

What are the complications/side effects of the treatment received?

Over-distension (overfilling) of the bladder can cause some long term effect such as difficulty in emptying of the bladder. However this is not a very common occurrence and to counteract this risk we propose to scan your bladder hourly during the time the catheter outflow has been closed to ensure it does not fill excessively.

What are the possible benefits of taking part?

The information we obtain might help to improve our understanding of bladder sensation/function after different forms of delivery and anaesthesia. In addition you would have your bladder scanned after delivery and detection of any abnormality might be helpful to you.

What if there is a problem?

Complications due to the study should be extremely rare but in the unlikely event that something does go wrong and you are harmed during the research study there are no special compensation arrangements. If you are harmed and this is due to someone's negligence then you may have grounds for a legal action for compensation but you may have to pay for your legal costs. The normal National Health Service complaints mechanisms are still be available to you.

Contact number for complaints: 0121 472 1377 ext 2951 (PALS – Patient Advisory Liaison Services)

Contact details:

Contact for further information:
If you have any problems or queries about the study then please do not hesitate to contact
Dr Richard Foon (Clinical Research Fellow) at 0121 627 2756.

New Information

If new information arises that might affect the study, your research doctor would then inform you and discuss with you if you want to continue with the study. If you decide not to continue your research doctor would make arrangements for your care to continue. In addition upon receiving new information your research doctor might consider it to be in your best interest to withdraw you from the study.
If the study is stopped for any reason, you will be told why and your continuing care will be arranged.

Will my taking part in this study be kept confidential?

All information which is collected about you during the course of the research will be kept strictly confidential. Your information for the purpose of the study
would be stored securely using our hospital number (not name as a form of identification). All the data would be retained for at least 15 years and would be disposed of securely.

Would my General Practitioner/Family doctor (GP) be involved?

This is entirely up to you. Under normal circumstances we would send a standard letter indicating the nature of the trial and the fact that you have taken part in the trial.
However if you do not want your General Practitioner to know then we ask that you indicate this on the consent form.

What will happen to the results of the research study?

Your name and other details would remain strictly confidential and will NOT be identified. The results of the study are available upon request.

Who has reviewed the study?

The Hereford and Worcester Research Ethics Committee have reviewed the study.

We would like to thank you for considering to take part and taking the time to read this information leaflet.

PATIENT INFORMATION

Anaesthesia for incontinence surgery- Chapter 5

We would like to invite you to take part in a study we are doing to see which is the best way of making patients comfortable during their surgery

What is the study about?
The operation is different from most since you need to be able to listen to your surgeon and cough when s/he asks. This means we cannot use a general anaesthetic. A common practise is for the anaesthetist to give you a sedative drug, called propofol, and a painkiller through a drip during the operation.
The anaesthetic may also be given by spinal injection, which numbs the area below your waist without taking all the movement from your legs. We are carrying out a study to see which method patients prefer and which is better for bladder function.

What will I have to do?
If you agree to take part you will have an equal chance of receiving sedation or the spinal injection, but you will not be able to choose which you have. You will not be told until the end of the operation whether you received the spinal injection or the sedation.
Every volunteer taking part in the study will get an injection of local anaesthetic on the skin of their back even if the volunteer receives the sedation technique afterwards. If you receive the spinal, your anaesthetist will inject the anaesthetic drugs into your back using a very fine needle after local anaesthetic has been used on your skin to make the injection more comfortable. A drip will be connected through which fluid, sedation and painkillers can be given as necessary even if the patient received a spinal anaesthesia.
After your operation we will ask you to complete a short questionnaire inquiring about how you felt during the procedure.
A doctor will measure your bladder function using an ultrasound machine and by filling your bladder with fluid and asking if you feel the urge to pass water. This is part of the normal surgical routine.

What are the benefits and risks?
Giving sedation carries the risk of a patient becoming too ‘sleepy’. The anaesthetist will be present throughout the whole procedure and monitor your level of sedation and the amount of drug you need.
The main risk from spinal anaesthetics is that patients can occasionally drop their blood pressure. This can make you feel lightheaded. Your anaesthetist will give you some fluid through a drip before the anaesthetic to prevent this happening. There is a small risk of developing a headache after a spinal, which can be unpleasant. By using a very thin needle, we minimise the chance of this problem.

