Evaluation of Diagnostic Culdoscopy Under Local Anaesthesia in Women with Infertility

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Abstract

Assessments of infertile couples involve several investigations including semen analysis, assessment of ovulation and assessment of pelvic viscera. Diagnostic laparoscopy is considered the gold standard for investigating pelvic pathology in infertile women. Although it is generally safe, it involves surgery and requires general anaesthesia and the risk of complications. Our aim was to evaluate a new method of investigating pelvic pathology in infertile women and to determine its feasibility and acceptability as an outpatient investigation.

Culdoscopy was introduced first by Decker and Cherry in 1944, but it did not advance after 1960’s as the technology of laparoscopy was continuously improving and so it was the preferred approach by most gynaecologists. Culdoscopy was reintroduced recently after it has been modified for application to modern practice of gynaecology under the name of transvaginal hydrolaparoscopy (THL).

The One-Stop Fertility Clinic was started in the Royal Free Hospital in 2000 a single out-patient visit where pelvic ultrasound, hysteroscopy and culdoscopy are performed and the results and management plan were available immediately was acceptable to most patients.
The diagnostic accuracy of culdoscopy was assessed and compared to standard laparoscopy. The comparison of pelvic findings was done in the same patient by two different operators blind to each other.

The acceptability of out-patient culdoscopy under local anaesthesia was compared with in-patient culdoscopy under light sedation combined with local anesthesia and with in-patient laparoscopy under general anaesthesia. Also the comparison was made in terms of recovery and return to work between the three groups of patients.

The costs of out-patient culdoscopy was compared to in-patient laparoscopy and showed that although there were other factors which may influence the costs of out-patient culdoscopy, it did provide noticeable savings to the healthcare.
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Declaration

This work was carried out solely by myself with the assistance and supervision of my supervisor, Mr Adam Magos BSc MD FRCOG at The Royal Free Hospital between May 2000 to December 2003.
Infertility is a common problem and often badly managed. With the move to less invasive therapy across all areas of modern medical care, this thesis aims to assess one possible solution in this field, namely the use of culdoscopy as an integral part of the investigative process of female subfertility as an alternative to laparoscopy. Culdoscopy is attractive because if can be done as an office or out-patient procedure without the need for in-patient admission to hospital and general anaesthesia. However, just how good the technique is and who is the most suitable for this approach remains to be determined.
Chapter 1

Traditional methods of investigating the infertile couple
1.1 Introduction

Infertility is a common problem affecting 10 -15% of couples in the population. Four decades ago, very little was known about infertility and it was hardly discussed socially as many societies considered it as an untreatable problem. With the recent advances in medical technologies, the problem of infertility has increased in the past 15 – 20 years in the Western societies (Jones and Toner, 1993; Lincoln, 1995). The number of infertile couples seeking medical help has increased, but this should not be understood as evidence that infertility rates are rising (Mosher and Pratt, 1991). The greater number of couples seeking help is because they are more aware of the help available from media attention (Balasch, 2000).

The basic infertility investigation of the 1990s have been modified and expanded (Campana et al., 1995). Some investigations are controversial and there can be several tests to investigate the same causes of infertility. Care must therefore be taken not to expose the infertile couple to expensive and invasive unnecessary tests, procedures and treatments (Jaffe and Jewelewicz, 1991; ESHRE Capri Workshop, 1996). Furthermore, investigations should be carried out within a reasonable period so that an appropriate treatment can be instituted and reassurance is provided to the couple.

1.2 Definition of infertility and fecundity
The most accepted definitions of infertility involve the number of months during which the couples have been exposed to the chance of pregnancy prior to the consultation. As most couples who seek treatments are not sterile but have decreased fertility, some consider the term "subfertile" is more appropriate.

Infertility is defined as the state in which a couple, desirous of a child, cannot conceive after 12 months of unprotected intercourse (Mueller and Daling, 1989; Thonneau et al., 1991), or the occurrence of more than two consecutive natural miscarriages or stillbirths. However, couples should be seen and investigated earlier than the usual one year of trying whenever they think there is a problem or in the presence of factors such as the female's age (more than 37 years), previous surgery, or irregular menstrual cycles (Williams et al., 2003).

Within a year of regular intercourse 80% of fertile couples should become pregnant. After two years, fertility is 95%. This means that some normal fertile couples (5-10%) take more than a year or two to conceive – they have low normal fertility rather than infertility (Cahill and Wardle, 2002). The most important determinant of couple's fertility is the age of female partner as it is difficult to define infertility in couples with older female partners.

To understand infertility better, it is important to know the epidemiological term fecundity (Spira, 1986; Jansen, 1993). Fecundity is defined as the probability of achieving a live birth within a single menstrual cycle. The average monthly fecundity...
rate (MFR) for humans is only 20% (Leridon and Spira, 1984). The fecundity of a
couple is measured by their fecundability i.e. the monthly probability of conception
within a single cycle without the use of contraception (Jansen, 1993). The
fecundability rate amongst young couples who discontinue contraception in order to
become pregnant is quoted to range from 25% to 36% (Cramer et al., 1979; Harlap
et al., 1984; Spira. 1986). It is not known exactly when the decline in fecundity occurs
in the aging process of women (Shwartz and Mayaux, 1982). By the age of 35 years
there is a significant fall in fertility, and by the age 45 years natural fecundity is
minimal (Hanson, 1986). Abdulla et al, (1993), have suggested that the age-related
decline in fecundity is associated with the age of the oocytes rather than the age of
the uterus.

1.3 Prevalence of infertility

Greenhall et al., 1990 have reported the difficulties inherent in measuring the
prevalence of infertility in the United Kingdom. From their two studies they found that
one quarter of all the women who attempt to conceive experience an episode of
infertility at some stage in their reproductive life and about one in eight women
experience this when attempting to conceive a subsequent child. 3% of women are
involuntarily childless and 6% of parous women are unable to have as many children
as they would wish. The ratio of patients presenting with primary and secondary
infertility has remained remarkably stable with 67% - 71% of patients with infertility
presenting with primary infertility and 29% - 33% presenting with secondary infertility (Hull et al., 1985; Templeton et al., 1991; Thoneau et al., 1991).

For many years, the incidence of infertility was thought by many to be 10%, but several recent studies give a clear indication as to the true figure is in the range of 13.5% to 18.4% (Hull et al., 1985; Thonneau et al., 1991). This translates to one in seven women. These studies have demonstrated that infertility is a real health problem because of its high prevalence. However, the above figures relate to the prevalence of infertility in Western communities and there is likely to be some variation worldwide. Ethnic differences in prevalence and attitudes to female infertility have not been adequately reported (Fageeh et al., 2002).

1.4 Causes of infertility

Common causes of infertility include ovulation disorders account for approximately 25% of all infertility cases, tubal disease in about 20%, Sperm defects or dysfunction in approximately 20% -26% and unexplained infertility in about 25% of cases. Other causes include uterine abnormalities (<1%), endometriosis causing damage (5%), coital failure or infrequency (5%), cervical mucus defects (3%) and 15% of couples have more than one cause of infertility (Hull et al., 1985) The main causes of infertility are shown in table 1.1.

1.5 Assessment of the infertile couple
Investigating infertile couples requires sensitivity and the management plan should be provided to the couple as soon as they are referred which may involve reassurance, fertility investigations and treatment. History taking is very important to establish the plan of investigation, a clear protocol should be designed where the role of each level of health care is well determined and information provided to the couple on the proposed plan of action (Lashen, 2001).

1.5.1 Assessment of the male partner

A male factor is the main cause of infertility in 20-26% of couples (Hull et al., 1985; Snick et al., 1997).

1.5.1.1 History and examination

The initial assessment is to take full history including duration of infertility and any history of previous fatherhood, testicular maldescent, testicular infections, previous surgery involving the testes or inguinal region. Sexual function may also be relevant and can influence prognosis. Gonadal dysgenesis associated with chromosomal abnormalities should be considered; Klinefelter's syndrome is the most common and occurs in 1:1000 live males. The first presentation of this may be one of infertility. Exposure to environmental factors and history of smoking, alcohol, drugs (e.g. Sulphasalazine, Cyclophosphamide, Procabazine, tetracycline and Cimetidine) should be considered. There is an association between male infertility and the use of
anabolic steroids by body builders and this is usually reversible once the medication is stopped (Hargreave and Mills, 1998).

Examination of the man is not usually necessary unless indicated by his medical history or if his initial semen analysis result is abnormal (Cahill and Wardle, 2002). If semen analysis is abnormal, general physical examination becomes very important including body mass index, blood pressure, secondary sexual characteristics, the abdomen and genitalia. The penis should be examined with regard to the size and structure. Congenital deformities of the penis can cause problems with semen deposition, scrotal swellings should be identified on inspection, small soft testicles indicate damage to spermatogenesis. A hard lump within the testes may give a clue to a possible testicular tumour. The association between infertility, maldescended testes and testicular tumour should not be forgotten (Swerdlow et al., 1997). Testicular tumour is the commonest malignancy in men aged 15-45.

Varicoceles are found in about 25% of men seeking infertility assessment and the efficacy of treatment is not clear (Hargreave, 1997). More recently, systemic review of surgical treatment of varicoceles in infertile couples has failed to show a definite improvement (NICE, 2004). Until further data are available, it does not seem justified to offer surgical repair in this setting if the sole aim is to improve fertility.

1.5.1.2 Investigation
1.5.1.2.1 Semen analysis

Semen analysis is an inexpensive and a noninvasive test that should be performed at the initiation of every infertility workup. It is the most relevant test performed by the male partner during fertility assessment and is a universally accepted test (Helmerhorst et al., 1995; Glastein et al., 1997) although it is a poor predictor of sperm function and male fertility. In general it is sufficient to consider the sperm concentration, motility and volume of ejaculate. Although semen analysis is basic to the investigation of the infertile couple, the normal range for above variables varies between laboratories. In the UK, Hargreave and Mills (1998) have stressed that it is best to use a laboratory service that participates in the British quality control scheme (NEQAS). Normal semen analysis parameters according to World Health Organization, 1999 are shown in Table 1.2.

If the first result of the semen analysis is abnormal, it should be repeated two to three months later (Hargreave and Mills, 1998; Cahill and Wardle, 2002). According to Hargreave and Mills, (1998) if no sperm are seen, then the couple should be referred. Glazener and Ford, (2001) have stated that a better index of male fertility is needed as the standard semen analysis according to World Health Organization (WHO) protocol has little prognostic power for conception unless the results are very poor, and they regretted that there is no widely accepted test of sperm function.
available to provide an accurate prognosis for conception in couples with sperm dysfunction.

Many workers have shown over the past years that the quality of human semen may be deteriorating (Nelson and Bunge, 1974; Leto and Frensilli, 1981; Bostofte et al., 1983; Menkveld et al., 1986; Osser et al., 1984), although there are others who have come to opposite conclusions (Rasmussen et al., 1997). Carlsen et al. (1992) for instance have observed a significant decline in average sperm concentration and they related that this change was happening in association with an increase in the reported incidence of congenital malformations of male genital tract, such as cryptorchidism (Jackson, 1988) and hypospadias (Giwercman and Skakkebaek, 1992). Irvine et al. (1996), have confirmed and supported previous reports (Carlsen et al., 1992; Auger et al., 1995) that there is a decline in semen quality by 2.1% per year in the United Kingdom.

However, there is no evidence that male fertility as opposed to semen quality is declining. It is difficult to judge from the available epidemiological evidence whether the prevalence of infertility is changing (Templeton et al., 1990).

1.5.1.2.2 Sperm function tests
There are numerous tests of sperm function, but in the main they are only utilized by clinics offering assisted conception. I have summarized some of the more common tests.

1.5.1.2.2.1 Sperm Penetration Assay (SPA)

Sperm Penetration Assay or hamster egg sperm penetration assay measures the ability of the patient's sperm to undergo capacitation and the acrosome reaction prior to incubation with the hamster ova. It is not widely used due to the high incidence of false negative results, although this may be due to short incubation time (Aitken, 1994).

1.5.1.2.2 Hemizona assay

The ability of spermatozoa to bind to the zona pellucida may be tested in ova stored in a high salt solution. As the zona binding depends on oocyte maturity, the oocyte is divided in half with a micropipette so that one half can be incubated with fertile donor sperm and the other half with the patient's sperm. This test correlates well with subsequent in vitro fertilization (Bamzu et al., 1994).

1.5.1.2.3 Post-coital test (PCT)
The use of the post-coital test is controversial, although many clinicians believe that it has some diagnostic value as sperm behavior at postcoital testing depends on natural conception in couples and the duration of infertility (Glazener et al., 2000). Oei et al. (1995) assessed differences in opinion and practice with regards to the PCT in 16 European countries. This test was rated as one of the least useful of the standard fertility investigations. The PCT is of predictive value for natural conception mainly in couples with <3 years duration of otherwise unexplained infertility (Hull and Evers, 1998). Evidence-based medicine seems to be against the prognostic value of the PCT (Griffith and Grimes, 1990; Helmerhorst et al., 1997; Oei et al., 1998).

Other workers based on their clinical experience have shown that there is a strong association between the PCT results and pregnancy rates (Eimers et al., 1994; Hall and Montgomery Rice, 1995; Cohlen et al., 1998; Hull and Evers, 1998).

According to Speroff et al. (1999), whether the PCT is normal or abnormal, the treatment is the same. Glazener and Ford (2001) concluded that the PCT result does not affect outcome in couples with prolonged infertility (more than 3 years) and it might be unnecessary to test these patients. Although the PCT does test sperm function, it is essential that intercourse is timed in the pre-ovulatory phase of the cycle, and that valid negative tests are repeated before they are accepted.

On the basis of their results, the PCT should not be performed routinely, but should be reserved for those couples with <3 years infertility and in whom results will clearly
influence treatment strategy (Glazener and Ford, 2001). However, the widespread use of intra-uterine insemination (IUI) combined with ovulation stimulation has made the assessment of sperm-cervical mucus interactions merely an academic exercise, at least according to some experts (Balasch, 2000).

1.5.1.2.4 Further evaluation of the male partner

If the repeated semen analysis is still abnormal, the male partner should be referred to the urologist for further investigation. Available tests include hormone profile, scrotal ultrasound (+Doppler flow studies), venography or thermography, vasography and testicular biopsy.

1.5.1.2.4.1 Hormone profile

Hormone profile should be performed in men with oligospermia or if there are signs and symptoms suggestive of endocrine disease. These include measurement of serum testosterone, FSH and LH levels, and prolactin.

1.5.1.2.4.1.1 Testosterone

The normal range is 10-35 nmol/L in blood. A low serum testosterone concentration may result from severe seminiferous tubule damage as well as an elevated serum prolactin and hypothalamic or pituitary insufficiency.
1.5.1.2.4.1.2 FSH and LH

Serum FSH concentration is used as a guide to the integrity of spermatogenesis. The combination of azoospermia with normal sized testes and normal levels of testosterone, FSH and LH indicates a mechanical obstruction to the passage of sperm. High level of FSH combined with high level of LH, indicates germinal cell insufficiency or primary testicular failure and the level of serum testosterone will be low. Elevated serum FSH with combination of azoospermia is been taken as indication of no spermatogenesis, however, few spermatozoa were found in some cases during testicular biopsy for IVF. Low serum level of FSH, LH and testosterone indicate hypothalamic or pituitary insufficiency.

1.5.1.2.4.1.3 Prolactin and thyroid function

These hormones are measured if serum testosterone levels are low or if there is gynecomastia or thyroid disease.

1.5.1.2.4.2 Imaging

Ultrasound scan can be used to detect varicoceles, cysts and other testicular masses. A combination of ultrasonography (±Doppler flow studies), venography and nuclear scintigraphy may be used to investigate varicoceles. Vasography is performed in cases of suspected obstruction.
1.5.1.2.4.3 Testicular biopsy

Testicular biopsy is indicated when the sperm density is low and the serum FSH level is normal. It aids in the diagnosis of severe oligospermia or azoospermia.

1.5.2 Assessment of the female partner

Assessment of the female partner should include clinical and gynaecological examination, assessment of ovulation, tubal patency, adequate endometrial response to ovarian hormones, survival of spermatozoa at the level of cervix at the time of ovulation and assessment of pelvic viscera.

1.5.2.1 History and clinical examination

General history should be taken including duration of having unprotected intercourse, coital frequency and timing, dyspareunia, and coital difficulties. Previous history of fertility, past medical and surgical history, gynaecological history (cervical smears, cone biopsy), menstrual history (including dysmenorrhoea, intermenstrual or postcoital bleeding), current medication, allergies, smoking, alcohol consumption, and diet should also be sought.

Examination of the female partner should include measurement of body mass index (BMI) and blood pressure. A patient’s general appearance may give clues to either
systemic or endocrine disorder. Breast examination should be done looking for lack of development and galactorrhoea. Abdomen and pelvic examination looking for pelvic tenderness, the presence of masses can lead to identification of tuboperitoneal pathology.

1.5.2.2 Investigations

1.5.2.2.1 Ovulation

The only absolute proof of ovulation is pregnancy. There are many tests available to assess ovulation but are all inferential; these include menstrual cycle history, thinning of cervical mucus, basal body temperature, midluteal serum progesterone, ultrasound monitoring of folliculogenesis and ovulation, endometrial biopsy, and the detection of LH surge in urine. More than 95% of women who have a regular menstrual cycle have serum progesterone concentrations or endometrial biopsy results, or both, indicative of ovulation (Rosenfeld and Garcia, 1976; Speroff et al., 1994).

In patients with irregular cycles it is more difficult to ascertain whether or not ovulation is taking place. The best way to assess ovulation in these patients is by a combination of serial ultrasound scans and serum endocrine measurements (FSH and LH in the follicular phase and progesterone in the luteal phase). A value of
serum progesterone of >30 nmol/L is considered a proof of adequate ovulation, although the WHO uses a value of 18 nmol/L to confirm ovulation.

A mistimed sample is the most common cause of an abnormal result, the sample must be taken seven days before the onset of the next menstrual cycle and in patients with long or unpredictable cycles, the sample may need to be repeated weekly until the next menstrual cycle starts (Williams et al., 2003).

1.5.2.2.2 Other hormone profile

The endocrine profile is usually performed during day 2-5 of the cycle (if there is one). Reference ranges vary from laboratory to laboratory and depends on the type of assay used. The main hormones being measured are FSH, LH, TSH, prolactin, oestradiol and testosterone and SHBG. These tests are usually performed if the cycle is less than 21 days or greater than 35 days and will identify the main causes of ovulatory failure (normogonadotrophic anovulation, hyperprolactinaemia, hypogonadotrophic hypogonadism and hypergonadotrophic hypogonadism).

Follicle stimulating hormone (FSH) is the best indicator of ovarian function. A value of <12 IU/L taken in the early follicular phase is normal. A result of >12 IU/L is indicative of reduced ovarian reserve, while >20 is suggestive of menopause or premature ovarian failure.
A high serum concentration of LH suggests polycystic ovary syndrome (PCOS) and this is usually measured in the early to mid-follicular phase of the cycle. Other causes of high serum level of LH are the mid-cycle surge and ovarian failure.

Serum prolactin measurement can vary day to day. Mild elevation of serum prolactin may be associated with stress, when serum oestrogen is normal, the maximum normal prolactin should be in the range 600-800 mlU/ml (Speroff et al., 1994). High serum prolactin > 1000mlU/ml may indicate pituitary prolactinoma, stalk compression by hypothalamic or pituitary tumours, thyroid failure, PCOS, psychotherapeutic medication or other pathology. The Royal College of Obstetricians and Gynaecologists recommends that prolactin measurement should be reserved for those women with amenorrhoea, oligomenorrhoea, or clinical symptoms of hyperprolactinaemia.

Measurement of thyroid stimulating hormone (TSH) is the most sensitive test of the thyroid function, high serum level of TSH suggesting hypothyroidism. If the serum level of TSH is low and free T4 is high then hyperthyroidism is diagnosed. The Royal College of Obstetricians and Gynaecologists suggested that thyroid function tests should be performed in infertile women with irregular cycles and those with signs and/or symptoms of thyroid disease.

The most usual cause of raised serum testosterone is PCOS. If serum testosterone is elevated, it is important to exclude other causes of hyperandrogenaemia such as
late onset congenital adrenal hyperplasia (CAH), Cushing's syndrome and androgen-secreting tumors.

Measurement of sex hormone binding globulin concentration (SHBG) will allow the calculation of the "free androgen index". Although some studies showed that measurement of SHBG is not helpful in infertility investigations, either directly or in combination with other tests (Koskinen et al., 1996; Robinson et al., 1992; Turhan et al., 1999).

1.5.2.2.3 Pelvic viscera

Pelvic abnormalities are present in 30-40% of women with infertility (Witt, 1991). Various methods are available to demonstrate abnormalities of the pelvic viscera.

1.5.2.2.3.1 Pelvic ultrasound

It is important that all infertile women should have ultrasound examination. It is a noninvasive and relatively inexpensive method for detecting abnormalities of the uterine cavity in infertile women. Transvaginal ultrasound is preferred to abdominal ultrasound as the transducer is much closer to the organ to be assessed and so the images improved, with a higher resolution and greater precision in measurements of the pelvic structures.
Ultrasound is an effective method in identifying PCO and other ovarian pathologies including functional cysts, dermoid cysts and endometriomas. Ultrasound examination may detect fibroids causing uterine cavity distortion, a uterine septum, other abnormalities of the uterine cavity and the presence of uterine scars. It will also detect any features suggestive of loculated fluid collections or hydrosalpinx. A study by Loverro et al. (2001) to evaluate the accuracy of transvaginal sonography in detecting uterine cavity abnormalities in infertile women found that it is a highly sensitive and a well-tolerated tool which can provide valuable information in the work-up of the infertile patients.

Kelly et al. (2001) have suggested a one-stop ultrasound-based approach for investigation of the infertile couple, which would be more cost-effective. However, ultrasound gives no information about tubal patency, which is of vital importance in the investigation of women complaining of infertility and distortions of the uterine cavity by either pathological or congenital abnormalities can be difficult to assess (Balen et al., 1993). Ultrasound will not detect endometriosis and pelvic adhesions, therefore, further investigations may be required.

1.5.2.2.3.2 Hysterosalpingography

The X-ray hysterosalpingogram (HSG) can demonstrate abnormalities of both the uterine cavity and the fallopian tubes. This procedure should be performed by an experienced radiologist or by a gynaecologist and radiologist. Contra- indications are
a recent history of uterine or tubal surgery, a past history of pelvic inflammatory disease, and the presence of uterine bleeding or pregnancy. There are several types of different cannulae that can be used to perform this test. The oldest type is the metal Leish-Wilkinson or Green-Armytage cannulae which has to be screwed into the cervix. A more modern type is the plastic Malmstrom–Westerman vacuum suction cup that fits over the cervix. There are also special balloon catheters that can fit into the uterine cavity and can minimize patient discomfort.

Contrast media used are either water or oil soluble. The ideal medium should be viscid enough to reveal abnormalities accurately and be sufficiently dense for better shadows, so that an accurate diagnosis can be made. A water soluble contrast is usually used as the oil soluble media are more irritant and can be associated with granuloma formation in the presence of hydrosalpinx and embolisation. Other disadvantages of oil-based media is that their use is more painful due to its high viscosity and leads to a prolonged injection time. However, oil-soluble media are thought to "unblock" tubes more than water-soluble media. A meta-analysis of 10 studies showed that spontaneous pregnancy rates were significantly higher after oil-based contrast media than after the use of water-soluble contrast media (Watson et al., 1994).

The hysterosalpingogram is able to demonstrate abnormalities of the uterine cavity as well as the fallopian tubes. The uterine cavity distortion whether due to congenital defect, polyps, intracavity fibroids, or intrauterine adhesions secondary to scarring
following delivery or curettage can be demonstrated. The tubal lumen is assessed from the tubal ostia to fimbria. The dye flow can be assessed to determine if it is in a continuous fashion or interrupted. Spill of the dye into the peritoneal cavity and any distension of the ampulla (hydrosalpinx) will be seen.

The main disadvantage of HSG is that it is unable to visualize the fimbriae or detect peritubular adhesions, and it cannot confirm endometriosis. Siegler et al., 1977 have found that a number of potentially serious disorders can result from HSG (Table 1.3).

Deaths from HSG is rare, occurred years ago and in most instances was only indirectly connected with the procedure when using heavy, oily media. Mol et al. (1996) documented in their study the limitations of HSG in the detection of tubal patency and distal tubal obstruction. However, Henig et al., 1991 reported that HSG should remain an integral part of the female infertility investigation and must be performed before laparoscopy and hysteroscopy. There is a debate about the usefulness of diagnostic laparoscopy in infertile women with normal hysterosalpingogram (Fatum et al., 2002).

Hysterosalpingogram can be used as a screening test for tubal patency in low risk couples, but in women with risk factors for pelvic or tubal disease (such as pelvic inflammatory disease, previous ectopic pregnancy, or endometriosis) they should proceed directly to laparoscopy and dye (Williams et al., 2003).
1.5.2.2.3.3 Ultrasound contrast hysterosalpingography (HyCoSy)

This technique not only allows us to detect tubal patency but also enable the uterine cavity contour to be assessed. Here the HSG is performed using ultrasonography and an ultrasound contrast medium. Various contrast media have been used for uterine distension while performing ultrasound in order to increase its sensitivity. Sterile saline provides an echo-free or negative contrast medium and has been used in the past for this purpose. Bonilla–Musoles et al. (1992) found this technique to be more sensitive than hysteroscopy for diagnosing intrauterine pathology, but found it to be an unreliable method for diagnosing tubal patency. More recently, a positive contrast medium designed for ultrasonographic use has become available. It is composed of a highly reflective solution of galactose microparticles which form stable microbubbles (Echovist, Schering).

Deichert et al, 1989 have studied this contrast medium and showed that tubal patency could be assessed more confidently because of direct observation of intraluminal flow was possible which indicates unobstructed tubal passage. Balen et al. (1993) in their study to evaluate this technique as an outpatient procedure, used both negative (sterile saline) and positive (Echovist) contrast media in 27 patients presenting with a wide range of gynaecological disorders. It was the first report to compare the use of the two contrast media with plain ultrasound on a purely outpatient basis. They have found ultrasound saline HSG to be superior for the delineation of uterine cavity. However, while Echovist could be demonstrated flowing
through patent fallopian tubes, they found ultrasound contrast HSG to be insufficiently accurate in the determination of tubal patency and do not feel that it can replace conventional X-ray HSG.

Another difficulty that is associated with HyCoSy is that it is not possible to visualize the complete length of the fallopian tube in a single scanning plane (Kelly et al., 2001).

Hauge et al. (2000) have done a study to compare the use of ultrasound based hysterosalpingography with diagnostic laparoscopy and hysteroscopy. They found that it can be used effectively as an initial examination modality during the couple’s work-up, but there is a need for a larger study to confirm that laparoscopy and hysteroscopy can be avoided in infertile women with normal ultrasound based HSG, and they confirmed that this procedure failed to detect minimal to mild endometriosis and mild adhesions that were found at laparoscopy.

1.5.2.2.3.4 Three-dimensional dynamic MR- hysterosalpingography

This is a new, radiation–free method for imaging the uterine cavity and fallopian tube patency using three-dimensional dynamic magnetic. Unterweger et al. (2002) found it to be a less painful technique which avoids exposure of the ovaries to ionizing radiation and by using higher viscosity MR-contrast agent allows not only
visualization of uterine cavity and fallopian tube patency but also direct visualization of fallopian tubes.

1.5.2.2.3.5 Other techniques

1.5.2.2.3.5.1 Selective Salpingography

Transvaginal selective salpingography and tubal catheterization under fluoroscopic guidance is a procedure for the diagnosis and treatment of proximal tubal blockage. The diagnostic advantages of this technique is claimed to be substantial. Woolcott et al. (1999) have shown in a prospective randomized controlled trial that this technique is more accurate than laparoscopy and dye for the diagnosis of proximal tubal block and is equally accurate for the diagnosis of distal tubal blockage. The most common complication of selective salpingography is tubal perforation.

1.5.2.2.3.5.2 Falloposcopy and salpingoscopy

Falloposcopy allows the fallopian tube lumen and wall to be visualized using a fibreoptic flexible telescope passed through the cervix, across the uterine cavity and through the ostia into the fallopian tube. This technique was developed by Kerin et al. (1990). Falloposcopic assessment of the ampulla is difficult without the aid of laparoscope, while the salpingoscope provides a better assessment of the ampullary mucosa during either laparotomy or laparoscopy. Salpingoscopy enables
visualization of the tubal mucosa of the distal tubal segment (ampulla) during laparoscopy (Cornier et al., 1984; Henry-Suchet et al., 1985; Brosens et al., 1987).

Some workers (Henry-Suchet et al., 1985; Puttemans et al., 1987) have stressed the superiority of salpingoscopy over HSG because of the better and direct visualization of the endoluminal mucosa during salpingoscopy. The ampulla normally have three to five folds (4mm in height) and several minor folds (1mm in height) (Fortier et al., 1985). Visualization of these folds during salpingoscopy may direct either towards tubal surgery or IVF.

Various microsurgical workgroups have shown the importance of the tubal mucosa as a prognostic factor for pregnancy outcome (Hulka, 1982; Boe-Meisel et al., 1986; Vasquez et al., 1995). These techniques can be used as diagnostic and therapeutic tools. De Bruyne et al., 1997 have shown in their study that there is a correlation between salpingoscopy and postoperative pregnancy rates, and also showed that the salpingoscopic classification has a prognostic effect not covered by AFS classification, and that there is no significant extra prognostic effect of the AFS classification. They concluded that salpingoscopy can be of use in the counseling of patients towards either reconstructive surgery or IVF and embryo transfer.

The disadvantages of salpingoscopy versus fallopscopy is that the mucosa of the isthmic segment of the tube is not visualized (Kerin et al., 1990).
1.5.2.2.3.6 Diagnostic hysteroscopy

Diagnostic hysteroscopy is usually combined with laparoscopy when investigating infertility. It enables direct visualization of the uterine cavity and the cervical canal and if there is any defect or abnormalities in the cavity that may interfere with fertility, it can be identified and treated.

Hysteroscopy can be performed in an outpatient clinic with or without local anaesthesia using a rigid or flexible endoscope. For instance, in our clinic we use a 30 degree 4 mm or 2.9 mm diameter rigid telescope fitted with a diagnostic sheath (5 mm and 3.5 mm respectively). Gas (e.g. carbon dioxide), low viscosity fluids (e.g. Normal saline) or high viscosity fluids (e.g Hyskon) can be used for distension of the uterus.

Taylor et al., 1979 have reported in their study that hysteroscopy is a simple procedure carrying little risk, it is superior to HSG in detecting intrauterine disease which may be a cause of infertility. Many other studies have demonstrated that hysteroscopy is much more accurate than HSG for investigating the uterine cavity for infertility workup (Prevedourakis et al., 1994; Wang et al., 1996). The rate of intrauterine defects associated with infertility has traditionally been 5 – 10% (Seibel MM, 1990). Common findings include endometrial polyps (11%), submucous fibroids (25%) (Nagele et al., 1996). In comparison with ultrasound scan, hysteroscopy can distinguish between hyperplasia, polyps and fibroids and it also allows assessment
for hysteroscopic surgery. It is uncertain how polyps and submucosal fibroids contribute to infertility. Polyps may affect the endometrial environment by bleeding and presenting an abnormal site for implantation of the embryo, while fibroids may decrease or block normal vascular supply to the trophoblastic tissue of the implanting embryo (Garcia and Tureck, 1984).

Loverro et al, (2001) in a comparison study of transvaginal sonography and hysteroscopy in infertile women found transvaginal sonography to be an accurate diagnostic tool when compared with hysteroscopy, in detecting uterine cavity abnormalities in infertile patients while hysteroscopy provides both diagnostic and therapeutic capabilities.

1.5.2.2.3.6.1 Complications

Hysteroscopy is generally a safe procedure when performed by an experienced gynaecologist. However, like any invasive technique it may carry a risk of complications including: cervical trauma, uterine perforation, infections and complications related to distension medium.

1.5.2.2.3.6.1 Implications for treatment

Operative hysteroscopy is used for treating infertility such as removal of submucous fibroids and polyps (large polyps), resection of uterine septa (metroplasty) and
division of adhesions in Asherman's syndrome and all these operative techniques can be performed using a monopolar electrosurgical system. Recently, the Versapoint bipolar vaporization system has been used. Fernandez et al. (2000), have used a coaxial bipolar electrode surgical system to treat 40 infertile patients with submucous myomas (n=12), uterine septum (n=12), uterine adhesions (n=11) and uterine hypoplasia (n=5). They found the Versapoint bipolar system to be advantageous in infertility surgery, as it reduces the risk of complications related to the distension medium and to cervical dilatation (such as cervical laceration and uterine perforation).

Fibroids associated with infertility have long been treated with abdominal myomectomy and many studies showed a high pregnancy rate after surgery (Verkauf BS, 1992). Only a few uncontrolled series have evaluated reproductive outcomes after hysteroscopic myomectomy, reporting pregnancy rates ranging from 31% to 77% (Brooks et al., 1989; Valle RF, 1990; Hallez JP, 1995; Donnez et al., 1999).

In a study to compare the reproductive benefits of hysteroscopic myomectomy and polypectomy for infertility to outcomes in infertile couples with normal hysteroscopic findings, Varasteh et al, (1999), have found that both hysteroscopic polypectomy and hysteroscopic myomectomy appeared to enhance fertility compared with infertile women with normal cavities. Although concern that hysteroscopic resection of a large fibroid might ablate a large surface area of the endometrial cavity, the
reproductive benefit appeared to be greater than this risk in this study (Varasteh et al., 1999).

The pregnancy rate in infertile women following hysteroscopic resection of an intrauterine septum or adhesions was 53% and 48% respectively (Goldenberg et al., 1995).

1.5.2.2.3.7 Diagnostic Laparoscopy

Diagnostic laparoscopy is generally accepted to be the gold-standard technique and the most accurate procedure for identifying pelvic pathology and tubal abnormalities in infertile women. It enables visualization of pelvic viscera and so the site and extent of adhesions and endometriosis can be noted, and an assessment of the health of the tubes and fimbriae can be made.

The question that is still a matter of debate to many gynaecologists is should all infertile patients undergo diagnostic laparoscopy or only patients with positive symptoms and those with abnormal basic investigations as outlined above?

Many studies have addressed this topic. Forman et al, 1993 stated “In the current financial climate of limited resources many hospitals have a long waiting list for non-urgent laparoscopy. If it is possible to identify those patients at increased risk of pelvic pathology they could be preferentially admitted for laparoscopy and so benefit
from more rapid diagnosis and treatment”. They found from their study that patients with a history of severe dysmenorrhoea, a coloured vaginal discharge, previous use of a coil and previous abdominal or pelvic surgery are significantly more likely to have pelvic pathology than patients with negative history.

However, Corson et al, (2000), in their study to determine the prevalence of reproductive pathology in a group of infertile women thought to be at low risk for altered pelvic anatomy, they found that the yield of pelvic pathology was high.

Some studies suggested that diagnostic laparoscopy should be performed in patients with secondary infertility and should be reconsidered in patients with primary infertility as the positive findings were low in these patients in comparison to patients with secondary infertility (Hovav et al, 1998). Several others have suggested that diagnostic laparoscopy may have added value as it can detect pelvic pathologies in 36% to 68% of infertile patients, even in those with negative histories and those with a normal HSG (Wood, 1983; Henig et al, 1991; Opsahl et al, 1993; Cundiff et al, 1995; al Badawi et al, 1999; Corson et al, 2000).

The reported prevalence of endometriosis found at laparoscopy in infertile women is 25% to 35% while the prevalence in general population is only 3% to 10% (Strathy et al, 1982; Olive and Schwartz, 1993; Guzick et al, 1994). This high prevalence of endometriosis in infertile women has led to the assumption that there might be a causal relationship between infertility and the presence of endometriosis. We know
that moderate and severe endometriosis can cause impaired tubal motility and ovum-pickup function, but the pathophysiological mechanisms of minimal and mild endometriosis have not yet been clarified (Tanahatoe et al, 2002).

1.5.2.2.3.7.1 Complications

However, it should be recognized that diagnostic laparoscopy is an invasive and costly procedure, and is not without complications (Jansen et al, 1997). Although diagnostic laparoscopy is generally safe, like any surgical procedure there are anaesthetic and surgical risks as well as the need for hospitalization (Table 1.4). As the lay population feels that what has been named “minimally invasive surgery” is easy, risk-free surgery associated with short hospitalization and quick recovery, complications are tolerated much less when they occur and an increase in medical-legal actions is thus to be anticipated (Querleu et al, 1993).

Although the risk of complications for diagnostic laparoscopy is low in comparison to operative laparoscopy (Bateman et al., 1996), every patient is still to be warned of the possibility of conversion to laparotomy due to the risk of injury to the viscera or hemorrhage due to accidental vascular injury. Chapron et al, (1997), have reported about the six major injuries which occurred in diagnostic laparoscopies.

The set-up phase for laparoscopy (creation of pneumoperitoneum and installation of the trocars) is an essential part of the operation, Chapron et al, 1998, found from
their study that one-third of the accidents occurred during this phase of the procedure.

Other complications of diagnostic laparoscopy include complications resulting from general anaesthesia and complications associated with laparoscopy such as CO\textsubscript{2} pneumoperitoneum which is a risk factor for gas embolism, causes aerolization and spread of tumour cells (Neuhaus et al, 1998; Martineez-Serna et al, 1998). The financial cost of diagnostic laparoscopy will be address later in the thesis (Chapter 6).

1.5.2.2.3.7.2 Implications for treatment

Whatever the cause of minimal and mild endometriosis is, there is evidence that surgical treatment of minimal and mild endometriosis increases fecundity in infertile patients. Marcoux et al, 1997 have done a large randomized trial of laparoscopic ablation of minimal and mild endometriosis versus no treatment in infertile women, they found that fecundity doubled in the treatment group. A more recent study came to similar conclusions (Millingos et al., 2002). In contrast, another Italian study carried out by Parazzini et al, 1999 used the same design as Marcoux et al, found no difference in fecundity rates after surgical treatment. Neither Parazzini et al. nor Hughes et al, 1996 found any evidence from systematic review of randomized controlled trials that medical treatment of minimal and mild endometriosis improves pregnancy rates.
Adhesions are well known to cause infertility as they impair ovum pick-up by the tube. Logically, adhesiolysis is the treatment of choice for adhesions, and it has indeed been shown that laparoscopic adhesiolysis increases the mean pregnancy rate (Saravelos et al., 1995). However, this was based on the findings of non-controlled studies. Only one nonrandomized controlled study showed a significantly higher pregnancy rate in the treated group (32% and 45%) compared with the control group (11% and 16%) (Tulandi et al., 1990). These data have never been confirmed in a prospective randomized trial. Adhesiolysis has the best results if the adhesion is the only factor responsible for the infertility (Posaci et al., 1999). However, other workers reported that pelvic adhesions in the presence of tubal patency are less important and laparoscopy in this case should be determined by patient preference rather than the gynaecologist’s wish (Collins, 1998). The effectiveness of adhesiolysis depends on the site and extent of pelvic adhesions, severe underlying intratubal adhesions may be impossible to repair and extensive periadnexal adhesions carry a very poor prognosis (Adamson and Baker, 2003).

Diagnostic laparoscopy in contrast with HSG or ultrasound based HSG can reveal mild diseases such as minimal and mild endometriosis and filmy adhesions that may affect fertility which if treated can help to increase the pregnancy rate even in those patients with negative histories and negative HSG findings.

Some studies showed that diagnostic laparoscopy was helpful in making a decision to whether go to assisted reproductive technology or not (Corson et al., 2000).
Tanahatoe et al, (2002) reported that diagnostic laparoscopy altered treatment decisions in an unexpectedly high number of patients before IUI suggesting that diagnostic laparoscopy is of considerable value even after normal HSG.

1.5.2.2.3.8 Minilaparoscopy

After the technological advances in optics development of small diameter endoscopes, Dorsey and Tabb, (1991) were the first to report in the use of minilaparoscopy in gynaecology. The main advantage of minilaparoscopy is that it could be performed under local anaesthesia thus avoiding general anaesthesia complications. Minilaparoscopy has been used for investigation of infertility by many authors (Palter and Olive, 1996; Molloy D, 1995; Barisic et al., 1996; Bauer et al., 1995; Haeusler et al., 1996).

The diagnostic accuracy of minilaparoscopy has been compared with conventional laparoscopy (Molloy D, 1995; Barisic et al., 1996; Bauer et al., 1995). A 2mm minilaparoscope was as accurate as a 10mm laparoscope in 99 out of 100 cases, while only 17 out of 20 cases showed the same findings when a 1.2mm laparoscope was used, a difference which was statistically significant.

Although, the complications of minilaparoscopy have not been well established but abdominal discomfort in patients with chronic pelvic pain due to CO₂ insufflation or manipulation of pelvic viscera has been reported (Palter and Olive, 1996); (nitrous oxide) does not have this side effect, but is contra-indicated with the use of
electrosurgery because of the risks of explosions. Risquez et al. (1993) reported
breathing movement interference during minilaparoscopy.

1.6 Conclusions

We are always looking to improving the way we manage patients, and this applies to
the infertile couple. Ideally, there is a need for a less invasive, safer procedure than
laparoscopy which could be performed in an outpatient settings under local
anaesthesia. As well as these advantages we need a technique that is able to detect
lesions such as endometriosis and adhesions which are not detected by less
invasive investigations such as ultrasound, HSG and ultrasound contrast HSG.
Culdoscopy appears to address at least some of these concerns.
### Table 1.1 Main causes of infertility

<table>
<thead>
<tr>
<th>Category</th>
<th>Causes</th>
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<tbody>
<tr>
<td>Coital problems</td>
<td>Low coital frequency</td>
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<td></td>
<td>Impotence</td>
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<td></td>
<td>Ejaculatory disorders</td>
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<td>Male factors:</td>
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<td>Abnormal semen</td>
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<td>Testicular disease</td>
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<td>Obstruction of excurrent ducts</td>
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<td>Accessory gland dysfunction</td>
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<td></td>
<td>Hypogonadotrophic hypogonadism</td>
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<td>Ovulation disorders</td>
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<td>Anovulation</td>
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<td></td>
<td>Hypothalomic anovulation</td>
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<td></td>
<td>Hyperprolactinaemia</td>
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<td></td>
<td>Polycystic ovarian syndrome</td>
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<td>Premature ovarian failure</td>
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<td>Pelvic disease</td>
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<td></td>
<td>Pelvic inflammatory disease</td>
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<td></td>
<td>Tubal damage/ obstruction</td>
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<td></td>
<td>Adhesions</td>
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<td></td>
<td>Endometriosis</td>
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<td></td>
<td>Endometriomas</td>
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<td></td>
<td>Adhesions</td>
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<td>Bowel disease</td>
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<td>Ruptured appendix</td>
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<td>Ulcerative colitis / Crohn’s disease</td>
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<td>Sperm antibodies</td>
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<td>In the male</td>
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<td></td>
<td>Sperm-bound</td>
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<td>In the female</td>
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<td></td>
<td>Cervical mucus</td>
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<td>Fallopian tubes and follicular fluid</td>
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<td>Non-immunological cervical factors</td>
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<td></td>
<td>Hormonal</td>
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<td>Infection</td>
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<td>Uterine factors</td>
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<td></td>
<td>Submucus fibroids</td>
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<td></td>
<td>Intrauterine adhesions</td>
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<tr>
<td>Unexplained</td>
<td></td>
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</table>

Table 1.2 Normal seminal fluid analysis

<table>
<thead>
<tr>
<th></th>
<th>Normal range</th>
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</thead>
<tbody>
<tr>
<td>Ejaculate volume</td>
<td>&gt;2.5 ml</td>
</tr>
<tr>
<td>pH</td>
<td>7.2-8.0</td>
</tr>
<tr>
<td>Sperm concentration</td>
<td>&gt;20 million/ml</td>
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<tr>
<td>Motility</td>
<td>&gt;50% with forward progression</td>
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<td></td>
<td>&gt;25% with rapid progression</td>
</tr>
<tr>
<td>Viability</td>
<td>&gt;75%</td>
</tr>
<tr>
<td>Morphology</td>
<td>&lt;85% or &gt;15% normal forms</td>
</tr>
<tr>
<td>Inflammatory cells</td>
<td>&lt; 1 million cells/ml</td>
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<tr>
<td>Antibodies (Immunobead test)</td>
<td>&lt;20% sperm binding to bead</td>
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</tbody>
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World Health Organization, 1999
Table 1.3 Complications of HSG

<table>
<thead>
<tr>
<th>Mechanical complications</th>
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<tbody>
<tr>
<td>Pain, uterine perforation or tubal rupture, endometiosis, hemorrhage, shock</td>
</tr>
<tr>
<td>Chemical and toxic complications</td>
</tr>
<tr>
<td>Granulomas, allergic reactions, iatrogenic thyroid dysfunction</td>
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<tr>
<td>Genetic hazards</td>
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<tr>
<td>Intravasation</td>
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<tr>
<td>Uterovenous intravasation, lymphatic structures, interstitial intravasation</td>
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<tr>
<td>Embolism</td>
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<tr>
<td>Pelvic infection</td>
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<tr>
<td>Mortality</td>
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<td>Table 1.4 Complications of laparoscopy</td>
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<tr>
<td><strong>Anaesthetic and cardiopulmonary</strong></td>
</tr>
<tr>
<td>Hypoventilation</td>
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<td>Oesophageal intubation</td>
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<tr>
<td>Gastro-esophageal reflux</td>
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<tr>
<td>Bronchospasm</td>
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<tr>
<td>Cardiac arrhythmias and arrest</td>
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<tr>
<td>Pneumonitis and pneumonia</td>
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<td>Carbon dioxide embolism</td>
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<tr>
<td><strong>Cardiovascular</strong></td>
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<tr>
<td>Cardiac arrhythmias</td>
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<td>Hypotension</td>
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<td><strong>Gastric reflux</strong></td>
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<td>Gastric regurgitation</td>
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<td>Gastric aspiration</td>
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<td><strong>Extraperitoneal insufflation</strong></td>
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<tr>
<td>Subcutaneous emphysema</td>
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<td>Pneumothorax</td>
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<td>Hypercarbia</td>
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<td>Cardiovascular collapse</td>
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<tr>
<td><strong>Electrosurgical</strong></td>
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<tr>
<td>Active electrode trauma</td>
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<tr>
<td>Trauma secondary to current diversion</td>
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<tr>
<td>Insulation defect</td>
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<tr>
<td>Direct and capacitive coupling</td>
</tr>
<tr>
<td>Dispersive electrode burns</td>
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<tr>
<td><strong>Haemorrhagic</strong></td>
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<tr>
<td>Great vessels injury</td>
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<tr>
<td>Abdominal wall vessel injury</td>
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<td>Intraperitoneal vessel injury</td>
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<tr>
<td>Hypovolemic shock</td>
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<tr>
<td><strong>Gastrointestinal</strong></td>
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<td>Insufflation needle injuries</td>
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<td>Trocar injury</td>
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<tr>
<td>Dissection and thermal injury</td>
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<tr>
<td><strong>Urologic</strong></td>
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<td>Bladder injury</td>
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<td>Ureteral injury</td>
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<td><strong>Neurologic injury</strong></td>
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<td>Peripheral nerve injuries</td>
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<tr>
<td>Sensory</td>
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<td>Motor</td>
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<tr>
<td><strong>Incisional hernia and wound dehiscence</strong></td>
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<td><strong>Infection</strong></td>
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*Modified from Novak's Gynaecology (Thirteenth edition, J S Berek, 2002)*
Chapter 2

Background and history of culdoscopy
2.1 Earlier background and history

The history of endoscopy began in 1806 when P. Bozzini invented an instrument to project candlelight through a double-lumen urethral cannula so that the inner surfaces of the urethra and bladder could be inspected. During the seventy-five years that followed, many investigators have unsuccessfully attempted to perfect an instrument for adequate visualization of bladder. Nitze (1878) described the first successful illumination of an internal body cavity and then introduced the cystoscope. This method of inspection was tried for other body cavities after its value was established.