The benefit of the spinal is that it could keep you comfortable during the operation without having to use any other sedative or pain killing drugs.

Who is taking part?
All patients who are scheduled to have this surgery will be invited to take part. If you do not wish to, the standard technique of that particular gynaecologist and anaesthetist will be used in agreement with you and your treatment and the relationship with your doctor will not be affected.

What happens if I change my mind?
You can opt out the study at any point. If you opt out after the spinal you may still have a sedative injection.

What happens if something goes wrong?
Both techniques are routinely used for this surgery in this hospital and have been proven to be safe and effective. The drugs are not experimental and are used in everyday practise. Any complication arising from the anaesthetic or surgery will be treated with the same high standard of care as a patient not taking part in the study.

What happens to the information collected?
All information we collect is confidential and will only be used for research purposes with no names attached.

What happens if I have more Questions?
If you do not understand about the study or want more information there will be doctors on hand to answer your questions, please do not hesitate to ask!

Thank you for taking the time to read this information and considering taking part.

Study contact numbers:

APPENDIX SEVEN: DATA COLLECTION SHEET/Questionnaires

The impact of anaesthesia and mode of delivery on the urinary bladder following delivery

Data collection sheet (version 2.0 – 11th July 2007)

Patient Number:
Age;
Parity:
Weight: BMI HC
Birth weight of neonate
Duration of labour: Caesarean section Y/N Indication:
1st stage
2nd stage

Mode of delivery (tick one)	Time of delivery	Time at which sensation of urinary bladder returns	Total time for sensation to return (min)	Ultrasound estimation of urine in the bladder when sensation returns (mls)	Actual volume of urine passed when sensation returns (mls)	Residual volume after delivery (ultrasound estimation)	Total urine production when sensation to the bladder returns (mls)
Vaginal delivery (with epidural)							
Vaginal delivery (without Epidural)							
Forceps delivery							
Ventouse delivery							
Caesarean Section							

Type of anaesthesia used
Level of regional anaesthesia
Drugs used for regional anaesthesia
Other drugs used

Urine flow rate

Questionnaire for surgeon (Chapter seven)

Patient number:

Date:

Surgeon:

1 Please mark with a cross your satisfaction with patient co-operation.

Patient did not Co-operate at all — **Patient co-operation was optimum.**

|_____|

2 Please mark your satisfaction with overall surgical conditions (f.e.bleeding/muscle relaxation).

Very difficult surgical conditions — **Very good surgical surgical conditions**

|_____|

Patient questionnaire

Patient number: **Date:**

This series of questions is designed to assess how you felt about the anaesthetic you received during your operation. Please read the questions carefully and answer them to the best of your ability.

1 How helpful was the sedation/anaesthetic you received? Please tick one answer.

- ☐ It hardly helped at all
- ☐ It relaxed me but not enough
- ☐ It relaxed me enough
- ☐ It made me sleepy
- ☐ It made me much too sleepy