The history of culdoscopy begins as the history of laparoscopy when in 1901 Georg Kelling, a surgeon of Dresden, Germany, visualized the abdominal organs of a dog by inserting a cystoscope through an abdominal incision (Kelling, 1902). Jacobaeus of Sweden, was the first to report, in 1910, the application of this procedure to human patients, and he introduced the name "laparoscopy" for transperitoneal endoscopic examination of the abdominal organs (Jacobaeus, 1910).

Table 2.1 shows some of the investigators, the year and their contribution. Laparoscopy was first introduced in United States in 1911 by Bernheim. The following year, Nordentoeft added the use of pneumoperitoneum and the Trendelenburg position to the procedure.
Beginning in 1891, D.O. von Ott, a Russian gynaecologist from St. Petersburg, utilized normal incandescent light with a reflector for gynaecological operations. The light was fastened to the forehead with a band, and he also attached a mirror to the light, adjustable to the demands of examination at hand. Ott most frequently used "ventroscopy" for the postoperative examination of gynaecological operations (von Ott, 1902).

Von Ott, (1903) was also the first to describe the visualization of the pelvic viscera through an incision in the vaginal vault when he reported on more than 606 operations carried out per vaginam.

Te Linde had attempted pelvic endoscopy in 1940, by the vaginal route with the patient in the lithotomy position, but he had given up this approach quickly because the presence of small intestine behind the uterus caused difficulty (Te Linde, 1948).

In the late 1920s, Albert Decker, a surgeon at the Knickerbocker and Gouverneur hospital in New York, began to use a peritoneoscope for viewing the abdominal cavity. "I started coelioscopy in 1928 and worked with it for ten or eleven years before giving it up" he stated.

Decker was aware that another physician, Ruddock, in California, was performing coelioscopies as well, but decided to against pursuing this direction. "I gave up
coelioscopy because it required general anaesthesia, and I gave up doing any operative procedure through the coelioscope because with a good anaesthesia and the use of an operating room, I felt it was just as well to explore the abdomen and find out what was wrong, and at the same time correct the condition properly” he stated (Decker, 1964).

Throughout the 1930s, laparoscopy was utilized for investigation of both upper and lower abdominal pathology, the most notable contribution was a series reported by Ruddock in 1934.

In 1940, Decker was able to demonstrate the pelvic organs in the cadaver and, in 1942 he began to work exclusively in the gynaecology department and soon turned to a vaginal approach to view the abdomen. “The route to the pelvis by abdominal puncture with the aid of vaginal manipulation and various postures did not give uniformly satisfactory results”, explained Decker. He attributed the failure of proper visualization to the presence of intestinal loops and inability to isolate the pelvic organs correctly. To solve this problem, Decker built an endoscopic instrument in 1943 (Decker, 1946). Figure 2.2

The “Decker culdoscope” represented in principle a modified peritoneoscope, consisting of a trocar and an optical system, but the most important alteration involved not the instrument, but rather the investigatory technique: female patients, were examined in the knee-chest position (Figure 2.3), a method
invented by Decker and Cherry in 1944. It was principally through their work that culdoscopy gained recognition and acceptance (Litynski, 1997).

Between 1943 and 1949 several excellent papers followed, describing the use of culdoscopy in infertility, endocrine dysfunction and other gynaecological problems. In 1949, the Lancet reported that "culdoscopy offers considerable advantages" (Dillon and Smith, 1970).

As the Second World War drew to a close, Decker began to advocate culdoscopy. He published a series of studies dating from 1944 to 1952 in the medical press (Decker, 1952). This method won over many physicians in the United States and came to occupy a privileged space in the range of endoscopic examination methods then available.

He encouraged the use of culdoscopy in the knee-elbow position, although it took at least four people to bring the patient into this position, buttocks raised, and hold her there. It took only few minutes to perform culdoscopy, in contrast, the average length of laparoscopy including general anaesthesia and pneumoperitoneum was about 30 minutes (Litynski, 1997).

Decker advocated the use of thigh straps suspended from long vertical rods at the sides of an operating table (Decker, 1967). Later on, Munsick and Hood in 1973 mentioned a portable knee-chest support for culdoscopy. Decker was so
sucœssfui with his publications on the culdoscopy that for over 20 years it was the only endoscopic method to examine the abdomen in the United States.

Due to the Second World War the first report on culdoscopy appeared in Germany in 1949 (Antonovitch, 1949). There, and in contrast to many of his colleagues, Hans Frangenheim of Wuppertal, was not satisfied with culdoscopy and turned to an abdominal approach. He worked in an American military hospital in 1946, moved to a German university clinic for surgery four years later, and started his training in gynaecology at a women's clinic in Wuppertal. In 1951, an internist at the Wuppertal clinic happened to notice a tumour in the lower abdomen of a female patient during laparoscopy and called Frangenheim for assistance. As Frangenheim recalls "I realized that this could mean a new aid for gynaecology and I began to look into the literature".

He started to modify laparoscopic instruments and a year later he was performing laparoscopic examinations on a regular basis. He could not find any reports on endoscopy in gynaecology except for culdoscopy. He soon came across Palmer’s articles on sterility and coelioscopy in French medical press. As Palmer’s guest book in Paris indicates, Frangenheim paid his first visit in October 1955 – the beginning of a life-long cooperation and friendship between the two.

Frangenheim had performed over 350 laparoscopies. His first article for the medical press appeared in 1958 and included a summary of the spread of
endoscopy in Europe. "Following Decker's recommendation, the university clinics for gynaecology in Hamburg, Leipzig, Kiel, and Heidelberg...have given almost unanimous endorsement to the culdoscopy...for the endoscopic examination of the abdominal cavity", he wrote. Frangenheim noted that only Palmer in Paris, Guggisberg in Bern, and Schwalm in Mainz were using laparoscopy. He left open the issue whether culdoscopy or laparoscopy was to be the method of choice for gynaecology (Litynski, 1997).

While the technology of laparoscopy was continuously improving, the technique of culdoscopy did not advance after the 1960s. Eventually, culdoscopy was abandoned in the 1970s as laparoscopy provided a panoramic view of the pelvis and was superior for tubal sterilization (McCann and Col, 1978). In 1974, Palmer stressed the advantages of culdoscopy in infertility in the French and English literature and also suggested the dorsal decubitus position (Palmer, 1974; Mintz, 1987). Odent (1973) suggested hydroflotation, and Van Lith et al. (1979) suggested the use of miniculdoscopy. Later on, no further attention was given to culdoscopy.

2.2 Recent background and history

A renaissance of culdoscopy took place in the late 1990's, brought about by the work of Gordts and his colleagues from the Leuven Institute for Fertility and Embryology, Belgium. The group described a new technique based on
culdoscopy for exploration of the pelvic viscera in infertile patients calling it “transvaginal hydrolaparoscopy” (THL) (Gordts et al., 1998).

THL is performed under local anaesthesia using the newly developed miniature endoscopes (cf. large diameter endoscope), the patient being in the lithotomy position (cf. knee chest), and normal saline being used to hydroflotate bowel away from the pelvis (cf. air) (Gordts et al, 1998). The difference between the new technique and the old culdoscopy are summarized in Table 2.2

When Gordts et al. first developed the new technique for the exploration of the tubo-ovarian structures in infertile women, their aim was to avoid laparoscopy in those patients without obvious pelvic pathology. As the technique was new, it needed a full evaluation of its accuracy, risks and benefits before it could be accepted as a first line technique in gynaecological practice.

In the initial feasibility study, 28 infertile patients with normal findings both on gynaecological examination and transvaginal ultrasound scan were studied (Gordts et al., 1998). They found that the procedure allowed atraumatic and detailed exploration of the tubo-ovarian structures in infertile women without obvious pelvic pathology and it offered patients a complete and early exploration of the reproductive tract in a painless and safe way.

The Leuven group published a comparative study of THL in the following year to establish whether the new investigation was as good at assessing the pelvis as
laparoscopy, generally considered the "gold standard" investigation for pelvic pathology. To increase accuracy, the study used two experienced and independent investigators who were blinded to the findings of the other; they both carried out assessment of the pelvis using THL followed by laparoscopy. All assessments were recorded on videotape in case findings needed to be confirmed. Using this protocol, the investigators were able to calculate the interobserver variability for both investigations (Campo et al., 1999).

Seven of the 10 patients investigated were found to have endometriosis and one had evidence of pelvic inflammatory disease. The interobserver agreement for tuboovarian adhesions was 95% at transvaginal hydrolaparoscopy and 74% at standard laparoscopy. Ovarian adhesions were reported by both observers in 12 of 19 ovaries (63%) at transvaginal hydrolaparoscopy and in 7 of 19 (37%) at standard laparoscopy. The authors suggested from their results that THL had comparable diagnostic accuracy to standard laparoscopy. The authors did not specify what they meant by "standard laparoscopy", and in particular whether a single or multiple-puncture approach was used; the accuracy of laparoscopy would be expected to be less with the former because of the inability to manipulate the pelvic organs.

Another study by Gordts et al. (2000) evaluated the feasibility of culdoscopy for early office screening of subfertile women. They enrolled 157 infertile patients who underwent culdoscopy in the office under local anaesthesia. They found that
access to pouch of Douglas was achieved in 95% of patients, in 58.5% the findings were normal and 28% of patients required operative laparoscopy. They concluded that culdoscopy was a safe endoscopic procedure for the investigation of subfertility in an office setting and allows early and accurate screening.

Brosens et al. (2001) in a study to determine whether culdoscopy is superior to standard laparoscopy for detection of subtle endometriotic adhesions of the ovary, enrolled forty-three infertile patients with negative findings on gynaecologic examination and vaginal sonography who were scheduled for diagnostic laparoscopy as part of their fertility investigations. Culdoscopy was performed first under general anaesthesia and both procedures were recorded in each patient. The videotapes were viewed in random order and in a blinded manner by one of the authors who was not involved in the recording of the cases.

This study showed that culdoscopy was superior to laparoscopy for detecting subtle endometriotic adhesions of the ovary. Patients with minimal and mild endometriosis and unexplained infertility had significantly more ovarian adhesions on culdoscopy than on laparoscopy. These adhesions were filmy, microvascularized, and nonconnecting.

Gordts et al. (2001), in a multinational retrospective survey based on confidential, self-reported cases to determine the risk and outcome of bowel injury associated with culdoscopy, have shown that the prevalence of bowel injury was minor.
(0.65%). All of the injuries were diagnosed during the procedure and 92% of the cases were managed without consequences.

Several other workers in France, United States and UK have started culdoscopy or transvaginal hydrolaparoscopy since. Watrelot et al. (1998) in France, using the term “fertiloscopy” to describe a combination transvaginal hydropelviscopy, dye test, optional salpingoscopy and hysteroscopy, performed under local anaesthesia or neuroleptanalgesia in the operating theatre. They proposed fertiloscopy as an alternative to diagnostic laparoscopy as the primary endoscopic procedure in the routine assessment of an infertile woman as most subfertile women who undergo diagnostic laparoscopy have normal findings (Watrelot et al., 1998).

In a recent prospective randomized multicentre study to establish the diagnostic accuracy of fertiloscopy in relation to laparoscopy in the same patient, they found a high degree of concordance between the two techniques, in that if fertiloscopy did not detect any abnormalities, this was also confirmed by laparoscopy. They showed that fertiloscopy could allow laparoscopy to be avoided in up to 93% of patients, as the relevant information regarding the tubo-ovarian structures was obtained by this less-invasive procedure (Watrelot et al., 2003).
In the UK, culdoscopy was introduced on an experimental basis at the Royal Free Hospital in 1998. The One Stop Fertility Clinic saw its first patient in early 2000.

In the United States, some workers started performing diagnostic and operative transvaginal hydrolaparoscopy. Moore and Cohen (2000) began performing transvaginal hydrolaparoscopy in 1999 and in their first study of 29 infertile patients and 11 with pelvic pain who required pelvic anatomic investigation as the next step in their evaluation, they concluded that transvaginal hydrolaparoscopy can be performed in the office with minimal pain and that it is a more accurate procedure than HSG and is similar to laparoscopy (Moore and Cohen, 2001).

Bajzak et al (2000) performed transvaginal hydrolaparoscopy in 15 patients prior to operative laparoscopy and found it to be a practical and convenient office diagnostic procedure.

Many others worldwide have shown that transvaginal hydrolaparoscopy is an accurate alternative to diagnostic laparoscopy for the diagnosis of adhesions and endometriosis in infertile women without obvious pathology (Campo et al., 1999; Darai et al., 2000; Dechaud et al., 2001; Jonsdottir and Lundorff, 2002).

Several authors have performed operative procedures during culdoscopy. Ovarian capsule drilling in clomiphene resistant women with PCOS (Fernandez
et al., 2001), vaporization of endometriosis and adhesiolysis (Moore and Cohen, 2001), and electrocoagulation of ovarian endometrioma (Gordts et al., 2000) have all been described. All these authors have reported that the risk of infections during operative culdoscopy was greatly reduced in contrast with the original culdoscopy.

Operative culdoscopy for vaporization of minimal and mild endometriosis performed in infertile women by Moore et al. (2003). Although the number of patients was small, their results in terms of fertility were similar to those for laparoscopy (Seiler et al., 1986; Marcoux et al., 1997). Fernandez et al., 2001, reported that the pregnancy rate at 6 months after culdoscopy performed in 13 clomiphene citrate resistant anovulatory women with PCOS was 71%, which was in line with laparoscopic series (Gjonnaess H, 1984).

Fertiloscopy developed by Watrelot et al, in France, is a combination of culdoscopy, dye-test, optional salpingoscopy and hysteroscopy. Operative fertiloscopy has been successful in treating moderate peritubal adhesions and minimal endometriosis (Watrelot, 2001).

2.3 Culdoscopy at the Royal Free Hospital, London

We started culdoscopy in 1998 to investigate women with infertility. Our setup has changed since then as we developed our technique (Table 2.3)
We use a similar technique as in Leuven, with the patient in lithotomy (Figures 2.6-2.11). Our instrumentation, has however, altered with experience (Figure 2.12). We first used the minilaparoscopy set, including the Veress needle and the standard trocar. We used Spackman cannulae for dye hydrotubation initially. Later on, in March 1999, we changed this to Leech-Wilkinson cannulae as we were having difficulties with the previous cannulae.

We were still not happy using Leech-Wilkinson cannulae to perform the dye test as they did not stop the problem of leakage. As a result, in September 1999, we started using paediatric Foley catheters.

At that time we were not sure what would be the best angle for the introduction of the Veress needle into the Pouch of Douglas to avoid bowel and rectal injuries. Initially, therefore, we performed culdoscopy at the time laparoscopy and monitored culdoscopic entry laparoscopically. Based on this experience, we determined that the optimum angle of insertion of the Veress needle through the posterior vaginal fornix to be approximately 45° to the horizontal, which basically meant aiming the needle towards the umbilicus ( ).

We performed 19 successful culdoscopies in the main operating theatre, of which the first few were under general anaesthesia and the rest were under local anaesthesia.
We were still not satisfied with our progress with culdoscopy so we decided to travel to Leuven in Belgium in May 2000, where we met Professor Gordts and his team. We observed several diagnostic and operative culdoscopies and discussed the instruments that were being used to perform culdoscopy. Since then, we used the Collin’s speculum which we found very useful and HSG catheter for dye hydrotubation (Figure 2.13).

Although we were performing culdoscopy in the One-Stop Fertility Clinic (OSFC) regularly, there was a fear of visceral injury due to blind entry of the Veress needle. Therefore, we developed an alternative technique based on an optical cannula that allows insertion of the culdoscope under visual control (Scott and Magos, 2002) (Figures 2.15-2.17).
Table 2.1: Important dates in early laparoscopy and culdoscopy

<table>
<thead>
<tr>
<th>Name</th>
<th>Year</th>
<th>Contribution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bozzini</td>
<td>1806</td>
<td>Invented an instrument to project candlelight through urethra and bladder</td>
</tr>
<tr>
<td>Nitze</td>
<td>1878</td>
<td>Cystoscope</td>
</tr>
<tr>
<td>Von Ott</td>
<td>1891</td>
<td>Utilized normal incandescent light with a reflector for gynaecological operations</td>
</tr>
<tr>
<td>Keling</td>
<td>1901</td>
<td>Visualized the abdominal organs of a dog by inserting a cystoscope through an abdominal incision</td>
</tr>
<tr>
<td>Von Ott</td>
<td>1902</td>
<td>First to visualize pelvic viscera through an incision in the vaginal vault</td>
</tr>
<tr>
<td>Jacobaeus</td>
<td>1910</td>
<td>First to introduce laparoscopy in Europe</td>
</tr>
<tr>
<td>Bernheim</td>
<td>1911</td>
<td>First to introduce laparoscopy in the USA</td>
</tr>
<tr>
<td>Nordentoeft</td>
<td>1912</td>
<td>First to introduce pneumoperitoneum and Trendelenburg position</td>
</tr>
<tr>
<td>Telinde</td>
<td>1940</td>
<td>Attempted pelvic endoscopy by vaginal route with patient in lithotomy position</td>
</tr>
<tr>
<td>Decker</td>
<td>1943</td>
<td>Invented “Decker Culdoscope”</td>
</tr>
<tr>
<td>Decker and Cherry</td>
<td>1944</td>
<td>Knee-chest position for culdoscopy</td>
</tr>
<tr>
<td>Hans Frangenheim</td>
<td>1952</td>
<td>Modified laparoscopic instruments</td>
</tr>
<tr>
<td>Clyman</td>
<td>1957</td>
<td>Modified culdoscopic instruments</td>
</tr>
</tbody>
</table>
Table 2.2 Comparison of old technique with new technique

<table>
<thead>
<tr>
<th>Patients position</th>
<th>Old technique as described by Decker and Cherry, 1944</th>
<th>New technique as described by Gordts et al., 1998</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anaesthesia</td>
<td>Knee-chest Conduction or local Cul-de-sac Spontaneous (air) 90 degree angle 3.1 inches (7.9mm)</td>
<td>Lithotomy Local Cul-de-sac Normal saline 30 degree angle 2.9 mm</td>
</tr>
</tbody>
</table>
Table 2.3 Development of outpatient culdoscopy at the Royal Free Hospital

<table>
<thead>
<tr>
<th>Time</th>
<th>Speculum</th>
<th>Endoscope for entry</th>
<th>Entry technique</th>
<th>Hydrotubation</th>
</tr>
</thead>
<tbody>
<tr>
<td>May 1998</td>
<td>Sims</td>
<td>30°</td>
<td>Veress</td>
<td>Spackman cannula</td>
</tr>
<tr>
<td>March 1999</td>
<td>Sims</td>
<td>30°</td>
<td>Veress</td>
<td>Leech-Wilkinson cannula</td>
</tr>
<tr>
<td>September 1999</td>
<td>Sims</td>
<td>30°</td>
<td>Veress</td>
<td>Paediatric Foley</td>
</tr>
<tr>
<td>May 2000</td>
<td>Collin</td>
<td>30°</td>
<td>Veress</td>
<td>HSG catheter</td>
</tr>
<tr>
<td>December 2000</td>
<td>Collin</td>
<td>0°</td>
<td>Optical</td>
<td>HSG catheter</td>
</tr>
</tbody>
</table>
Figure 2.1 Collins' speculum
Figure 2.2 Deckers culdoscope
Figure 2.3 The patient positioned at Knee-chest position for culdoscopy
(From Corkill B, 1967)
Figure 2.4 The knee-chest position for culdoscopy under general anaesthesia.

Figure 11—The knee-chest position for culdoscopy under general anaesthesia. Whatever method of support is used the abdominal wall must be free from pressure. For safety intratracheal anaesthesia is essential. (Photograph presented by Professor James Scott.)
Figure 2.5 Culoscopy with the patient in the knee-chest position (From Principles of Gynaecology, 4th Edition. Sir Normal Jeffcoate, 1975)

Minor operative procedures can now be done taken through endoscopes, although this may require the passage of a second cannula. Such procedures include removal of fluid from cystic ovaries for analysis, ovarian biopsy, the collection of ova from ripe follicles, the division of peritubal and peri-ovarian adhesions and especially division or destruction of the inner ends of the fallopian tubes for the purpose of sterilization (see page 629).

Because it necessitates only a short stay in hospital, sterilization by way of an endoscope has much to commend it. In regard to certain other operations, better and safer results may be obtained by way of a laparotomy incision. All operations carried out through an endoscope carry the risk of inadequate haemostasis, injury to viscera and other hazards.

The operating laparoscope is a new toy which tempts the surgeon to extend its use beyond reason. In general, ‘keyhole surgery’ is to be avoided.

Culoscopy

In this operation the endoscope is inserted through the posterior vaginal fornix under local, spinal or general anaesthesia. The patient must be in the knee-chest position to protect the intestines and
Figure 2.6 Infiltration of the posterior lip of the cervix at the start of culdoscopy
Figure 2.7 Infiltration of the posterior fornix prior to the vaginal incision
Figure 2.8 Insertion of the HSG catheter
Figure 2.9 Identifying the entry point in the posterior fornix using a narrow dilator
Figure 2.10 Guiding culdoscope into the pelvis under direct vision
Figure 2.11 Inspecting the pelvis using the culdoscope
Figure 2.12 The instruments for transvaginal hydrolaparoscopy

(Manufactured by Circon ACMI, Stamford, CT).
Figure 2.13 HSG catheter used for hydrotubation at outpatient culdoscopy
Figure 2.14 The Veress needle system
Figure 2.15 The optical cannula system
Figure 2.16 The tip of the optical cannula
Figure 2.17 The optical cannula viewed laparoscopically

**FIGURE 2**

The optical cannula viewed laparoscopically.

Chapter 3

One Stop Fertility Clinic
3.1 Introduction

The recommended assessment for infertile couples involves semen analysis, assessment of ovulation, evaluation of the uterus and fallopian tube and laparoscopy (AFS, 1992). Typically, these investigations require several hospital visits and inpatient admission for laparoscopy under general anaesthesia for the female partner. With the possibility to perform all the fundamental investigations in an outpatient setting, we started a One Stop Fertility Clinic in 2000 (Taylor et al., 2002). Our intention was to identify women with normal pelvic organs and thereby avoid unnecessary laparoscopy in this group. Detailed assessment would be provided at a single outpatient visit involving pelvic ultrasound (looking for polycystic ovaries, adnexal masses and uterine lesions), hysteroscopy (looking for endometrial polyps, submucous fibroids and uterine anomalies) and culdoscopy (looking for adhesions, endometriosis and tubal damage). Findings could be discussed with the couple and an immediate management plan made.

This chapter is a detailed analysis of our initial experience with the One Stop Fertility Clinic.

3.2 Materials and Methods

We set up the clinic in the February 2000. Patients referred with subfertility, defined as failure to conceive after at least 12 months of unprotected intercourse, were sent an information pamphlet and a screening questionnaire to assess their suitability for out-patient investigation. The questionnaire contained items on demography, duration of infertility, menstrual pattern, and relevant clinical history. The couples
were also asked if they would like to be seen in the One Stop Clinic.

Couples who fulfilled our criteria (Table 1) were offered an appointment in the Clinic and asked to undergo relevant blood and semen analysis prior to attending; patients who appeared to be unsuitable or did not want outpatient investigation were sent an appointment to the general gynaecology clinic (Figure 3.1). In the One Stop Clinic, a full history was taken, the test results reviewed and informed consent obtained for pelvic ultrasound, hysteroscopy and culdoscopy (Study approved by Local Ethics Committee, No. 118-2K). In view of the need for uterine instrumentation, all women were given doxycycline as prophylaxis against Chlamydia trachomatis; they were also prescribed mefenamic acid as an analgesic during the procedure.

The investigations were performed in a Minor Procedures room with the woman in lithotomy position. Vaginal ultrasound was done using a 5 MHz probe (Toshiba USBU-221A, Japan). We used a 2.9 mm 30° hysteroscope fitted with a 3.5 mm sheath (Karl Storz, Germany) and saline distension for hysteroscopy, with the option of intracervical local anaesthesia if required (Nagele et al., 1996).

Culdoscopy was done provided clinical and ultrasound examination had excluded gross pelvic pathology (Table 3.1). The posterior lip of the cervix was grasped and pushed cephalad and anteriorly to stretch the posterior fornix. The posterior fornix was infiltrated with 2.2 ml 2% lignocaine and 1:80,000 adrenaline using a dental syringe and 24 gauge needle. A small incision was made in the midline 2 cm below the posterior margin of the cervix, and the Pouch of Douglas entered using a modified Veress needle and dilating cannula which allowed insertion of a rigid wide-
angled 2.7 mm 30° endoscope through a 3.5 mm irrigation cannula (Circon Corporation, Santa Barbara, California, USA and Cory Brothers, London, UK). For the last 58 patients we used an optical cannula instead of the modified Veress needle to gain entry into the pelvis under direct vision (Scott and Magos, 2002).

At culdoscopy, the pelvis was inspected systematically including the posterior aspect of the uterus, fallopian tubes, ovaries, pelvic side wall, uterosacral ligaments and rectal peritoneum (Figures 3.2 - 3.6). Methylene blue dye was injected via the uterus to check tubal patency; initially we used a 10 Fr Foley catheter inserted into the uterine cavity, subsequently a Leech Wilkinson cannula, and now a 5 or 7 Fr HSG cannula (Cook UK Ltd., Letchworth, Hertfordshire, England) connected to a pressurised bag of dilute methylene blue.

All results were reviewed with the couple at the end of the investigations and a management plan formulated. All results were entered on to a dedicated computer database (Access, Microsoft) and a printed summary of our findings and recommendations was given to the patient and sent to their General Practitioner. Finally, patients were asked to complete a short questionnaire to assess their views about the One Stop Clinic.

Statistical analysis was done using GraphPad Prism 2 software (GraphPad Software Inc., California, USA).

Results

In the 3 years period of February 2000 to January 2003, a total of 335 couples were referred to the One Stop Fertility Clinic by their general practitioner. All were sent a
screening questionnaire. The return of 67 questionnaires is awaited. Of the 268 questionnaires returned so far, 164 (61.2%) respondents met the selection criteria for the clinic and have been given an appointment, and 123 have attended at the time of writing. The 104 couples who were felt to be unsuitable for or did not wish office investigation were sent a routine gynaecology outpatient appointment.

The characteristics of the 123 couples seen in the One Stop Clinic are summarised in Table 3.2. Review of the tests done prior to the clinic visit showed that 36 women had suboptimal serum progesterone (<30 nmol/L), with 26 results unavailable at the time of the Clinic appointment, while 43 seminal fluid analyses showed either oligospermia (<20M/ml) and/or reduced motility (<50%), with 17 samples still awaited and 12 not done by the male partner.

The outcome of the three investigations done in the clinic are shown in Figure 3.7. As 15 women had undergone a recent pelvic ultrasound scan, it was not repeated. Hysteroscopy was not attempted in 13 (10.6%) cases for the reasons given in Table 3. In a further 4 patients, diagnostic hysteroscopy failed because of cervical stenosis (3 cases) or pain (1 case). Culdoscopy was not attempted in 23 (18.7%) women, including all 13 who were not hysteroscoped, and in 3 of the 4 in whom hysteroscopy could not be done (Table 3.3). In 24 (19.5%) cases, culdoscopy could not be done because of technical difficulties with entering the Pouch of Douglas.

The overall success rate of culdoscopy in those women where the investigation was attempted was 76% (76/100), and in all but 5 cases the view was judged to be good; although the view was inferior in 5 cases, the procedure was still considered
successful as we were able to identify pelvic abnormalities. There was a definite learning curve, the success of culdoscopy increasing from 52.9% for the first 20 patients seen in the clinic (17 culdoscopies attempted of which 9 were successful) to 78.75% for the last 103 (80 culdoscopies attempted of which 63 were successful). For those women who underwent all three procedures, the investigations took an average of 41.2 (SD 17.2) minutes. There was a single complication related to an attempted culdoscopy; the second patient in our series bled from the colpotomy incision and required admission to hospital and suture under general anaesthesia.

The results of ultrasound, hysteroscopy and culdoscopy are summarised in Table 3.4. The commonest findings at ultrasound were polycystic ovaries, fibroids and ovarian cysts, at hysteroscopy submucous fibroids and polyps, and at culdoscopy pelvic adhesions, endometriosis and tubal blockage.

The management plan made in the One Stop clinic are summarised in Figure 3.8, ranging from reassurance to assisted conception. Patients who did not undergo culdoscopy were generally scheduled for in-patient laparoscopy. Arrangements were made to review almost a quarter of couples because of incomplete test results. Corrective hysteroscopic or laparoscopic surgery was offered to about 1/5th of women, and 9% were commenced on ovulation induction with clomiphene.

Assessment of patient anxiety, pain and acceptability showed that culdoscopy was the most uncomfortable of the three procedures, but our impression was that this was largely linked to discomfort during hydrotubation (Table 3.5). While pelvic ultrasound was both the least painful and most acceptable procedure, there was no statistically
significant difference between the acceptability of diagnostic hysteroscopy and culdoscopy. The need for a single hospital visit was ranked as the most important advantage of a One Stop Clinic, closely followed by the availability of immediate results. The avoidance of inpatient admission and general anaesthesia were perceived as less important benefits of the clinic, while the chance to follow the various investigations on the monitor was ranked lowest.

Discussion

Our experience of an outpatient based One Stop Fertility Clinic for the investigation of infertility demonstrates both the benefits and problems with such an approach. On the positive side, the concept of outpatient investigation involving pelvic ultrasound, diagnostic hysteroscopy and culdoscopy was acceptable to most women. There was a high rate of pathology detected even in women who had no obvious risk factors in their history or on clinical examination. Complications were unusual, and the total procedure time was short. Patients appreciated the fact that all the basic investigations were done at a single clinic visit, an immediate diagnosis was possible, and a treatment plan could be formulated quickly. On the negative side, our selection criteria meant that almost 40% of couples referred with infertility were judged to be unsuitable for outpatient examination. Procedural failure, mainly related to difficulties with culdoscopic entry, was not uncommon, especially early on. Finally, we found considerable difficulties with the organisation of pre-clinic investigations which meant that a large number of couples had to return to hospital just for blood and semen results.
Based on our initial screening questionnaire, approximately one third of the couples referred were felt to have contra-indications to culdoscopy. The commonest reason for excluding couples was a history of moderate or severe pain associated with menstruation, sexual intercourse and/or cervical smears. We took such a response to mean either that such women would find the investigations too uncomfortable, or that there was a high probability of conditions such as endometriosis or pelvic inflammatory disease (Forman et al., 1993). In contrast, the rationale for the clinic was to identify and screen women at low risk of pelvic pathology and thereby avoid the need for laparoscopy and general anaesthetic. We were also concerned to minimize the procedural risks of culdoscopy, which would be increased by adhesive disease in the Pouch of Douglas. Our exclusion criteria might have been too strict (Lee et al., 1984) but we were naturally cautious when introducing a new technique.

Of those who were felt to be suitable for the One Stop Clinic, culdoscopy was not attempted in almost 1:4 (24 out 100 patients). There were a variety of reasons for this, ranging from obvious discomfort with vaginal examination to palpable pathology behind the uterus. Our screening questionnaire did not identify these patients. Whether by asking different questions or obtaining additional information from general practitioners would reduce the procedural cancellation rate remains to be determined.

The rate of successful investigation was further compromised by a relatively high failure rate for culdoscopy even in those who appeared to have no obvious adverse features on history and examination. We feel there are three reasons for this: the learning curve, the out-patient nature of the clinic, and because we were actively
involved with developing an alternative technique for peritoneal entry. For instance, the rate of successful entry into the Pouch of Douglas increasing from just over 50% early in the series to almost 80% subsequently. The out-patient nature of the clinic meant that we were disinclined to persist with culdoscopy if the initial attempt at entry failed. Finally, during the study period we gradually modified the technique of entering the cul-de-sac, starting with blind insertion using the Veress needle and culminating in the use of an optical cannula which allowed insertion under direct vision. Although advocates of “blind entry” report a low rate of rectal injury at culdoscopy (Lane E, 1980; Brosens et al., 1999; Watrelot et al., 1999; Gordts et al., 2001; Cincinelli et al., 2001), we feel much more comfortable using a technique which provides visual control; a similar approach is already using in laparoscopy (Melzer et al., 1995). During insertion with the optical cannula, it is possible to identify retroperitoneal connective tissue and fat, and subsequent entry into the peritoneal cavity is immediately obvious. The disadvantage of this approach to culdoscopy is the inconvenience of changing from a 0° endoscope, used during entry, to a 30° oblique view endoscope for visualising the pelvic structures (Scott and Magos, 2002). We expect that refinement in the prototype optical cannula we currently use would lead to a higher success with pelvic entry.

There is debate at to whether hysteroscopy should be part of the basic infertility workup. Historically the hysterosalpingography (HSG) has been the most commonly used test to assess the shape and regularity of the uterine cavity. Several studies have, however, demonstrated that hysteroscopy is much more accurate than HSG. For instance, Kessler and Lancet reported that in about two thirds of the cases hysteroscopy did not correlate with findings at HSG (Kessler and Lancet, 1986).
Wang et al. found that among 79 women with a normal HSG, 28 had abnormal findings on hysteroscopy (Wang et al., 1996). As a result, hysteroscopy has become the gold standard for the diagnosis of intrauterine abnormalities (Ruach et al., 1998). Hysteroscopy also allows a clear display of the test result to the patient without exposure to ionising radiation or allergic reactions to iodinated contrast media.

Similarly, laparoscopy has been shown to be superior to hysterosalpingography when investigating infertility. Ben et al. (1999) compared HSG with laparoscopy in 794 patients and found that, despite not providing information about tubal contour, the endoscopic investigation was a better predictor of future fertility. Of note, they found that laparoscopy revealed no abnormality in 42% of women with apparent bilateral tubal disease on HSG, and fertility was only slightly impaired in this group. Hysterosalpingography is also relatively poor at characterising pelvic adhesions and cannot be used to diagnose endometriosis (Rice et al., 1986), two conditions which are important causes of female infertility, and which respond to treatment (Marcoux et al., 1997). For all these reasons, it seems that a combination of hysteroscopy with laparoscopy (or culdoscopy) is more accurate than HSG and offers patients the option of immediate therapy. Admittedly we did have problems with hydrotubation during culdoscopy because of uterine pain, we think secondary to the injection of dye under high pressure through the narrow fallopian tubes, but this was not unexpected as hysterosalpingography, which also involves the injection of liquid medium into the uterine cavity, is also acknowledged to be relatively uncomfortable (Lorino et al., 1990). For this reason we eventually changed to using a narrow HSG catheter in combination with a bag of dilute methylene blue under 150 to 200 mmHg pressure, and this combination was much better tolerated by patients than when bolus
injections were used.

While diagnostic laparoscopy is considered the gold standard to investigate tubo-peritoneal infertility, it is often delayed to the later stages of infertility evaluation or even after initial treatments have failed due to the requirement for general anaesthesia and the risk of complications (Jansen et al., 1997; Haakki-Siren et al., 1999). Such delay to the management of infertility can be illogical. For instance, in women with dual pathology such as anovulation and tubal disease, ovulation induction may not only be ineffective but is associated with serious sequels if treatment is prolonged (Venn et al., 1995). In contrast, culdoscopy in the out-patient setting does not require general anaesthesia or in-patient stay and is available at the same time as an ultrasound scan and hysteroscopy.

In terms of diagnostic accuracy, the available evidence shows that culdoscopy and laparoscopy are comparable. Darai et al. conducted a prospective comparative blind trial on 60 women to assess the accuracy of culdoscopy with laparoscopy (Darai et al., 2000). Diagnoses such as tubal pathology, endometriosis and adhesions at culdoscopy correlated with that of laparoscopy in 92.3%, and there were no false positive findings at culdoscopy. They concluded that culdoscopy is a highly accurate technique for assessing the pelvis comparable to laparoscopy, and confirmed Campo et al.'s earlier preliminary data (Campo et al., 1999). Admittedly, endometriosis anterior to the uterus would not be visualised at culdoscopy, but it is rare for the condition to be confined solely to the anterior pelvic compartment (Jenkins et al., 1986). While laparoscopy can be done using small diameter endoscopes without general anaesthesia in an office setting, intravenous sedation and local anaesthesia
are still required, and patients need to stay in hospital for several hours afterwards (Bauer et al., 1996). Culdoscopy seems an easier and more convenient option and avoids multiple abdominal incisions

A purely ultrasound based assessment of the female partner in a One Stop setting has been suggested relying detailed pelvic ultrasound and hystero-sonography to assess tubal patency (Kelly et al., 2001). While this is a less traumatic approach than the one we are proposing, ultrasound cannot exclude endometriosis or pelvic adhesions which are commonly associated with subfertility. In contrast, as at laparoscopy, pelvic endometriosis and adhesions are obvious at culdoscopy.

In conclusion, as for other symptoms such as dyspepsia and menorrhagia (Baskett et al., 1996; Rutter et al., 1998), the investigation of infertility could be rationalised to a One Stop approach (Gordts et al., 2002). Pre-visit blood and semen testing combined with pelvic ultrasound, hysteroscopy and culdoscopy in the outpatient clinic provides a thorough assessment of infertile couples. In principle, several visits to hospital, inpatient admission and general anaesthesia are all avoided. Although attractive and liked by patients, such an approach is not suitable for all infertile couples, and not all opt for outpatient investigation. There is a definite learning curve to the procedures; whilst ultrasound and to a lesser extent hysteroscopy are established outpatient techniques, culdoscopy is unknown to most gynaecologists and will have to be learnt from first principles. The entry technique for culdoscopy itself needs to be improved to make it easier. There are also major organisational issues which have to be resolved to ensure the efficient running such a service and avoid the need for further outpatient visits. Whether a One Stop approach is cost
effective compared with traditional sequence of investigations, and whether culdoscopy is the optimal office diagnostic investigation remain to be seen.

**Conclusions**

A One Stop approach to the investigation of infertility is attractive but not suitable for or desired by all infertile couples.
### Table 3.1 Attendance criteria for the One Stop Fertility Clinic

<table>
<thead>
<tr>
<th>Inclusion criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Failure to conceive after 12 months of unprotected sexual intercourse (unless age &gt; 35 years)</td>
</tr>
<tr>
<td>Agree to outpatient investigation</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Exclusion criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight &gt; 100 kg</td>
</tr>
<tr>
<td>Endometriosis</td>
</tr>
<tr>
<td>Large fibroids</td>
</tr>
<tr>
<td>Pelvic adhesions</td>
</tr>
<tr>
<td>Pelvic infection</td>
</tr>
<tr>
<td>Laparotomy</td>
</tr>
<tr>
<td>Ectopic pregnancy</td>
</tr>
<tr>
<td>Major medical or psychiatric illness</td>
</tr>
<tr>
<td>Period pains rated as moderate to severe</td>
</tr>
<tr>
<td>Pain during sexual intercourse rated as moderate to severe</td>
</tr>
<tr>
<td>Pain during cervical smear rated as moderate to severe</td>
</tr>
</tbody>
</table>
Table 3.2 Patient characteristics

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of couples seen</td>
<td>123</td>
</tr>
<tr>
<td>Age *</td>
<td>34.9 (21 to 46) years</td>
</tr>
<tr>
<td>Weight *</td>
<td>62.6 (42 to 93) kg</td>
</tr>
<tr>
<td>Height *</td>
<td>163.8 (150 to 180) cm</td>
</tr>
<tr>
<td>Duration of infertility *</td>
<td>28.8 (6-240) months</td>
</tr>
<tr>
<td>Nature of infertility *</td>
<td>64 (Primary) 59 (Secondary)</td>
</tr>
<tr>
<td>Previous surgery *</td>
<td>12</td>
</tr>
</tbody>
</table>

* Refers to female partner
Table 3.3 Reasons for cancelling investigations in the One Stop Fertility Clinic

<table>
<thead>
<tr>
<th>Hysteroscopy not done (n=13)</th>
<th>Culdoscopy not done (n=23)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Extreme anxiety (4)</td>
<td>Hysteroscopy not done or failed (16)</td>
</tr>
<tr>
<td>Ovarian cyst on ultrasound (3)</td>
<td>Anxiety (1)</td>
</tr>
<tr>
<td>Possible early pregnancy (2)</td>
<td>Large fibroid uterus (1)</td>
</tr>
<tr>
<td>Fixed retroverted uterus (1)</td>
<td>Acutely retroverted uterus (1)</td>
</tr>
<tr>
<td>Unable to tolerate vaginal exam. (1)</td>
<td>Small pelvis/vagina (1)</td>
</tr>
<tr>
<td>History of chlamydia PID (1)</td>
<td>Thickening in Pouch of Douglas (1)</td>
</tr>
<tr>
<td>Polycystic ovaries (1)</td>
<td>Ovarian cyst on scan (1)</td>
</tr>
<tr>
<td></td>
<td>Could not tolerate hydrotubation (1)</td>
</tr>
</tbody>
</table>
Table 3.4 Abnormal findings

<table>
<thead>
<tr>
<th>Ultrasound</th>
<th>Hysteroscopy</th>
<th>Culdoscopy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polycystic ovaries (13)</td>
<td>Fibroids (7)</td>
<td>Adhesions (19)</td>
</tr>
<tr>
<td>Fibroids (10)</td>
<td>Thickened endometrium (4)</td>
<td>Endometriosis (18)</td>
</tr>
<tr>
<td>Ovarian cyst (9)</td>
<td>Endocervical polyp (4)</td>
<td>Tubal block (17)</td>
</tr>
<tr>
<td>Thickened endometrium (3)</td>
<td>Endometrial polyp (3)</td>
<td>Fibroids (5)</td>
</tr>
<tr>
<td></td>
<td>Adhesions (2)</td>
<td>Hydrosalpinx (1)</td>
</tr>
<tr>
<td></td>
<td>Atrophic endometrium (1)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Uterine septum (1)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Arcuate cavity (1)</td>
<td></td>
</tr>
</tbody>
</table>

* More than one abnormal finding possible per patient
### Table 3.5 Patient anxiety, pain and acceptability scores

<table>
<thead>
<tr>
<th></th>
<th>Median (25% to 75% percentile)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>linear analogue score</td>
</tr>
<tr>
<td>Anxiety level before procedures</td>
<td>5 (3 to 5.75)</td>
</tr>
<tr>
<td>Discomfort during vaginal ultrasound</td>
<td>0 (0 to 0)</td>
</tr>
<tr>
<td>Acceptability of vaginal ultrasound</td>
<td>0 (0 to 0)</td>
</tr>
<tr>
<td>Discomfort during hysteroscopy</td>
<td>3 (2 to 5)</td>
</tr>
<tr>
<td>Acceptability of hysteroscopy</td>
<td>1 (0 to 3)</td>
</tr>
<tr>
<td>Discomfort during culdoscopy</td>
<td>5 (3.5 to 7)</td>
</tr>
<tr>
<td>Acceptability of culdoscopy</td>
<td>1.5 (0 to 4)</td>
</tr>
</tbody>
</table>

Patients assessed using a 10 cm linear analogue score (0=favourable)

\(^a\) Kruskall Walllis statistic 60.33, p<0.0001

\(^b\) Kruskall Walllis statistic 19.03, p<0.0001
Figure 3.1 Clinic protocol

GP refers infertile couple

Couples sent information pamphlet and questionnaire

Couple meet Clinic criteria and want outpatient investigation

Couple sent forms for blood tests and seminal analysis with appointment for Clinic

Couple seen in One Stop Fertility Clinic for consultation, ultrasound, hysteroscopy and culdoscopy

Findings explained and treatment plan made

Couple do not meet criteria or do not wish outpatient investigation

Couple sent appointment to general out-patient clinic
Figure 3.2 Culdoscopic view of right ovary showing functional cyst.
Figure 3.3 Culdoscopic view of fimbrial end of right fallopian tube.
Figure 3.4 Right ureter
Figure 3.5 Left fallopian tube
Figure 3.6 Loops of bowel in the pelvis
Figure 3.7 Overall outcome of the three investigations

- Ultrasound
  - Not done: 15
  - Failed: 0
  - Done: 108

- Hysteroscopy
  - Not done: 13
  - Failed: 4
  - Done: 116

- Culdoscopy
  - Not done: 23
  - Failed: 24
  - Done: 75
Figure 3.8 Management plan

- Assisted conception: 7
- Medical treatment: 11
- Reassurance: 16
- Surgery: 24
- Further tests: 29
- In-patient investigation: 36
Chapter 4

Comparison of findings at culdoscopy and laparoscopy under general anaesthesia
4.1 Introduction

To assess the diagnostic accuracy of culdoscopy, it has to be compared with standard investigation. At the time when we started this study at the year 2000, there was relatively little data available about the diagnostic accuracy of culdoscopy. Later on, several investigators have demonstrated the accuracy of culdoscopy in comparison to laparoscopy for the diagnosis of tubo-ovarian disease (Darai et al., 2000; Dechaud et al., 2001; Moore and Cohen, 2001; Shibahara et al., 2001; Brosens et al., 2001; Watrelot et al., 2003).