2 How pleasant was the effect of sedation/anaesthesia you received?
Please put a cross on the scale.

Very pleasant Very unpleasant

|_____|

3 How anxious were you during the procedure?
Please put a cross on the scale below.

Felt normal Very anxious

|_____|

4 If you had to have the surgery done again, would you like to be given the sedation/anaesthesia in the same way?

- ☐ Yes
- ☐ No

5 How would you describe the pain you experienced during the procedure ?

No pain Worst pain Imaginable

|_____|

6 Did you feel any pain in your arm when the sedative drug was injected ?

☐ Yes
☐ No

7 Did you feel in control of your thoughts and actions during the procedure ? Please put a cross on the scale below.

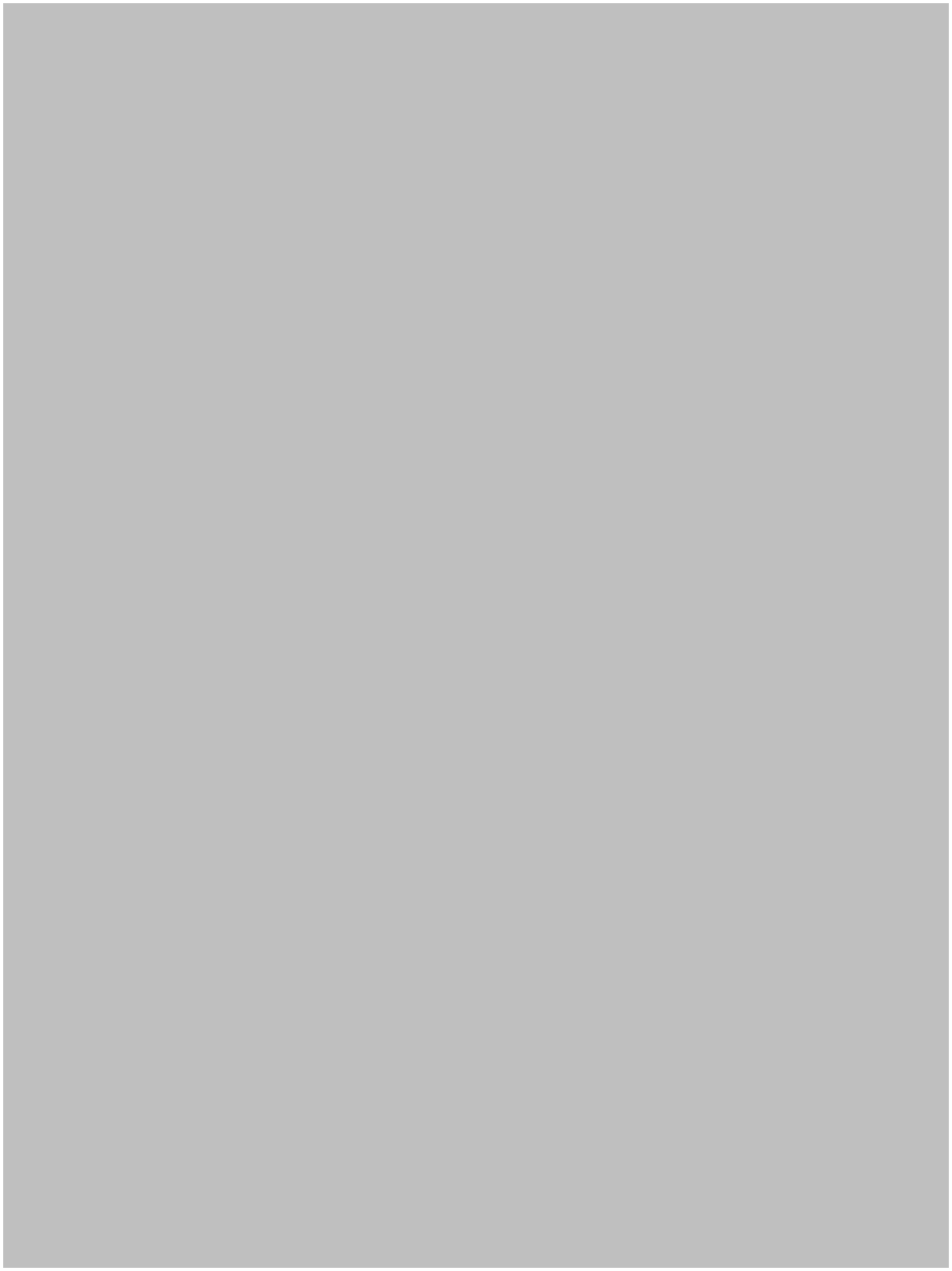
In complete Control — Not at all in control

|_____|

8 Do you have any further comments you wish to add ?

_____
_____
_____
_____
_____
_____
_____
_____

APPENDIX EIGHT: ETHICS COMMITTEE APPROVAL



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