Brosens et al., 2001, have shown that culdoscopy is superior to standard laparoscopy for detection of subtle endometriotic adhesions of the ovary. Filmy, microvascularized, non-connecting adhesions are present in the majority of infertile women with minimal and mild endometriosis and in some patients with unexplained infertility.

Other workers have agreed with Brosens et al that culdoscopy is superior to laparoscopy for the visualization of filmy, connecting and nonconnecting adhesions (Campo et al., 1999; Jonsdottir and Lundorff, 2002). It is not yet clear whether these adhesions are of any significant regarding infertility as they are only visible during culdoscopy due to hydroflotation (Brosens I, 1996).
However, Darai et al, 2000 have studied and compared the findings between the two procedures in 60 patients, they found standard laparoscopy to be superior to culdoscopy in detecting pelvic pathology, as it was difficult to perform complete evaluation of all the pelvic organs, without manipulation of the adnexia in some of the cases, especially in patients with pelvic adhesions and this lead to misdiagnosis of endometriosis in these patients, but they found culdoscopy to be a highly accurate technique for the diagnosis of tubal pathology.

Nawroth et al, 2001 have agreed with Darai, that culdoscopy is an accurate method in comparison with laparoscopy for detection of adhesions and tubal pathology, but they reported a low detection rate of endometriosis by culdoscopy and that laparoscopy should be considered in order to exclude the possibility of unidentified endometriosis or to enable treatment should exist.

Dechaud et al, 2001, in their comparative study have found that laparoscopy has identified more lesions of peritoneal endometriosis, such as in the Pouch of Douglas between the uterosacral ligaments than culdoscopy and this is due to the limitation of the inspection to the posterior pelvis and the inability of culdoscopy to explore the area close to the entry in the Pouch of Douglas.

The aim of this study was to evaluate the accuracy and usefulness of culdoscopy in comparison to standard laparoscopy under general anaesthesia in the same patient and to demonstrate the concordance between the two procedures.
4.2 Patients and Methods

We planned to study 30 patients for this comparative study, with the expectation that 10 to 15 will have pelvic pathology. To allow for drop-outs, we recruited a total 35 patients from the OSFC and gynaecology outpatient clinic.

10 patients had culdoscopy under local anaesthesia in the OSFC where pelvic pathology was detected (endometriosis, adhesions or tubal occlusion) and therefore were booked for operative laparoscopy. The other 25 patients were recruited from the general Infertility Clinic for diagnostic laparoscopy and dye hydrotubation and who agreed to have culdoscopy at the same time of laparoscopy for the purpose of this study. All patients had full history taken and examination, all relevant blood tests, semen analysis and pelvic ultrasound scan.

Results were reviewed prior to procedures and informed consent obtained from all patients (Ethic Committee No. 118 – 2K).

The patients who had culdoscopy under local anaesthesia in the OSFC and were booked for operative laparoscopy, diagnostic laparoscopy was first performed and full inspection of the pelvis was made and recorded.

The patients who agreed to have culdoscopy at the time of laparoscopy had diagnostic laparoscopy first (operator A), at which time the abdominal and pelvic
structures and organs were inspected and evaluated, including hydrotubation. If Pouch of Douglas was shown to be safe to perform culdoscopy, then the pelvis was irrigated to clear any dye, and the abdomen was deflated. Hysteroscopy, culdoscopy and hydrotubation as done by a different surgeon who was not in the operating theatre during the laparoscopy (operator B). Both operators were experienced in gynaecological endoscopy (Senior Registrar grade or above); all culdoscopies were either done by AM or under his supervision. The operators were blind to each other’s findings, and both procedures were recorded on videotape for later comparison.

The primary end point was a comparison between the findings by laparoscopy and culdoscopy in terms of endometriosis, adhesions and tubal disease. Secondary end points included the rate of successful entry into the Pouch of Douglas at culdoscopy, and complications.

4.3 Results

The mean age of patients was 33.7 years (range 21 to 42 years). 21 (77.7%) complained of primary infertility. Most of the patients who were recruited from the general Infertility Clinic were those patients who were not suitable for the One Stop Fertility Clinic (OSFC) and had either history of pelvic disease and / or previous pelvic surgery.
Out of the 25 patients who were recruited from the Infertility Clinic, two patients became pregnant while on the waiting list. In a further three cases, culdoscopy was not attempted as laparoscopy showed adhesions in the Pouch of Douglas, and in a further three culdoscopy was attempted but entry into the peritoneal cavity was unsuccessful. Including the ten women from the OSFC, a total of 27 patients were therefore available for comparison.

The findings at laparoscopy in the 30 patients are summarized in Table 4.1. We found a normal pelvis in two (7.4%), endometriosis in 21 (70.0%), adhesions in 14 (46.6%), tubal blockage by hydrotubation in 6 (22.2%), ovarian cysts in 3 (11.1%) and uterine fibroids in 7 (25.9%). The median AFS score for women with endometriosis was 3.5 (range 1 to 30). Three of the tubal blockages were bilateral distal blocks, including two women with bilateral hydrosalpinges. The remaining tubal blocks were unilateral (right side 2, left side 1), distal in 2 cases and proximal in 1; in all these cases, the fallopian tubes looked normal externally and there were no adhesions. The myomas were sited solely anteriorly in two patients.

The results for culdoscopy in the 27 patients where peritoneal entry was successful are summarized in Table 4.2. The pelvic view was judged to be good in all but one case (96.2%); in one patient the endoscope used for culdoscopy proved to be faulty. The mean duration of culdoscopy plus hysteroscopy and dye hydrotubation was 24.6 minutes (SD 11.2). Culdoscopy showed normal pelvis in three patients (11.1%), endometriosis in 16 (22.2%), adhesions in 17 (62.9%), tubal blockage in 6 (22.2%),
fibroids in 5 (18.5%), and ovarian cyst in 1 patient (3.7%). The entire pelvis could not be visualized in 6 women (22.2%) because of the presence of adhesions or an ovarian cyst (Table 4.3). All three patients who could not have culdoscopy had pelvic pathology (Table 4.1).

There were no complications either immediately or after long-term of the procedures in this series.

4.3.1 Comparison of laparoscopy and culdoscopy: Overall results (Table 4.4)

Culdoscopy showed normal findings in three patients out of the 27, while laparoscopy showed normal pelvis in two. The patient misdiagnosed by culdoscopy had an endometriotic spot on the ovary and the uterovesical fold, with an AFS score of 3. Abnormal pelvic findings were diagnosed by culdoscopy in 24 patients out of the 25 patients who had pelvic abnormalities by laparoscopy. If culdoscopy did not detect any abnormalities, this was also confirmed by laparoscopy.

4.3.2 Comparison of laparoscopy and culdoscopy: Endometriosis (overall)
(Table 4.5)

Culdoscopy has shown endometriosis in 16 (59%) patients, while standard laparoscopy diagnosed endometriosis in 20 (74%) patients. Three of the four cases where culdoscopy missed endometriosis had side wall pelvic adhesions; the
endometriosis was located pelvic side walls, on the ovarian surface and in the Pouch of Douglas (1 case), and on the pelvic side walls (2 cases). In the remaining case, culdoscopy was normal but laparoscopy revealed a single spot of endometriosis on the ovarian surface as well as the utero-vesical fold (AFS 3).

Although it is not possible to compare laparoscopy and culdoscopy for the detection of endometriosis situated in the uterovesical fold, of the five patients who were found to have the condition at this site by laparoscopy, all had deposits elsewhere in the pelvis which were amenable to culdoscopic diagnosis.

4.3.3 Comparison of laparoscopy and culdoscopy: Ovarian endometriosis
(Table 4.6)

Ovarian endometriosis was diagnosed in 13 patients by laparoscopy and 9 by culdoscopy. In one case, culdoscopy visualized endometriosis on the right ovary which was not seen at laparoscopy as it was obscured by adhesions. As previously discussed, three of the four women in whom endometriosis was not seen by culdoscopy had pelvic adhesions.

4.3.4 Comparison of laparoscopy and culdoscopy: Pelvic side wall endometriosis (Table 4.7)
Culdoscopy diagnosed pelvic side wall endometriosis in 10 patients which were all confirmed by laparoscopy. Laparoscopy detected pelvic side walls endometriosis in four more patients; all these patients had pelvic adhesions which obscured the view at culdoscopy.

4.3.5 Comparison of laparoscopy and culdoscopy: Cul-de-sac endometriosis (Table 4.8)

Culdoscopy diagnosed endometriosis in the cul-de-sac of six of the 27 patients. Laparoscopy confirmed endometriosis of the cul-de sac in a further six cases. As in the case of side wall endometriosis, pelvic adhesions limited the view of the Pouch of Douglas and utero-sacral ligaments at culdoscopy in three cases.

4.3.6 Comparison of laparoscopy and culdoscopy: Adhesions (overall) (Table 4.9)

Culdoscopy has diagnosed adhesions in 17 patients out of the 27 patients while laparoscopy diagnosed adhesions in 12 patients. The 6 women in whom adhesions were not seen at laparoscopy all had filmy adhesions between the ovaries and lateral pelvic side walls; all these cases also had endometriosis detected by both laparoscopy and culdoscopy. In one case, laparoscopy identified pelvic side wall adhesions but these were not seen at culdoscopy; this patient also had endometriosis affecting the ovaries and pelvic side wall.
4.3.7 Comparison of laparoscopy and culdoscopy: Tubal adhesions (Table 4.10)

There was total agreement between laparoscopy and culdoscopy with regard to adhesions affecting the fallopian tubes. There was free fill and spill of dye from both tubes at hydrotubation done during laparoscopy, but bilateral tubal patency could not be confirmed at culdoscopy as one case, one of the affected tubes was completely obscured by adhesions.

4.3.8 Comparison of laparoscopy and culdoscopy: Ovarian adhesions (Table 4.11)

Culdoscopy diagnosed ovarian adhesions in 9 patients, in all cases the adhesions being between the ovary and the lateral pelvic side wall. As discussed in 4.3.6, 6 of these adhesions were not seen at laparoscopy. Conversely, one patient with endometriosis also had ovarian adhesions which were missed at culdoscopy. None of the patients had adhesion between the ovaries and the fallopian tubes or bowel.

4.3.9 Comparison of laparoscopy and culdoscopy: Pelvic side wall adhesions (Table 4.12)

All adhesions involving the pelvic side were to the ovaries and none were to bowel. The analysis therefore is the same as for 4.3.8.
4.3.10 Comparison of laparoscopy and culdoscopy: Tubal blockage (Tables 4.13A and 14.3B)

Four patients have been excluded from the comparison as both fallopian tubes could not be seen at culdoscopy because of adhesions or the presence of an ovarian cyst; laparoscopy revealed bilateral block in one case and bilateral patent tubes in the other three.

In case of the remaining 23 women in whom a comparison could be made, two patients with apparently bilateral blocked fallopian tubes at laparoscopy had unilateral patency at culdoscopy. Conversely, three women appeared to have blocked fallopian tubes at culdoscopy which were found to be patent at laparoscopy.

4.3.12 Comparison of laparoscopy and culdoscopy: Uterine fibroids (Table 4.14)

Culdoscopy diagnosed subserosal uterine fibroids in five patients out of the 27 patients and these fibroids were situated in the posterior wall of the uterus. Laparoscopy confirmed this and also showed fibroids in two other patients but these were situated in the anterior wall of the uterus.

There is a summary of the diagnostic indeces comparing laparoscopy with culdoscopy in Table 4.15.
4.4 Discussion

This study shows both the strengths and weakness of culdoscopy in the assessment of subfertile women. In all cases, if culdoscopy showed a pathology, laparoscopy was also abnormal. Overall, our comparative data with laparoscopy as the "gold standard" show that culdoscopy has a sensitivity of 96% (24/25 patients) in detecting pelvic abnormalities, with a specificity of 100% and positive predictive value of 100%. Culdoscopy is particularly efficient at detecting tubal and ovarian adhesions, and indeed culdoscopy picked up several patients with fine, filmy adhesions which were not apparent at laparoscopy. However, culdoscopy had a negative predictive value was 67% although this was based on a single patient with a spot of endometriosis on the ovary which was not seen by culdoscopy. Laparoscopy was, in our experience, superior to culdoscopy in diagnosing endometriosis; several patients had adhesions which were seen at culdoscopy but which obscured areas of endometriosis. We also had a 10% failure rate of culdoscopic entry, despite prior laparoscopy, but this we feel was related to poor technique rather than a limitation of the procedure.

The majority of patients in this study had pelvic pathology (92.5%) as the patients in this group were recruited from a high risk population. They were recruited from the general infertility clinic as they were not suitable for the OSFC. Therefore, these patients had either a past history of pelvic disease or/and previous pelvic surgery. In addition, 10 women already had undergone culdoscopy in the OSFC and were found
to have pelvic pathology; operative laparoscopy was arranged subsequently, but we were also able to obtain comparative data from them for this study.

4.4.1 Comparison with other studies

Several studies have demonstrated the accuracy of culdoscopy in comparison to laparoscopy for the diagnosis of pelvic pathology (Campo et al., 1999; Watrelot et al., 1999; Bajzak et al., 2000; Darai et al., 2000; Dechaud et al., 2001; Moore and Cohen, 2001; Nawroth et al., 2001).

Campo et al, in ten infertile women without obvious pelvic pathology, culdoscopy was performed before laparoscopy. Two gynaecologists performed culdoscopy and laparoscopy separately, and reported their findings to a third person. Interobserver agreement for tuboovarian adhesions was 95% for culdoscopy and 74% for standard laparoscopy. An unexpected finding was the detection of nonconnecting adhesions under fluid at culdoscopy but not with CO2 pneumoperitoneum at laparoscopy. In our study, culdoscopy also diagnosed these nonconnecting adhesions which could not be detected by laparoscopy, and are due to inspection of the tuboovarian structures under fluid.

Darai et al, have compared pelvic findings at laparoscopy and culdoscopy in 60 women with unexplained infertility. Different surgeons performed laparoscopy after culdoscopy. Failed entry occurred in 10% of patients. Eleven women at laparoscopy
showed to have endometriosis while only six women were diagnosed to have endometriosis by culdoscopy. In four of five women who were misdiagnosed by culdoscopy, pelvic adhesions have prevented a thorough visualization of the pelvic anatomy. Culdoscopy showed normal pelvis in thirty women, whereas only 24 had a normal pelvis by laparoscopy. Comparing their results regarding endometriosis with our study we found that in our study culdoscopy misdiagnosed endometriosis in four women, three of these patients had pelvic adhesions. Therefore, both our study and their study agree in that, culdoscopy misdiagnosed endometriosis mainly due to the presence of adhesions which obscured the view. We wonder if culdoscopic adhesiolysis of these adhesions would overcome this problem, and in addition of the possibility in improving assessment it would be helpful as a therapy.

4.4.2 Endometriosis

The overall sensitivity of culdoscopy for detection of pelvic endometriosis was 80%(16/20), specificity was 100%, positive predictive value was 100% but the negative predictive value (NPV) was only 63%. The low NPV with respect to endometriosis was due to the fact that culdoscopy did not diagnose endometriosis in four cases; in three of these cases there were pelvic adhesions which obscured the vision and so we were not able to visualize the endometriosis which were mainly situated on the cul-de-sac, pelvic side walls and on the ovarian surfaces (AFS 2-12). In a further patient, the endometriosis were mainly situated in the uterovesical fold with an isolated endometriotic spot on the ovarian surface (AFS 3) which was
missed by culdoscopy. Although culdoscopy had a problem of visualizing all deposits of endometriosis, particularly if involving the posterior cul-de-sac, because the condition tends to be multi-focal, the overall specificity was still good (100%).

Certainly, we would not expect to visualize endometriosis affecting the uterovesical fold, but it is relatively uncommon for the disease to be solely localized over the bladder with no deposits elsewhere in the pelvis. For instance, Darai et al., 2000 reported the presence of endometrial implants exclusively in the uterovesical folds in only in 4% of cases. This finding is usually associated with a severely anteflexed uterus (Jenkins et al., 1986).

Culdoscopy also has limitations when it comes to inspecting the cul-de-sac, particularly close to the point of entry of the optic. It could be that a better visualization of the cul-de-sac could be obtained with a 70 degree or flexible optic, but we have no personal experience of either. One group has published their experience with the use of a flexible optic and reported good correlation with laparoscopy, but they positioned the patient in the knee-chest position for the vaginal inspection (Paulson et al., 1999).

Whether in practical terms missing a diagnosis of minimal or mild endometriosis is important in the management of the infertile couple is currently in debate. The three patients who had adhesions obscuring the endometriosis were offered laparoscopy surgery anyway. The fourth patient with uterovesical and ovarian endometriosis but
otherwise a normal pelvis would not have been brought back for surgical management, and she is the only one who might have received suboptimal treatment for her infertility if one believes that laparoscopic ablation of minimal endometriosis improves outcome. This, however, is uncertain at least with our current knowledge (see Chapter 1).

4.4.3 Pelvic adhesions

In this study, culdoscopy was found to be superior to standard laparoscopy in detecting fine, filmy pelvic adhesions in all but one patient. Culdoscopy identified adhesions in 17 patients, while laparoscopy diagnosed pelvic adhesions only in 12 patients. Typically, the adhesions which were missed at laparoscopy were either non-connecting arising from the ovary or connecting between the ovary and the pelvic side wall. Hydroflotation which is used at culdoscopy facilitates visualization of these filmy adhesions. In contrast, manipulation of the adnexa required to expose the full ovarian surface can break these adhesions before they can be identified (Brosens et al., 1998). In addition, the pressure exerted by CO₂ used for insufflation at laparoscopy has the effect of compressing these adhesions.

It is of interest to note that not only is culdoscopy superior to laparoscopy in diagnosing pelvic adhesions, culdoscopy is also more reliable; a comparative study by Campo et al., (1999), showed a 75% interobserver agreement for detection of ovarian adhesions with standard laparoscopy versus 90% with culdoscopy.
It is not clear yet whether these ovarian adhesions are significant to infertility or not. Brosens et al. (2001), in their comparison study to determine whether culdoscopy is superior to laparoscopy for detection of endometriotic adhesions of the ovaries found that patients with minimal and mild endometriosis and unexplained infertility had significantly more ovarian adhesions which were filmy, microvascularized, and nonconnecting. These were seen by culdoscopy but often missed at laparoscopy. Their interpretation was that these adhesions probably reflected early endometriotic disease of the ovary, and may interfere with ovum capture by the fimbriae. Identification of these adhesions in infertile patients by culdoscopy, and atraumatic surgical removal of these adhesions (operative culdoscop) is technically feasible and may be a suitable alternative to laparoscopy in selected patients (Moore and Cohen, 2001).

Culdoscopy was also very good at detecting tubal adhesions compared with laparoscopy, hence the sensitivity, specificity, positive predictive value and negative predictive value were all 100%.

4.4.4 Tubal patency

In contrast to the detection of adhesions, culdoscopy was poor at testing tubal patency with a considerable number of false positive results (0.50). It is difficult to explain this discrepancy,
We are not sure for the reason for this, but we hypothesize that the lack of filling of fallopian tubes may be related to tubal spasm, perhaps secondary to uterine manipulation.

Certainly, this kind of blockage is frequently caused by pain and subsequent contraction of the uterine musculature, and also occurs with hysterosalpingography (HSG). Bacevac and Ganovic, (2001), studied 140 infertile women to evaluate the reliability of HSG in the diagnosis of Fallopian tube and to compare the results with laparoscopic findings, they found that there were 17.1% of false positive findings and they related this to a possibility of tubal spasm and endometrial polyp in the area of the uterine opening of the tubes. In another multicentered trial, sponsored by World Health Organization, (1986) comparing the efficacy of gaseous tubal insufflation with HSG and/or laparoscopy plus dye hydrotubation in the assessment of tubal patency. 393 women from eight centers were involved (365 insufflation, 289 HSG, 189 laparoscopy). Comparison of insufflation and HSG showed a false-positive rate of 42% and false negative rate of 24% in 363 cases. The false positive rate of insufflation versus laparoscopy was 35% and the false negative rate 38% of 180 cases. Only 55% of 125 women undergoing both HSG and laparoscopy had similar findings.

Both the above studies showed a high rate of false positive rate of HSG in comparison to laparoscopy. The possible causes for this differential diagnosis of tubal blockage between HSG and laparoscopy may be due to unequal anaesthesia
during the two procedures. The same reason may apply to our study as ten patients had culdoscopy under local anaesthesia.

The diagnostic value of HSG for assessing tubal patency has been criticized. Swart et al, (1995), in a meta-analysis to investigate the accuracy of HSG in comparison to laparoscopy and dye, found that HSG had a low sensitivity (0.65) and specificity of (0.83) for tubal patency compared with laparoscopy. They concluded that HSG is only reliable when it shows total blockage. If HSG showed tubal patency, it was not reliable and laparoscopy and dye should be performed for confirmation.

However, laparoscopy and dye test will not determine whether the tubal blockage is due to true anatomic occlusion or due to tubal spasm (Mol et al., 1999)

In a study to compare HSG and laparoscopy in predicting fertility outcome, Mol et al, (1999) found that findings at laparoscopy had a stronger impact on spontaneous fertility course than HSG results. After a completely normal HSG or a one-sided occlusion with HSG, a one-sided occluded laparoscopy affected fertility prospects slightly, whereas no spontaneous pregnancies occurred after bilateral tubal blockage detected at laparoscopy. After a HSG with bilateral tubal occlusion fertility prospects were only slightly decreased in cases where laparoscopy showed patent tubes. However, in cases where laparoscopy showed one sided or two sided tubal blockage in these patients, fertility prospects were strongly decreased. The results of
this study indicate that laparoscopy is a better predictor for infertility than HSG, but it should not be considered as a perfect test in the diagnosis of tubal pathology.

Darai et al, (2000), in their study to assess the accuracy of culdoscopy in comparison to laparoscopy in 54 infertile women with complete pelvic examination, regarding tubal patency, all cases of proximal tubal obstructions, tubal phimosis and five out of six cases with hydrosalpinx were diagnosed correctly by culdoscopy. Only in one case hydrosalpinx was missed by culdoscopy in which severe adhesions were noted and prevented complete evaluation. Culdoscopy in this study had a sensitivity of 92.3% and specificity of 100%.

Nawroth et al, (2001), in a prospective comparison study of conventional laparoscopy and dye and culdoscopy in 43 infertile women without previous pelvic operations, there was a high level of agreement between laparoscopy and culdoscopy regarding tubal adhesions as 90% (72/80) of the tubes could be visible, only one tube showed to be blocked and 71/72 were patent at culdoscopy in comparison to 79/80 which showed to be patent at laparoscopy.

However, Dechaud et al, (2001), in their comparison study in 23 infertile patients with unexplained infertility, have found that the comparison between the two methods is excellent for the distal part of Fallopian tubes but culdoscopy was not good at identifying proximal blockage.
Other investigators have not had the same experience. For instance, in a comparative study between culdoscopy and HSG to evaluate tubal patency, it was found that there was a strong agreement (in 95% of cases) between culdoscopy and HSG findings regarding tubal patency (Cicinelli et al., 2001).

Shibahara et al, (2001), in their study to investigate the usefulness of culdoscopy to evaluate Chlamydia trachomatis tubal infertility compared HSG versus culdoscopy in a group of patients with and without a history of Chlamydia trachomatis infection. They found that there was no significant difference in the discrepancy rate of the diagnosis of tubal patency between HSG and culdoscopy, but the latter was more efficient in diagnosing peritubal adhesions. Our study agrees with this study in that culdoscopy is an efficient method in investigating distal tubal disease.

4.4.5 Fibroids

Not surprisingly, culdoscopy missed fibroids which were anterior as it is not possible to visualize this area from a posterior approach. Although this is a limitation of culdoscopy, in reality prior pelvic ultrasound would detect such lesions and provide the required information. Certainly the value of culdoscopy is not primarily to detect fibroids.

4.4.6 Other pathologies
Similarly, the main role of culdoscopy is not the detection of ovarian cysts which are far better seen with pelvic ultrasound. As in our study, the presence of pelvic adhesions can make examination of the whole ovarian surface difficult or even impossible.

Ovarian cysts were not seen by culdoscopy in two cases, both in patients with pelvic adhesions. In the other patient culdoscopy showed pelvic adhesions and normal ovaries, while laparoscopy diagnosed endometriosis and right ovarian cyst. In this patient the comparison was made at different time, culdoscopy was performed in the OSFC and eleven months later, laparoscopy was followed, therefore, she may have developed the cyst after culdoscoptic examination.

In one patient, a chronic ectopic pregnancy of the right tube was missed by culdoscopy although culdoscopy has diagnosed a right ovarian cyst in this patient. This patient had endometriosis and adhesions of the pelvic side wall bilaterally which were diagnosed by both culdoscopy and laparoscopy.

4.4.6 Failure of culdoscoptic entry

Culdoscopic entry failed in three patients (10%) despite a prior laparoscopy. We put this down to a relative lack of experience and confidence with the technique. We were using the Veress approach to entry which we subsequently abandoned in favour of the use of an optical cannula (Scott and Magos, 2002). We do not feel that
was of relevance that all three cases were found to have pelvic pathology at the laparoscopy (two cases adhesions and one case had endometriosis).

### 4.4.7 Complete visualization of the posterior pelvis

Complete visualization of the pelvis was not possible in 4 cases by culdoscopy. In three cases, this was due to the presence of pelvic adhesions involving the adnexae, and in one case due to the presence of a large ovarian cyst which was diagnosed earlier by ultrasound scan. At present, it is not possible to manipulate the pelvic organs at culdoscopy unless an operating system is introduced; this, however, increases the diameter of the cannula and is not standard practice. Any instrument used in such a fashion would be less efficient than at laparoscopy as the point of entry would be very close to the optic. Culdoscopy, therefore, tells the physician that the pelvis is normal or abnormal, but is not as good as laparoscopy at delineating all the abnormalities.

### 4.5 Conclusion

This study showed that culdoscopy is generally not as good as laparoscopy in detecting all diseases of the pelvis, but is good at identifying patients who have pathology, therefore it is a useful screening tool. It can be used as a first line procedure in the early stages of infertility investigations and may be used as an
alternative to HSG and laparoscopy in selected patients. Laparoscopy should be indicated in cases of abnormal findings or incomplete evaluation by culdoscopy.

Although we planned to record complications during either of the procedures, there were none in this study. We appreciate that the study groups were small, and that entry complications were less likely with culdoscopy in this setting because of the prior laparoscopic check of the Pouch of Douglas.
Table 4.1 Findings at laparoscopy

<table>
<thead>
<tr>
<th>Condition</th>
<th>Culdoscopy successful n=27</th>
<th>Culdoscopy failed n=3</th>
<th>Total n=30</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>2</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Abnormal: *</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Endometriosis</td>
<td>20</td>
<td>1</td>
<td>21</td>
</tr>
<tr>
<td>Adhesions</td>
<td>12</td>
<td>2</td>
<td>14</td>
</tr>
<tr>
<td>Fibroids</td>
<td>7</td>
<td>0</td>
<td>7</td>
</tr>
<tr>
<td>Tubal disease (incl. tubal blockage)</td>
<td>6</td>
<td>0</td>
<td>6</td>
</tr>
<tr>
<td>Ovarian cysts</td>
<td>3</td>
<td>0</td>
<td>3</td>
</tr>
<tr>
<td>Chronic ectopic pregnancy</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
</tbody>
</table>

* Some patients had more than one abnormality
Table 4.2 Findings at culdoscopy

<table>
<thead>
<tr>
<th>Abnormality</th>
<th>Culdoscopy successful</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>3</td>
</tr>
<tr>
<td>Abnormal: *</td>
<td></td>
</tr>
<tr>
<td>Endometriosis</td>
<td>16</td>
</tr>
<tr>
<td>Adhesions</td>
<td>17</td>
</tr>
<tr>
<td>Fibroids</td>
<td>5</td>
</tr>
<tr>
<td>Tubal disease (incl. tubal blockage)</td>
<td>6</td>
</tr>
<tr>
<td>Ovarian cysts</td>
<td>1</td>
</tr>
<tr>
<td>Chronic ectopic pregnancy</td>
<td>0</td>
</tr>
</tbody>
</table>

* Some patients had more than one abnormality
Table 4.3 Complete visualisation of the pelvis by culdoscopy in 27 patients

<table>
<thead>
<tr>
<th></th>
<th>Left side</th>
<th>Right side</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uterus</td>
<td></td>
<td>27 (100%)</td>
</tr>
<tr>
<td>Ovary</td>
<td>26 (96.2%)</td>
<td>25 (92.5%)</td>
</tr>
<tr>
<td>Fallopian tube</td>
<td>25 (92.5%)</td>
<td>24 (88.8%)</td>
</tr>
<tr>
<td>Pelvic side wall</td>
<td>25 (92.5%)</td>
<td>24 (88.8%)</td>
</tr>
<tr>
<td>Pouch of Douglas</td>
<td></td>
<td>24 (88.8%)</td>
</tr>
<tr>
<td>Utero-sacral ligaments</td>
<td>25 (92.5%)</td>
<td>25 (92.5%)</td>
</tr>
</tbody>
</table>
**Table 4.4** Comparison of laparoscopy and culdoscopy: Overall results

<table>
<thead>
<tr>
<th>Culdoscopy</th>
<th>Normal</th>
<th>Abnormal</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>2</td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Abnormal</td>
<td>0</td>
<td>24</td>
<td>24</td>
</tr>
<tr>
<td>Total</td>
<td>2</td>
<td>25</td>
<td>27</td>
</tr>
</tbody>
</table>

Culdoscopy showed normal findings in three patients out of the 27, while laparoscopy showed normal pelvis in two patients only. The patient misdiagnosed by culdoscopy had an endometriotic spot on the ovary (as well as on the uterovesical fold (AFS 3). Abnormal pelvic findings were diagnosed by culdoscopy in 24 patients out of the 25 patients who had pelvic abnormalities by laparoscopy. If culdoscopy did not detect any abnormalities, this was also confirmed by laparoscopy.

- Sensitivity: 0.96
- Specificity: 1.00
- Positive predictive value: 1.00
- Negative predictive value: 0.67
- False negative: 0.33
- False positive: 0.00
### Table 4.5 Comparison of laparoscopy and culdoscopy: Endometriosis (overall)

<table>
<thead>
<tr>
<th>Culdoscopy</th>
<th>No endometriosis</th>
<th>Endometriosis</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>No endometriosis</td>
<td>7</td>
<td>4</td>
<td>11</td>
</tr>
<tr>
<td>Endometriosis</td>
<td>0</td>
<td>16</td>
<td>16</td>
</tr>
<tr>
<td>Total</td>
<td>7</td>
<td>20</td>
<td>27</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Metric</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity</td>
<td>0.80</td>
</tr>
<tr>
<td>Specificity</td>
<td>1.00</td>
</tr>
<tr>
<td>Positive predictive value</td>
<td>1.00</td>
</tr>
<tr>
<td>Negative predictive value</td>
<td>0.63</td>
</tr>
<tr>
<td>False negative</td>
<td>0.37</td>
</tr>
<tr>
<td>False positive</td>
<td>0.00</td>
</tr>
</tbody>
</table>
Table 4.6 Comparison of laparoscopy and culdoscopy: Ovarian endometriosis

<table>
<thead>
<tr>
<th>Culdoscopy</th>
<th>No endometriosis</th>
<th>Endometriosis</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laparoscopy</td>
<td>No endometriosis</td>
<td>13</td>
<td>4</td>
</tr>
<tr>
<td>Endometriosis</td>
<td>1 (0) *</td>
<td>9 (10) *</td>
<td>10</td>
</tr>
<tr>
<td>Total</td>
<td>14 (13)*</td>
<td>13 (14)*</td>
<td>27</td>
</tr>
</tbody>
</table>

Sensitivity 0.69 (0.71*)
Specificity 0.92 (1.00*)
Positive predictive value 0.90 (1.00*)
Negative predictive value 0.76 (0.76*)
False negative 0.24 (0.24*)
False positive 0.00 (0.10*)

*The diagnostic indices have been recalculated to take account of the fact that laparoscopy, which we are using as the gold standard for assessing the pelvis missed one case of ovarian endometriosis. The recalculated data gives the diagnostic indices for culdoscopy in terms of the presence or absence of the disease (i.e. ovarian endometriosis) rather than a comparison with laparoscopy.
Table 4.7 Comparison of laparoscopy and culdoscopy: Pelvic side wall endometriosis

<table>
<thead>
<tr>
<th>Culdoscopy</th>
<th>No endometriosis</th>
<th>Endometriosis</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>No endometriosis</td>
<td>13</td>
<td>4</td>
<td>17</td>
</tr>
<tr>
<td>Endometriosis</td>
<td>0</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Total</td>
<td>13</td>
<td>14</td>
<td>27</td>
</tr>
</tbody>
</table>

Sensitivity 0.71
Specificity 1.00
Positive predictive 1.00
Negative predictive value 0.76
False negative 0.24
False positive 0.00
Table 4.8 Comparison of laparoscopy and culdoscopy: Cul-de-sac endometriosis

<table>
<thead>
<tr>
<th>Culdoscopy</th>
<th>No endometriosis</th>
<th>Endometriosis</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>No endometriosis</td>
<td>15</td>
<td>6</td>
<td>21</td>
</tr>
<tr>
<td>Endometriosis</td>
<td>0</td>
<td>6</td>
<td>6</td>
</tr>
<tr>
<td>Total</td>
<td>15</td>
<td>12</td>
<td>27</td>
</tr>
</tbody>
</table>

- Sensitivity: 0.50
- Specificity: 1.00
- Predictive positive value: 1.00
- Predictive negative value: 0.71
- False negative: 0.29
- False positive: 0.00
### Table 4.9 Comparison of laparoscopy and culdoscopy: Adhesions (overall)

<table>
<thead>
<tr>
<th>Culdoscopy</th>
<th>No adhesions</th>
<th>Adhesions</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>No adhesions</td>
<td>9</td>
<td>1</td>
<td>10</td>
</tr>
<tr>
<td>Adhesions</td>
<td>6 (0*), 11 (17*)</td>
<td>17</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>15 (9*), 12 (18*)</td>
<td>27</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>Positive predictive value</th>
<th>Negative predictive value</th>
<th>False negative</th>
<th>False positive</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0.91 (0.94*)</td>
<td>0.60 (1.00*)</td>
<td>0.64 (1.00*)</td>
<td>0.90 (0.90*)</td>
<td>0.10 (0.10*)</td>
<td>0.36 (0.00*)</td>
</tr>
</tbody>
</table>

* The diagnostic indices have been recalculated to take account of the fact that laparoscopy, which we are using as the gold standard for assessing the pelvis, missed 6 patients with adhesions. The recalculated data gives the diagnostic indices for culdoscopy in terms of the presence or absence of the disease (i.e. adhesions) rather than a comparison with laparoscopy.
Table 4.10 Comparison of laparoscopy and culdoscopy: Tubal adhesions

<table>
<thead>
<tr>
<th>Culdoscopy</th>
<th>Laparoscopy</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No adhesions</td>
</tr>
<tr>
<td>No adhesions</td>
<td>25</td>
</tr>
<tr>
<td>Adhesions</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>25</td>
</tr>
</tbody>
</table>

Sensitivity 1.00  
Specificity 1.00  
Positive predictive value 1.00  
Negative predictive value 1.00  
False negative 0.00  
False positive 0.00
Table 4.11 Comparison of laparoscopy and culdoscopy: Ovarian adhesions

<table>
<thead>
<tr>
<th>Culdoscopy</th>
<th>No adhesions</th>
<th>Adhesions</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>No adhesions</td>
<td>17</td>
<td>1</td>
<td>18</td>
</tr>
<tr>
<td>Adhesions</td>
<td>6 (0*)</td>
<td>3 (9*)</td>
<td>9</td>
</tr>
<tr>
<td>Total</td>
<td>23 (17*)</td>
<td>4 (10*)</td>
<td>27</td>
</tr>
</tbody>
</table>

Sensitivity 0.75 (0.90*)
Specificity 0.73 (1.00*)
Positive predictive 0.33 (1.00*)
Negative predictive value 0.94 (0.94*)
False negative 0.06 (0.06*)
False positive 0.67 (0.00*)

* The diagnostic indices have been recalculated to take account of the fact that laparoscopy, which we are using as the gold standard for assessing the pelvis missed 6 cases of ovarian adhesions. The recalculated data gives the diagnostic indices for culdoscopy in terms of the presence or absence of the disease (i.e. ovarian adhesions) rather than a comparison with laparoscopy.
Table 4.12 Comparison of laparoscopy and culdoscopy: Pelvic side wall adhesions

<table>
<thead>
<tr>
<th>Culdoscopy</th>
<th>No Adhesions</th>
<th>Adhesions</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>No adhesions</td>
<td>11</td>
<td>1</td>
<td>12</td>
</tr>
<tr>
<td>Adhesions</td>
<td>6 (0*)</td>
<td>9 (15*)</td>
<td>15</td>
</tr>
<tr>
<td>Total</td>
<td>17(11*)</td>
<td>10 (16*)</td>
<td>27</td>
</tr>
</tbody>
</table>

<p>| | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity</td>
<td>0.90 (0.93*)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Specificity</td>
<td>0.64 (1.00*)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Positive predictive value</td>
<td>0.60 (1.00*)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Negative predictive value</td>
<td>0.91 (0.91*)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>False negative</td>
<td>0.09 (0.09*)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>False positive</td>
<td>0.40 (0.00*)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* The diagnostic indices have been recalculated to take account of the fact that laparoscopy, which we are using as the gold standard for assessing the pelvis, missed 6 cases of pelvic side wall adhesions. The recalculated data gives the diagnostic indices for culdoscopy in terms of the presence or absence of the disease (i.e. pelvic side wall adhesions) rather than a comparison with laparoscopy.
Table 4.13A Comparison of laparoscopy and culdoscopy: Tubal blockage

<table>
<thead>
<tr>
<th>Culdoscopy</th>
<th>No blockage</th>
<th>Blockage</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>No blockage</td>
<td>15</td>
<td>2</td>
<td>17</td>
</tr>
<tr>
<td>Blockage</td>
<td>3</td>
<td>3</td>
<td>6</td>
</tr>
<tr>
<td>Total</td>
<td>18</td>
<td>5</td>
<td>23†</td>
</tr>
</tbody>
</table>

Sensitivity 0.60
Specificity 0.83
Positive predictive value 0.50
Negative predictive value 0.88
False negative 0.12
False positive 0.50

† In 4 patients the fallopian tubes could not be visualized at culdoscopy,
Table 4.13B Comparison of laparoscopy and culdoscopy: Tubal blockage (more detailed analysis)

<table>
<thead>
<tr>
<th>Culdoscopy</th>
<th>Laparoscopy</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Bilateral patency</td>
</tr>
<tr>
<td>Bilateral patency</td>
<td>15</td>
</tr>
<tr>
<td>Unilateral block</td>
<td>2</td>
</tr>
<tr>
<td>Bilateral block</td>
<td>1</td>
</tr>
<tr>
<td>Not seen</td>
<td>3</td>
</tr>
<tr>
<td>Total</td>
<td>21</td>
</tr>
</tbody>
</table>
Table 4.14 Comparison of laparoscopy and culdoscopy: Uterine fibroids

<table>
<thead>
<tr>
<th>Culdoscopy</th>
<th>No fibroids</th>
<th>Fibroids</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>No fibroids</td>
<td>20</td>
<td>2</td>
<td>22</td>
</tr>
<tr>
<td>Fibroids</td>
<td>0</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Total</td>
<td>20</td>
<td>7</td>
<td>27</td>
</tr>
</tbody>
</table>

Sensitivity 0.71  
Specificity 1.00  
Positive predictive value 1.00  
Negative predictive value 0.90  
False negative 0.10  
False positive 0.00
Table 4.15 Summary of diagnostic indices comparing laparoscopy and culdoscopy

<table>
<thead>
<tr>
<th></th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>PPV</th>
<th>NPV</th>
<th>False negative</th>
<th>False positive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall pelvic pathology</td>
<td>0.96</td>
<td>1.00</td>
<td>1.00</td>
<td>0.67</td>
<td>0.33</td>
<td>0.00</td>
</tr>
<tr>
<td>Overall endometriosis</td>
<td>0.80</td>
<td>1.00</td>
<td>1.00</td>
<td>0.63</td>
<td>0.37</td>
<td>0.00</td>
</tr>
<tr>
<td>Ovarian endometriosis</td>
<td>0.69 (0.71*)</td>
<td>0.92 (1.00*)</td>
<td>0.90</td>
<td>0.76</td>
<td>0.24 (0.24*)</td>
<td>0.00 (0.10*)</td>
</tr>
<tr>
<td>Side wall endometriosis</td>
<td>0.71</td>
<td>1.00</td>
<td>1.00</td>
<td>0.76</td>
<td>0.24</td>
<td>0.00</td>
</tr>
<tr>
<td>Cul-de-sac endometriosis</td>
<td>0.50</td>
<td>1.00</td>
<td>1.00</td>
<td>0.71</td>
<td>0.29</td>
<td>0.00</td>
</tr>
<tr>
<td>Overall adhesions</td>
<td>0.91 (0.94*)</td>
<td>0.60 (1.00*)</td>
<td>0.64</td>
<td>0.90</td>
<td>0.10 (0.10*)</td>
<td>0.36 (0.00*)</td>
</tr>
<tr>
<td>Tubal adhesions</td>
<td>1.00</td>
<td>1.00</td>
<td>1.00</td>
<td>1.00</td>
<td>0.00</td>
<td>0.00</td>
</tr>
<tr>
<td>Ovarian adhesions</td>
<td>0.75 (0.90*)</td>
<td>0.73 (1.00*)</td>
<td>0.33</td>
<td>0.94</td>
<td>0.06 (0.06*)</td>
<td>0.67 (0.00*)</td>
</tr>
<tr>
<td>Side wall adhesions</td>
<td>0.90 (0.93*)</td>
<td>0.64 (1.00*)</td>
<td>0.60</td>
<td>0.91</td>
<td>0.09 (0.09*)</td>
<td>0.40 (0.00*)</td>
</tr>
<tr>
<td>Tubal blockage</td>
<td>0.60</td>
<td>0.83</td>
<td>0.50</td>
<td>0.88</td>
<td>0.12</td>
<td>0.50</td>
</tr>
<tr>
<td>Fibroids</td>
<td>0.71</td>
<td>1.00</td>
<td>1.00</td>
<td>0.90</td>
<td>0.10</td>
<td>0.00</td>
</tr>
</tbody>
</table>

PPV Positive predictive value

NPV Negative predictive value

* The diagnostic indices have been recalculated to take account of the fact that laparoscopy, which we are using as the gold standard for assessing the pelvis missed relevant pelvic pathology. The recalculated data gives the diagnostic indices for culdoscopy in terms of the presence or absence of the disease rather than a comparison with laparoscopy.
Chapter 5

Comparison of acceptability of culdoscopy under local anaesthesia with laparoscopy under general anaesthesia and in-patient culdoscopy under light sedation combined with local anaesthesia.
5.1 Introduction

In order to determine the place of culdoscopy in terms of acceptability as an outpatient procedure for infertility investigation, it has to be compared with both conventional endoscopic investigation (i.e. in-patient laparoscopy under general anaesthesia) and culdoscopy under sedation combined with local anaesthesia.

We designed a study to explore this aspect of culdoscopy further. We felt it would be difficult to justify a randomized trial involving the possibility of general anaesthesia to half the study group. We therefore decided to study women attending the One Stop Fertility Clinic and compare them with patients undergoing in-patient investigation by either laparoscopy under general anaesthesia or culdoscopy under sedation + local anaesthesia. We appreciated that not all end-points could be assessed and compared between the three groups (e.g. pain of culdoscopy cannot be assessed for those undergoing the procedure under general anaesthesia). We also realized that our conclusions could not be used to justify one or other of these approaches to investigation as being superior, but we felt nonetheless that it would provide useful background data about the experience of our patients.

5.2 Patients and Methods

For this study we studied a total of 120 infertile patients including 100 from the OSFC, 10 patients who had diagnostic laparoscopy and culdoscopy under
general anaesthesia and participated in the study described in Chapter 4, and a further 10 patients who were judged to be unsuitable for the OSFC by the criteria outlined in Chapter 3 for reasons of anxiety, obesity (BMI > 30) or pelvic pain but who had normal gynaecological examination including pelvic ultrasound and were therefore deemed suitable for culdoscopy under sedation combined with local anaesthesia.

The number of patients in each group was a pragmatic decision based on the flow of patients undergoing infertility investigations, including culdoscopy, under our care. The majority of patients are seen in the OSFC, with relatively few being unsuitable and needing either general anaesthesia or sedation. The patients recruited from the OSFC were the last 100 patients seen in the clinic at the time of the study. The 10 women investigated under G.A. were the last 10 patients involved in the study described in Chapter 4. All 10 patients who underwent sedation during this time period were invited to participate in this study.

5.2.1 Preoperative procedures

All patients due to have in-patient investigation were asked to attend a pre-admission clinic 1 to 2 weeks prior to their procedure date.

5.2.2 Operative technique
5.2.2.1 Local anaesthesia out-patients

As detailed in Chapter 3, these patients underwent a vaginal ultrasound, hysteroscopy prior to culdoscopy. Hysteroscopy was done using a “no touch” technique; local anaesthesia and vaginal instrumentation was only used if required. Conversely, posterior fornix injections of 3% prilocaine hydroxide with felypressin was always injected immediately prior to the culdoscopy. All patients were also given 500 mg mfenamic acid and 200mg doxycycline at least 15 minutes prior to the procedure. Additional analgesia was offered post-procedurally if required, and patients were advised to use mild analgesics such as paracetamol or ibuprofen once home if necessary. There were no food or drink restrictions before or after the procedure.

5.2.2.2 General anaesthesia in-patients

These patients were admitted at 7.30 am (morning operating list) or 9.30 am (afternoon operating list). Food intake was stopped 6 hours prior to surgery but clear fluids could be consumed up to 2 hours before. Most patients did not have pre-medication prescribed.

In the theatre, they were given a standard light anaesthetic (e.g. propofol, ketamine). Intra-operative analgesics included fentanyl or alfentanil.
Bladder catheterization was only done if the bladder was over full. After a bimanual examination, a no touch hysteroscopy was carried out. The uterus was then instrumented with a Spackman Cannula for later hydrotubation. A standard 3 port laparoscopy was done using 10 mm 30° oblique view laparoscope inserted infra-umbilically with CO₂ pneumoperitoneum. A 5 mm ancillary port was placed in the left iliac fossa. All port sites were infiltrated with 0.5% bupivacaine.

The pelvic organs were examined and dilute methylene blue injected to check tubal patency. All patients then underwent culdoscopy as discussed in Chapter 4.

At the end of the surgery, all instruments were removed and the abdomen was deflated. The abdominal skin incisions were sutured with subcuticular 2/0 undyed vicryl. All women were given 100 mg diclofenac p.r. at the finish.

5.2.2.3 Sedation in-patients

Patients in this group were admitted as the general anaesthesia patients and had the same management in terms of oral intake. On the ward they were given 10 mg Temazepam p.o., 100 mg diclofenac p.r. as well as 200 mg doxycycline 30-60 minutes prior to the procedure.

In the anaesthetic room, the patients were given light sedation (Midazolam and occasionally Propofol) plus opioid analgesics (fentanyl or alfentanly) by the anaesthetist. The dosages were adjusted so that the patient would not be very
drowsy or unconscious and could follow the procedures on the TV screen. Hysteroscopy was performed first using a "no touch" technique, the posterior fornix was injected with Citanest 3% with Octapressin (prilocaine hydroxide 30mg/ml and felypressin 0.03 unit/ml) followed by culdoscopy and dye hydrotubation. All the procedures were explained to the patient while watching the screen.

5.2.3 Patient assessment (Table 5.1)

5.2.3.1 Anxiety, pain and acceptability

Pre- and per-procedural anxiety, pain and acceptability were assessed in women undergoing investigation under sedation or in the OSFC using a 10 cm visual analogue scale (0: no symptom/totally acceptable to 10: worst possible symptom/totally unacceptable). Data regarding the procedure was collected within 30 minutes of the end of the procedure.

The acceptability of the procedure for the group undergoing laparoscopy under general anaesthesia was assessed after discharge from hospital by a telephone interview within two weeks of the admission.

5.2.3.2 Hospital stay
Hospital stay was defined as the interval between the end of surgery and the patient leaving hospital.

5.2.3.3 Analgesia requirements and recovery data

All patients were called by telephone approximately two weeks after their discharge, and data regarding analgesia usage, return to normal activities and return to work. Finally, they were asked if they would undergo the investigation again if it became necessary, and if they would recommend it to a friend.

5.2.4 Statistical analysis

Comparison between groups was done using one-way ANOVA and t tests (Student's t test, Mann Whitney test, Kruskall Wallace test). Post-test comparisons were done using Tukeys and Dunn's tests. $\chi^2$ and Fisher's exact tests were used to analyse contingency tables. All statistics were two tailed and $p<0.05$ was considered statistically significant.

5.3 Results

5.3.1 Patients' characteristics
Patients’ characteristics for the three groups of patients are shown in table 5.2. There were no significant differences in any of the variables. Of the 100 patients seen in the OSFC, culdoscopy was unsuccessful in 37 women.

5.3.2 Pelvic findings

The pelvic findings of 63 patients who underwent successful culdoscopy in the OSFC were similar to the summary given in Chapter 3. Findings of the 10 patients who underwent general anaesthesia and the 10 investigated under sedation are summarized in Table 5.3

5.3.2.1 Findings at laparoscopy for the GA group

Of the ten patients in this group, only one had a normal pelvis. In contrast, seven women had deposits of endometriosis and five had pelvic adhesions. Tubal blockage was found in four cases. Six patients had operative laparoscopy, two women had adhesiolysis combined with ablation of endometriosis, two other women had ablation of endometriosis only, one had adhesiolysis only and one had adhesiolysis plus tubal surgery.
5.3.2.2 Findings at culdoscopy for the sedation group

Out of the ten patients who were due to have culdoscopy under sedation, one patient was very anxious and it was decided it was in her interest to convert the procedure to general anaesthesia. The pelvis was normal in this patient. There were normal pelvic findings in three of the remaining nine cases who did have a culdoscopy. The commonest pathology seen in the rest was endometriosis and adhesions. Tubal patency was normal in 7 cases with one woman exhibiting unilateral and another bilateral blockage.

5.3.3 Preprocedure anxiety scores (Table 5.4 and Figure 5.1)

As discussed before, anxiety prior to investigation was not assessed for women undergoing general anaesthesia.

The median anxiety score for the OSFC group was 5 (range 0-10), and for the sedation group was 5 (range 1-9). Only one patient in the OSFC group gave a score of 10 for her anxiety level, but this patient was able to tolerate and complete the procedures under local anaesthesia in the OSFC. Similarly, only one patient in the sedation group scored 9 for anxiety, and she had to be converted to general anaesthesia.
Overall, there was no significant difference in preprocedural anxiety between the two groups (p=0.876).

5.3.4 Pain during hysteroscopy (Table 5.4 and Fig 5.2)

The median pain score during hysteroscopy for patients in the OSFC group was 3.5 (range 0 to 9) and for those patients in the sedation group was 3.5 (range 1 to 8). Table 5.4. There was no significant difference between the two groups (p=0.954).

5.3.5 Acceptability of hysteroscopy (Table 5.4 and Fig. 5.3)

The median acceptability score for the OSFC group was 1.0 (range 0 to 9), while for the sedation group it was 0.0 (range 0 to 4). Again, there was no statistical difference found. (p=0.259).

5.3.6 Pain during culdoscopy (Table 5.4 and Fig 5.4)

The median pain score for patients in the OSFC group was 5.0 (0 to 10) and for cases in the sedation group was 4.0 (0 to 6). This difference remained statistically insignificant (p=0.120).

5.3.7 Acceptability of culdoscopy (Table 5.4 and Fig. 5.5)
The median acceptability score for the OSFC group who had a successful culdoscopy was 1.0 (range 0 to 10) and for the sedation group 0.0 (0 to 4). This difference was not statistically significant (p=0.099).

5.3.8 General acceptability of in-patient investigation under GA (Table 5.4 Figure 5.6)

The median acceptability score of patients who had laparoscopy and culdoscopy under general anaesthesia was 0.0 (0 to 5). In general most patients found the procedures under general anaesthesia acceptable.

5.3.9 Duration of hospitalization (Table 5.5 Figure 5.7)

Duration of hospital stay post-procedure for the sedation and GA group are expressed in hours while for the OSFC group is in minutes as shown in table 5.5. As expected, women investigated as an outpatient remained in hospital for much less time than after sedation or general anaesthesia (p<0.0001 for both). Although patients who were sedated remained in hospital only for a few hours, comparison with the GA group was not statistically significant (p>0.05).

5.3.10 Analgesia requirements and recovery data

5.3.10.1 Analgesia requirements
Two weeks after discharge, patients from the three groups were asked if they required oral analgesia when they returned home: 31% of the OSFC group, 60% of the sedation group and 80% of the GA group required analgesia after discharge from the hospital. Despite this, these differences were not statistically significant (p=0.181).

5.3.10.2 Return to normal activity (Figure 5.8)

There was a significant difference in terms of recovery between the three groups (p<0.0001). The median time taken for the OSFC group to get back to normal activities was two hours (range 1 to 4), compared with 13 hours for the sedated group (range 10 to 16), and 3.5 days (range 2 to 5), with most of these patients reporting that they could only do light works for the first three to four days. Again, while there was a statistical difference between the patients seen in the OSFC and those who were sedated or anaesthetized, the difference between the sedation and general anaesthesia groups was not statistically significant.

5.3.10.3 Return to work (Figure 5.9)

There was also a significant difference between the three groups of patients in terms of return to work (p<0.0001). All the OSFC group went to work the next day and all the patients from the GA group took a week off work. As with normal
activities, the difference between the sedation and GA groups was not statistically significant.

5.3.10.4 Repeat investigation

All the sedation group stated that if they needed to repeat the investigation they would be happy to have it done under sedation. The response for the GA group was that 90% of patients said they would repeat the investigation if it would help their future fertility, in contrast, 92% of patients seen in the OSFC would choose the same approach if they had to be re-investigated, with 8% preferring sedation or general anaesthesia (p=0.461).

5.3.10.5 Recommendation to a friend

All patients from the sedation group answered “yes” to this question and said they would recommend investigation under sedation to their friends. 9 out of the 10 GA patients also responded positively, but one was not sure if she would recommend the procedure. All but one patient from the OSFC group stated that they would commend outpatient investigations to a friend who is having difficulty in getting pregnant.

5.4 Discussion
The overwhelming conclusion from our study is that the only significant difference in patient experience between the three modes of investigation for subfertility is shorter hospitalization and faster return to normal activities and work for those seen as outpatients. The acceptability and discomfort associated with the various procedures, where a comparison could be made, were similar irrespective of the type of anaesthesia used. We did not find any major differences in post-procedural analgesia requirements, and almost all patients stated that they would undergo repeat investigation by the original route if required, and recommend the same to their friends. Therefore, patients found the procedure acceptable whether it was performed under local, sedation or general anaesthesia.

Although outpatient culdoscopy is a recognized investigation, there is relatively little objective data about the discomfort associated with procedure. Most of our patients reported moderate discomfort during culdoscopy, with some experiencing no pain, and a few quite severe pain; none of the sedation patients scored the discomfort of culdoscopy as > 6/10. We asked our patients to provide a global score for their discomfort. In comparison, Moore and Cohen (2001) assessed the pain experienced by 17 patients undergoing culdoscopy under oral sedation at three different times (cannula insertion, midprocedure, and end of the procedure). Using a VAS scale of 0 to 10, they could not find any major difference with average scores of 2.1, 1.4 and 0.5 respectively. They also concluded that outpatient culdoscopy was well tolerated by infertile patients.
This aspect of culdoscopy has been addressed to some extent by few other investigators. Gordts et al (2000) in a study to evaluate the acceptability of culdoscopy asked 60 consecutive infertile women to score their most intense pain experienced during culdoscopy on a 10 cm visual analog pain scale immediately after the procedure. They found that the mean pain score was 2.7 (SD 1.5) and only five (8%) women marked a score above five. 96% of the patients agreed to repeat the procedure if required.

Another study reported the pain experienced during outpatient culdoscopy (Liu et al, 2001). Using visual analogue pain scores (0-10), 36 infertile patients having outpatient culdoscopy, chromopertubation, and hysteroscopy were investigated. They were given diazepam 10mg, oxycodone 5mg, and ibuprofen 600mg together with local anaesthesia. The worst reported pain occurred during insertion of the cannula and averaged 4.2 (SD 0.2) on the 10 point scale.

A further study reported on the acceptability and tolerability of culdoscopy. Cicinelli et al. (2001) randomized 23 infertile women to have out-patient minihysteroscopy and culdoscopy with hydrotubation prior to HSG or after HSG. Before the procedures (T0), each woman filled out an “affective experience rating” form to evaluate the pain expectation. The form contained a 20 cm visual analog scale for the patient to record responses as follows: 5cm, low pain (score 1); 10 cm, moderate pain (score 2); 15 cm, severe pain (score 3); and 20 cm, excruciating pain (score 4). Also patients scored the pain experienced at the end
of each procedure (T1) on the same visual analog scale. They found that pain expectation did not differ for either of the two kinds of approaches, but pain reported at T1 after HSG was significantly greater than that after culdoscopy and hysteroscopy.

We also looked at pain and analgesia after the procedures. Not surprisingly, there was a trend for a lesser requirement in the case of women investigated as out-patients, but this was not statistically significant. The reason for not finding a statistically significant difference between the treatment groups can probably be explained by the small sample size of the women undergoing laparoscopy. We also used a very simple index of analgesia requirements and it retrospect we should have collected quantitative data. Our result was especially unexpected as some of the women investigated laparoscopically underwent operative procedures under the same anaesthetic.

Whereas hospital stay was not surprisingly significantly shorter after outpatient investigation, comparison of the duration of hospitalization for the sedation group with the GA group showed a statistically insignificant difference. Although the sedation group spent only few hours (median = 4 hours) in the hospital in comparison to the GA group (median= 26 hours), the small number of patients involved meant that the comparison was underpowered. In practical terms, this difference in the duration of hospital stay between the two groups is important as
it will affect both the patients' inconvenience and the direct and indirect health care costs (this will be addressed in Chapter 6).

The same applies to recovery in terms of normal and activities and work. Whereas recovery was almost immediate after outpatient investigation, and significantly different to both sedation and general anaesthesia, we included too few patients in our study to confirm a difference between the latter two groups. Logically, one would expect patients who avoided GA to recover more quickly.

Our results can be compared with mini-laparoscopy under local anaesthesia and sedation. A study by Goldberg et al (1999), was designed to determine if patient recovery after diagnostic laparoscopy was influenced by anaesthesia type or laparoscope size, they scheduled the patients to undergo diagnostic laparoscopy for infertility evaluation and gave them a choice between general or local anaesthesia. For those who selected local anaesthesia combined with sedation a 2 mm scope was used, while those who elected general were randomized to a 2 or 10 mm laparascope. Patients with a history of prior pelvic surgery or pain were excluded as were patients who received laparoscopic treatment for any condition which required more than 15 minutes to complete during the study. The time from completing surgery until discharge home was noted. The patients were asked to record their pain level (from 0 to 10) and analgesia use on first postoperative day as well as the time to return to full activity. They found that there were no difference between the 2 and 10 mm laparoscope under general anaesthesia.
Patient who had a 2 mm scope under local anaesthesia were discharged home sooner and had less postoperative discomfort and a more rapid return to normal activity.

5.5 Conclusion

We could not find any difference in the acceptability of culdoscopy in the outpatient clinic under local anaesthesia compared with inpatient investigation under sedation. Similarly, pain during the procedure did not differ significantly between the two groups. Hospital stay and recovery were, however, significantly superior after outpatient investigation, particularly when compared with in-patient general anaesthesia. Despite this, the majority of patients were happy with whatever mode of investigation they underwent and would recommend it to a friend.
Table 5.1 Assessment protocol

<table>
<thead>
<tr>
<th></th>
<th>OSFC</th>
<th>In-patient GA</th>
<th>In-patient sedation</th>
</tr>
</thead>
<tbody>
<tr>
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<td></td>
<td></td>
</tr>
<tr>
<td>Anxiety</td>
<td>+</td>
<td>-</td>
<td>+</td>
</tr>
<tr>
<td><strong>Per-procedure</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain during hysteroscopy</td>
<td>+</td>
<td>-</td>
<td>+</td>
</tr>
<tr>
<td>Acceptability of hysteroscopy</td>
<td>+</td>
<td>-</td>
<td>+</td>
</tr>
<tr>
<td>Pain during culdoscopy</td>
<td>+</td>
<td>-</td>
<td>+</td>
</tr>
<tr>
<td>Acceptability of culdoscopy</td>
<td>+</td>
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<td>+</td>
</tr>
<tr>
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</tr>
<tr>
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</tr>
<tr>
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Table 5.2 Patient characteristics

<table>
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<td>100</td>
</tr>
<tr>
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<td>32.2 (21.6 to 40.3)</td>
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</tr>
<tr>
<td>Employed</td>
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<td>71</td>
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<tr>
<td>Type of infertility</td>
<td></td>
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</tr>
<tr>
<td>Primary</td>
<td>5</td>
<td>6</td>
<td>54</td>
</tr>
<tr>
<td>Secondary</td>
<td>5</td>
<td>4</td>
<td>46</td>
</tr>
<tr>
<td>Duration of infertility (months)</td>
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<td>29.2 (16-48)</td>
<td>26.8 (10 -240)</td>
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<td>Weight (kg)</td>
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</tr>
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<td>8</td>
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Table 5.3 Pelvic findings for the general anaesthesia and sedation groups

<table>
<thead>
<tr>
<th>Findings</th>
<th>General group (n=10)</th>
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<th>Culoscopy under sedation (successful) n=9</th>
</tr>
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<td>Normal</td>
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</tr>
<tr>
<td>Abnormal *</td>
<td>9</td>
<td>1</td>
<td>6</td>
</tr>
<tr>
<td><em>Endometriosis</em></td>
<td>7</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>*Adhesions</td>
<td>5</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>*Fibroids</td>
<td>2</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>*Tubal disease</td>
<td>3</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>*Ovarian cyst</td>
<td>0</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>*Tubal blockage</td>
<td>4</td>
<td></td>
<td>2</td>
</tr>
</tbody>
</table>

* Some patients had more than one abnormality
Table 5.4 Anxiety, pain and acceptability scores for the three groups (results expressed as median and range)

<table>
<thead>
<tr>
<th></th>
<th>Sedation group</th>
<th>OSFC group</th>
<th>GA group</th>
<th>Statistics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anxiety score</td>
<td>5.0 (1 to 9)</td>
<td>5.0 (0 to 10)</td>
<td>Not available</td>
<td>P = 0.876</td>
</tr>
<tr>
<td>Hysteroscopy pain</td>
<td>3.5 (1 to 8)</td>
<td>3.5 (0 to 9)</td>
<td>Not available</td>
<td>P = 0.954</td>
</tr>
<tr>
<td>Hysteroscopy acceptability</td>
<td>0.0 (0 to 4)</td>
<td>1.0 (0 to 9)</td>
<td>Not available</td>
<td>P = 0.259</td>
</tr>
<tr>
<td>Culdoscopy pain</td>
<td>4.0 (0 to 6)</td>
<td>5.0 (0 to 10)</td>
<td>Not available</td>
<td>P = 0.120</td>
</tr>
<tr>
<td>Culdoscopy acceptability</td>
<td>0.0 (0 to 5)</td>
<td>1.0 (0 to 10)</td>
<td>Not available</td>
<td>P = 0.099</td>
</tr>
<tr>
<td>General acceptability</td>
<td>Not available</td>
<td>Not available</td>
<td>0.0 (0 to 5)</td>
<td>Not available</td>
</tr>
</tbody>
</table>
Table 5.5 Duration of post-procedure hospital stay (expressed as median and range)

<table>
<thead>
<tr>
<th>Management group</th>
<th>Duration of hospitalisation</th>
</tr>
</thead>
<tbody>
<tr>
<td>OSFC</td>
<td>25 (15 – 55) minutes (^a)</td>
</tr>
<tr>
<td>Sedation</td>
<td>4.0 (2.5 – 4.0) hours (^b)</td>
</tr>
<tr>
<td>GA</td>
<td>26 (16 – 38) hours (^c)</td>
</tr>
</tbody>
</table>

\(^a\) vs \(^b\): \(p < 0.001\)

\(^a\) vs \(^c\): \(p < 0.001\)

\(^b\) vs \(^c\): \(p > 0.05\)
Figures 5.1 Preprocedure anxiety scores

Figure 5.1a

Figure 5.1b

Key: 5.1a – scattergram
5.1b – median and inter-quartile range
Figures 5.2 Pain during hysteroscopy

Key: 5.2a – scattergram
5.2b – median and inter-quartile range
Figures 5.3 Acceptability of hysteroscopy

Key: 5.3a – scattergram
5.3b – median and inter-quartile range
Figures 5.4 Pain during culdoscopy

Key:  5.4a – scattergram

5.4b – median and inter-quartile range
Figures 5.5 Acceptability of culdoscopy

**Figure 5.5a**

**Figure 5.5b**

Key:  
5.5a – scattergram  
5.5b – median and inter-quartile range
Figure 5.6 Acceptability of investigation under general anaesthesia
Figure 5.7 Duration of hospital stay

GA vs sedation  p>0.05
GA vs OSFC      p<0.001
Sedation vs OSFC p<0.001
Figure 5.8 Return to normal activity

GA vs sedation p>0.05 (not significant)

GA vs OSFC p<0.001

Sedation vs OSFC p<0.001
Figure 5.9 Return to work

GA vs sedation p<0.05
GA vs OSFC p<0.001
Sedation vs OSFC p<0.001
Chapter 6

The cost of out-patient culdoscopy compared to in-patient laparoscopy in women with infertility.
6.1 Introduction:

One of the main reasons for choosing culdoscopy as being an alternative diagnostic method to laparoscopy for infertility investigations is because it could be performed in an outpatient setting which means it would be a more cost effective technique than inpatient laparoscopy. In this study we estimated costs for outpatient and inpatient and follow-up care of infertile patients by the two methods.

Diagnostic laparoscopy is a common procedure performed in many hospitals worldwide to investigate infertile patients. However, morbidity and cost prevent its being considered a first-line diagnostic tool. Consequently, the diagnosis of endometriosis and adhesions is frequently delayed in these patients. Studies showed a mean delay of 3.5 years in the diagnosis of endometriosis in subfertile women (Hadfield et al, 1996; Dmowski et al, 1997). Therefore, in the current financial climate of limited resources many hospitals have a long waiting list for non-urgent laparoscopy. If it was possible to identify those patients at increased risk of pelvic pathology they could be preferentially admitted for laparoscopy and so benefit from more rapid diagnosis and treatment (Forman et al, 1993).

Attempts to screen for endometriosis include assays of endometrial antibodies (Wild and Shivers, 1985), CA-125 (Pittaway and Fayez, 1986) and endometrial secretory protein PP14 (Telimaa et al, 1989). None of these techniques have
found acceptance in routine clinical practice. The use of ultrasound as a screening tool for investigating infertile women and its diagnostic potential has been highlighted (Kelly et al., 2001). In spite of the advances in ultrasound technology, Kelly concluded that it does not yield sufficient information about the presence of tubal disease, pelvic adhesions or endometriosis.

Bates and Bates (1996) reported that the hospital costs for laparoscopy in the USA is about 70% of the total costs of infertility investigation. If outpatient culdoscopy could replace inpatient laparoscopy then a major component of the cost of investigations could be avoided. However, this benefit will be lost if the conversion rate to laparoscopy is high (Gordts et al., 2002), or if a large proportion of patients actually do have pelvic pathology which requires subsequent laparoscopic treatment.

We wished to compare the total cost of the two approaches to the investigation of infertility taking account of investigation failure and therefore the need for alternative investigation and treatment. Our aim was to determine whether culdoscopy under local anaesthesia in an outpatient setting is more cost-effective than laparoscopy under general anaesthesia in investigating infertile women.

6.2 Patients and Methods
As part of a retrospective study, we compared the hospital costs of consecutive infertile patients who had laparoscopy under general anaesthesia between March 2002 and April 2003 (Group A), with another ten who had culdoscopy under local anaesthesia between December 2002 and April 2003 in the OSFC (Group B). All procedures were carried out at the Royal Free Hospital. Patients were identified from our computer database and chosen randomly. We decided to study a relatively small number of cases in great detail because (a) we knew from our clinical experience that these women form a homogenous group, and (b) there were only a limited number of outcomes possible (e.g. women attending OSFC would either need to return for investigation/treatment or not).

6.2.1 In-patient laparoscopy group (Group A):

These patients were seen in the General Gynaecology Out-patient Clinic, where full history was taken and clinical examination was performed. The patients were asked to do the following tests: hormone profile, mid-luteal progesterone, semen analysis, pelvic US scan, rubella IgG antibody and thyroid function test if required. The patients were booked for diagnostic laparoscopy and dye hydrotubation and were seen a week before the hospital admission in the pre-admission clinic where the results and the procedure were discussed. On the day of the procedure, the patient was admitted in the gynaecology ward in the morning (8 am for the morning theatre list and 9 am for the afternoon list). All patients wore anti-embolic TED stockings and were given prophylactic antibiotics
(usually co-amoxiclav, Augmentin). The women were discharged from hospital in the evening if the surgery was carried out in the morning, and the following day if surgery was in the afternoon.

6.2.2 Out-patient OSFC group (Group B):

These patients were sent information pamphlet and screening questionnaire (as discussed in chapter 3). Suitable patients were seen in the OSFC with the results of hormone profile, mid-luteal progesterone and semen analysis. Full history was taken and the procedures and their risks were explained to the patients before asking them to sign the consent form.

All patients were given 200mg doxycycline and 500mg mefenamic acid 15 minutes before the investigations. Pelvic ultrasound scan was performed by the gynaecologist and followed by hysteroscopy and culdoscopy (as explained in chapter 3)

After the procedures, the patients were reviewed in the OSFC by the operator. All results were discussed and a treatment plan made.

6.2.3 Costs
We based our costs on internal cost accounting data from The Royal Free Hospital NHS Trust for the period 2002/03. Observed resource use (procedure duration) is multiplied by the 2002/03 estimates of resource unit cost (cost per minute of procedure time). The costs of drugs are taken from the British National Formulary (BNF, 2003).

6.2.3.1 Clinic costs

Attending the out-patient clinics, pre-admission clinics or OSFC cost £92 per patient, this is a full clinic cost and include consultation, examination and overheads.

6.2.3.2 Ward costs

Bed in the hospital ward costs £390 per day and this includes all medical, surgical, therapeutic and overheads.

6.2.3.3 Operating theatre costs

The average cost for diagnostic/operative laparoscopy and hysteroscopy is £14 per minute and this includes all theatres and recovery costs including that of the anaesthetist but not surgeons. The main cost driver here is the actual operating time.
6.3 Results

6.3.1 Patients’ characteristics and findings

The patients’ characteristics and findings for both groups are shown in table 6.1 and 6.2 respectively.

All ten women in Group A had a successful laparoscopy. Two patients had minor operative (therapeutic) procedures carried out under the same anaesthetic. For the purposes of the cost analysis, these additional procedures were excluded from the basic costs of diagnostic laparoscopy, but included in the pragmatic comparison of in-patient and out-patient management.

Eight patients from the OSFC group (group B) had successful culdoscopy and completed all the investigations in the outpatient clinic. One patient found the procedure too painful and preferred to have it done under general anaesthesia, while the other was found to have an ovarian cyst on ultrasound scan. Of the eight patients who had successful culdoscopy, two patients were booked for operative laparoscopy for pelvic adhesions. The others either had medical treatments or were advised IVF.

6.3.2 Costs for in-patient group (group A)
The unit costs, the unit utilization per patient and the mean cost per patients who were managed with laparoscopy are shown in Tables 6.3 to 6.6. The mean total cost was £1186.97 (range: £1019.36-£1356.31; 95% CI: £1046.52-£1329.91) per patient if the procedure was purely diagnostic. Two patients in fact underwent laparoscopic surgery for mild endometriosis during the same anaesthetic, bringing the mean cost up to £1310.09 (range: £1142.48-£1479.43; 95% CI: £1169.64-£1453.03) for the group as a whole because of the increased operating time (Table 6.7).

6.3.3 Costs for OSFC group (group B)

The unit costs, unit utilization per patient and the average cost per patients seen in the OSFC are also shown in Tables 6.3 to 6.6. The mean total cost for this group was £496.25 per patient (range: £170.67-£662.15; 95% CI: 178.87-622.10). However, this figure does not account of the fact that in two patients culdoscopy could not be completed, and a further two were subsequently admitted to hospital for operative laparoscopy. Allowing for these four cases increased the mean cost per patient to £942.66 (It is difficult to calculate range or confidence interval for this analysis).

6.3.4 Hospital savings
Attendance at the OSFC was associated with a saving of £367.43 or 28.0% per patient compared with traditional out-patient and in-patient investigation.

6.4 Discussion

We have found that in our sample of 20 women, out-patient investigation in an OSFC produced a saving of over £350 per case or 28% to the hospital compared with in-patient investigation. Although this is not a large amount, as the assessment of infertility represents a relatively large proportion of gynaecological referrals to hospital. As a result, the total savings for a department of gynaecology which may see 100 or so women with this complaint each year would be over £35,000 per annum, which is not an insignificant sum. This estimate includes an allowance for those patients who cannot be tolerate or are found to be unsuitable for outpatient investigation, as well as an adjustment for those who are readmitted for operative procedures based on the findings in the OSFC.

Clearly, the ultimate financial value of an OSFC type approach is influenced by two factors: firstly, the proportion of patients who do not or cannot complete all the necessary investigations, particularly culdoscopy, and secondly, the proportion of pelvic pathology which is detected, with special reference to pathology which is amenable to endoscopic management. Thus, a high failure rate or a high rate of pathology findings would tend to make out-patient
investigation less attractive, and potentially even more costly than the standard laparoscopic approach. We have calculated, that the OSFC approach remains less costly provided that no more than half the patients have to be readmitted because of failed outpatient investigation. Similarly, if at least half the patients require readmission for endoscopic surgery based on the findings in the OSFC, then it is cheaper to investigate all patients by in-patient laparoscopy from the start.

In reality, the failure rate of culdoscopy, which is the main limiting factor for outpatient investigation, is only 20% or so in our hands; others have reported even lower failure rates, although not in a One-Stop setting (Gordts et al., 1998; Watrelot et al., 1999; Darai et al., 2000; Gordts et al., 2000; Dechaud et al., 2001; Jonsdottir and Lundorff, 2002). As for pelvic pathology, it should be surprising that the pickup rate for conditions such as endometriosis and adhesions relevant to infertility is considerably less than 50%, as the clinic is designed to provide screening for low risk women who appear to be normal in all other respects.

As far as we are aware, this is the first study to attempt to cost a culdoscopic, out-patient approach to the investigation of the infertile couple. Anecdotal statements have been published suggesting the financial benefits of culdoscopy, but no firm supporting evidence has been provided. Clearly, our costings may not apply across different countries and health care systems, but it is likely that the
financial advantage of an OSFC approach to the investigation of infertility will remain.

6.5 Conclusion

We have shown that investigating infertile women in an OSFC makes financial sense even if some cases require in-patient investigation because of an inability to complete all investigations in the out-patient clinic or the need for further laparoscopic or hysteroscopic treatment.
### Table 6.1 patients' characteristics

<table>
<thead>
<tr>
<th></th>
<th>GA</th>
<th>OSFC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of cases</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Age (average) (years)</td>
<td>35 (29-41)</td>
<td>33 (23-42)</td>
</tr>
<tr>
<td>Type of fertility</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>Secondary</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>Duration of infertility (months)</td>
<td>23.1 (16-36)</td>
<td>22.8 (14-48)</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>62.8 (50-78)</td>
<td>59 (45-70)</td>
</tr>
<tr>
<td>Previous surgery</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>
Table 6.2 Pelvic findings for the out-patient and in-patient groups

<table>
<thead>
<tr>
<th>Findings</th>
<th>In-patient group</th>
<th>Out-patient group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Abnormal *</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Endometriosis</td>
<td>7</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>2</td>
</tr>
<tr>
<td>Adhesions</td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td>Fibroids</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Tubal disease</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>Ovarian cyst</td>
<td>0</td>
<td>3 **</td>
</tr>
<tr>
<td>Tubal blockage</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Some patients had more than one abnormality

** Two patients had unilateral tubal block and one patient had bilateral tubal block.
Table 6.3 Unit costs based on 2002/3 rates at the Royal Free Hospital

<table>
<thead>
<tr>
<th>In-patient laparoscopy</th>
<th>Cost/unit (£)</th>
<th>Out-patient OSFC</th>
<th>Cost/unit (£)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Out-patient clinic attendance</td>
<td>92.00</td>
<td>OSFC attendance</td>
<td>92.00</td>
</tr>
<tr>
<td>Pre-admission clinic</td>
<td>92.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tests</td>
<td></td>
<td>Tests</td>
<td></td>
</tr>
<tr>
<td>Full blood count</td>
<td>3.00</td>
<td>Full blood count</td>
<td>3.00</td>
</tr>
<tr>
<td>Hormone profile</td>
<td>18.38</td>
<td>Hormone profile</td>
<td>18.38</td>
</tr>
<tr>
<td>Mid-luteal progesterone</td>
<td>3.31</td>
<td>Mid-luteal progesterone</td>
<td>3.31</td>
</tr>
<tr>
<td>Semen analysis</td>
<td>37.00</td>
<td>Semen analysis</td>
<td>37.00</td>
</tr>
<tr>
<td>Thyroid function</td>
<td>10.55</td>
<td>Thyroid function</td>
<td>10.55</td>
</tr>
<tr>
<td>Rubella immunity</td>
<td>14.92</td>
<td>Rubella immunity</td>
<td>14.92</td>
</tr>
<tr>
<td>HSG</td>
<td>221.00</td>
<td>HSG</td>
<td>221.00</td>
</tr>
<tr>
<td>Pelvic US scan</td>
<td>89.00</td>
<td>Pelvic US scan</td>
<td>89.00</td>
</tr>
<tr>
<td>Hospital bed/day</td>
<td>390.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Operating theatre costs/min</td>
<td>14.00</td>
<td>OP procedure costs</td>
<td></td>
</tr>
<tr>
<td>Medical staff costs</td>
<td></td>
<td>Medical staff costs</td>
<td></td>
</tr>
<tr>
<td>Consultant/hour</td>
<td>45.67</td>
<td>Consultant/hour</td>
<td>45.67</td>
</tr>
<tr>
<td>SPR/hour</td>
<td>33.58</td>
<td>SPR/hour</td>
<td>33.58</td>
</tr>
<tr>
<td>SHO/hour</td>
<td>27.84</td>
<td>SHO/hour</td>
<td>27.84</td>
</tr>
<tr>
<td>Drug costs</td>
<td></td>
<td>Drug costs</td>
<td></td>
</tr>
<tr>
<td>Codydramol</td>
<td>0.27</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Votarol</td>
<td>6.13</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Paracetamol</td>
<td>0.15</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clomiphene</td>
<td>11.27</td>
<td></td>
<td></td>
</tr>
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### Table 6.4 Mean unit utilization per patient

<table>
<thead>
<tr>
<th>In-patient laparoscopy</th>
<th>Out-patient OSFC</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Out-patient clinic attendance</strong></td>
<td>1.0</td>
</tr>
<tr>
<td><strong>Pre-admission clinic</strong></td>
<td>1.0</td>
</tr>
<tr>
<td><strong>Tests</strong></td>
<td></td>
</tr>
<tr>
<td>Full blood count</td>
<td>1.0</td>
</tr>
<tr>
<td>Hormone profile</td>
<td>0.8</td>
</tr>
<tr>
<td>Mid-luteal progesterone</td>
<td>1.0</td>
</tr>
<tr>
<td>Semen analysis</td>
<td>0.9</td>
</tr>
<tr>
<td>Thyroid function</td>
<td>0.1</td>
</tr>
<tr>
<td>Rubella immunity</td>
<td>0.9</td>
</tr>
<tr>
<td>HSG</td>
<td>0.0</td>
</tr>
<tr>
<td>Pelvic US scan</td>
<td>1.0</td>
</tr>
<tr>
<td><strong>Hospital bed</strong></td>
<td>1.0</td>
</tr>
<tr>
<td><strong>Operating theatre costs</strong></td>
<td></td>
</tr>
<tr>
<td>Diagnostic laparoscopy and hysteroscopy</td>
<td>26.0</td>
</tr>
<tr>
<td>Operative laparoscopy and hysteroscopy</td>
<td>65.0</td>
</tr>
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<td></td>
<td></td>
</tr>
<tr>
<td><strong>Medical staff costs</strong></td>
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<td>SHO</td>
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<tr>
<td><strong>Drug costs</strong></td>
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</tr>
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<td>0.2</td>
</tr>
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<td>Votarol</td>
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<tr>
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<tr>
<td></td>
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</table>
Table 6.5 Mean cost per patient

<table>
<thead>
<tr>
<th>In-patient laparoscopy</th>
<th>Cost (£)</th>
<th>Out-patient OSFC</th>
<th>Cost (£)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Out-patient clinic attendance (including overheads)</td>
<td>92.00</td>
<td>OSFC attendance (including overheads)</td>
<td>92.00</td>
</tr>
<tr>
<td>Pre-admission clinic</td>
<td>92.00</td>
<td>Tests</td>
<td>Full blood count</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Mid-luteal progesterone</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Semen analysis</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Thyroid function</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Rubella immunity</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>HSG</td>
</tr>
<tr>
<td>Hospital bed (includes all medical/surgical, diagnostic, therapeutic and overheads)</td>
<td>390.00</td>
<td>Operating theatre costs</td>
<td>Pelvic US scan</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Operating theatre for diagnostic or therapeutic laparoscopy and hysteroscopy (all theatre and recovery cost including anaesthetists but not surgeons)</td>
<td>364.00</td>
</tr>
<tr>
<td>Medical staff costs</td>
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<td>Medical staff costs</td>
<td>Consultant</td>
</tr>
<tr>
<td>Consultant</td>
<td>42.60</td>
<td></td>
<td>SHO</td>
</tr>
<tr>
<td>SPR</td>
<td>14.30</td>
<td></td>
<td>Drug costs</td>
</tr>
<tr>
<td>SHO</td>
<td>25.88</td>
<td></td>
<td>Citanest with octapressin (4.4ml)</td>
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<tr>
<td>Drug costs</td>
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<td>Paracetamol</td>
</tr>
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<td>Codydramol</td>
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<td>Voltarol</td>
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<td>Paracetamol</td>
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Table 6.6 Mean cost per patient for planned investigation

<table>
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<tr>
<th>In-patient laparoscopy</th>
<th>Cost (£)</th>
<th>Out-patient OSFC</th>
<th>Cost (£)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Out-patient clinic</td>
<td>92.00</td>
<td>OSFC attendance</td>
<td>92.00</td>
</tr>
<tr>
<td>Pre-admission clinic</td>
<td>92.00</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Tests</td>
<td>157.78</td>
<td>Tests</td>
<td>79.18</td>
</tr>
<tr>
<td>Hospital bed</td>
<td>390.00</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Operating theatre costs</td>
<td>364.00</td>
<td>OP procedure costs</td>
<td>280.00</td>
</tr>
<tr>
<td>Medical staff costs</td>
<td>82.78</td>
<td>Medical staff costs</td>
<td>41.10</td>
</tr>
<tr>
<td>Drug costs</td>
<td>8.41</td>
<td>Drug costs</td>
<td>3.97</td>
</tr>
<tr>
<td>TOTAL</td>
<td>1186.97</td>
<td>TOTAL</td>
<td>496.25</td>
</tr>
</tbody>
</table>
## Table 6.7 Real cost per patient allowing for OSFC failure and need for further surgery

<table>
<thead>
<tr>
<th>In-patient laparoscopy</th>
<th>Cost (£)</th>
<th>Out-patient OSFC</th>
<th>Cost (£)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>TOTAL for diagnostic procedure</strong></td>
<td>1186.97</td>
<td><strong>OSFC</strong></td>
<td>496.25</td>
</tr>
<tr>
<td>Additional cost for operative procedures with same anaesthetic (2:10) (additional 39 minutes operative time)</td>
<td>123.12</td>
<td>Readmission for diagnostic laparoscopy (2:10 cases)</td>
<td>161.60</td>
</tr>
<tr>
<td></td>
<td>1310.09</td>
<td>Readmission for operative procedure (2:10 cases)</td>
<td>284.81</td>
</tr>
<tr>
<td><strong>TOTAL cost for patient including surgery in 2:10</strong></td>
<td>1310.09</td>
<td>TOTAL cost including diagnostic and operative laparoscopy in 4 cases</td>
<td>942.66</td>
</tr>
<tr>
<td></td>
<td></td>
<td>SAVING compared with in-patient laparoscopy</td>
<td>367.43</td>
</tr>
</tbody>
</table>
Chapter 7

Summary and the future of culdoscopy
7.1 Summary

From our experience with culdoscopy we found it to be:

1. **Accurate** procedure for screening when compared with laparoscopy particularly in confirming a “normal” pelvis. Culdoscopy tends to underestimate pathology if it is extensive.

2. **Tolerable and safe** as an out-patient procedure when combined with pelvic ultrasound and diagnostic laparoscopy.

3. **Cost-effective** as a method of infertility investigation in an outpatient setting under local anaesthesia compared with in-patient laparoscopy under general anaesthesia.

The problems we have identified with culdoscopy include the following:

1. **Patient selection** for out-patient investigation needs to be refined to avoid procedure cancellations at the time of clinic attendance mainly because of anxiety or pain (the two often go together), or unsuspected pathology. We plan to analyze the responses to our screening questionnaire in more detail to try to identify factors which are the most predictive of culdoscopy failure. We also plan to test new questions to see if they can identify this group more accurately.
2. **Technique failure** with culdoscopic entry remained a problem throughout the studies and was not totally eliminated by using an optical cannula. We feel that one reason for this was the use of a non-disposable instrument which tended to become blunt with usage. We are currently working with the industry to manufacture a disposable optical cannula for culdoscopy which will guarantee a sharp tip.

3. **Logistics** of ensuring that patients do undergo relevant investigations such as blood tests and semen analysis prior to OSFC visits remained a persistent problem. One possible solution to this problem may be to get the administrative staff in the clinic to telephone or text patients well before their appointment to ensure that the tests have been carried out.

4. **Language** difficulties were an occasional problem and we hope to be able to provide translated versions of our leaflets and questionnaire in common languages relevant to our population in North London.

### 7.2. The future of culdoscopy

Several factors would determine the future of culdoscopy as being a first-line technique to investigate the pelvis in infertile women and whether it would replace diagnostic laparoscopy in selected patients

#### 7.2.1. Safety and success of entry to Pouch of Douglas
The two major reasons for abandoning culdoscopy in the early days was the fear of pelvic infection and rectal injury. The use of prophylactic antibiotics has virtually eliminated the former, but there remains a fear of bowel injury when inserting a sharp instrument into the pelvis through the posterior fornix. The development of miniature instruments has not eliminated this fear which is confirmed by data showing a ten fold increased risk of bowel injury compared with laparoscopy.

We have a proposed one solution, namely the use of an optical system for entering the Pouch of Douglas. Although we have not had any bowel injuries using this technique, our database is admittedly small. Only a multi-centre assessment base on a large number of patients can answer this issue and prove or refute our hypothesis. If, however, it is proven that the use of an optical system is safe, then we suspect that the advantages of culdoscopy will be appreciated and the technique will be taken up on a larger scale.

Another factor in entry is avoided extra-peritoneal placement of the cannula. This is to some extent a function of experience, but we feel that the use of relatively blunt non-disposable cannulas also plays a major role with this problem with should be solved when disposable and reliably sharp instruments become commercially available.
Alternative strategies to increase the success rate of culdoscopy entry may involve the use of optical Veress needles (Bartzke et al, 2003), and possibly the use of simultaneous vaginal or rectal ultrasound during insertion of the optics.

7.2.2. Tolerability

We found during our studies that most of those patients who experienced pain during their investigation did so during hydrotubation. We used a standard HSG catheter under high pressure using pressure cuff, and in our opinion this high intrauterine pressure when injecting the dye caused the discomfort. It is possible that the use of a pump which delivers a lower but consistent pressure would avoid this pain.

Pain during the rest of the culdoscopy was not a major problem, but some patients did feel uncomfortable, particularly during the latter part of the procedure. Some found contact with the ovaries or peritoneum uncomfortable. It remains to be seen if using narrower optics or dilute local anaesthetic in the pelvic irrigant reduces this sensation even further.

7.2.3. Panoramic view

The lack of panoramic pelvic view with culdoscopy, as the anterior uterus and inferior cul-de-sac wall remained hidden from view, is a well recognized limitation
of the technique. Flexible culdoscopy was used by Paulson et al (1999), but they performed culdoscopy with patient in the knee-chest position. More studies are needed with flexible culdoscopy with the patient being in the lithotomy position to evaluate the efficacy of flexible culdoscopy. A 70 degree optic was also suggested by some authors, as it would allow a wider angle to view pelvis (Dechaud et al., 2001). Again, this remains to be proven by objective measure.

7.3. Operative Culdoscopy

Operative culdoscopy would make a great difference to the future of culdoscopy especially in infertile women with pelvic pathology, especially if it could be performed in an out-patient setting. Procedures such as the division of minor ovarian adhesions, drainage of ovarian cysts, ovarian drilling and ablation of endometriosis have already been reported but further data are required to prove the safety and efficacy of this approach to surgery. Such an approach is also likely to have considerable financial advantages to the health care system.
Appendix A

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Appendix B

One Stop Fertility Clinic Documents
Contents

1. Patient letter 1
2. Patient letter 2
3. General practitioner letter
4. Clinic pamphlet
5. Screening questionnaire
6. Clinic questionnaire
Dear

Your General Practitioner has referred you to the Royal Free Hospital as you are having difficulty becoming pregnant. Traditionally, you would be seen in the general gynaecology out-patient clinic, and we would organise the various investigations from there. Typically, couples have to make several hospital visits, and in-patient admission for laparoscopy is often also required. As an alternative, we have set up a One Stop Fertility Clinic with the aim of completing all the important investigations at a single hospital out-patient visit.

We enclose a pamphlet about the new clinic, and there is a flow chart showing the clinic protocol on the right.

If you are interested in being seen in the One Stop Fertility Clinic, please complete the enclosed questionnaire and return it to us in the stamped addressed envelope; make sure you answer all the questions. We will contact you once we have received the completed form.

If you do not wish to be seen in the new clinic but prefer to come to the general gynaecology clinic for a consultation, please mark the questionnaire accordingly and return it to us so we can send you an appointment.

We look forward to hearing from you.

Yours sincerely,

Amina Al-Khourl MB BS
Clinical Research Fellow to Mr. Adam Magos

Adam Magos BSc MD FRCOG
Consultant Gynaecologist
Date:

Dear

We are pleased to offer you an appointment for the One Stop Fertility Clinic on

...................................................... at ......................................................

At this clinic you will see a doctor who will review your history and test results and then perform the investigations as detailed in the information pamphlet. I enclose another copy for you.

It is necessary for you and your partner to have the following tests done at least two weeks before your appointment so that the results will be available in the clinic when you are seen:

1. Blood tests for you to check that your hormone profile and determine if you are ovulating; and
2. Seminal fluid analysis for your partner to check his sperm count and quality.

The request forms for these are enclosed. All the tests are very important so that we can help and advise you correctly. It is also important that the blood tests are performed as near to the day specified on the form as possible and for the instructions regarding the semen analysis to be followed closely.

The blood tests can be performed in the Community Gynaecology Clinic which is also where the One Stop Fertility Clinic is being held. There is a map on the information pamphlet showing where the clinic is situated and how to get there.

The total time to expect to be in the clinic for your appointment will be around 2 hours. When we have finished, all your results will be discussed with you and a plan made for any further treatment. We will also give you a printed summary of the various results. It would be advisable to bring a friend or partner with you so that they can accompany you home as a matter of precaution.

If you have any questions regarding the tests or clinic appointment, please contact Sister Spry on 020 7830 2495.

If for any reason you are unable to keep your appointment, please inform Sister Spry on the above number as soon as possible so the appointment can be given to another couple on our waiting list; there is no need to cancel your appointment if you are having a period at the time.

We look forward to seeing you in the clinic.

Yours sincerely,

Amina Al-Khouri MB BS
Clinical Research Fellow to Mr. Adam Magos

Adam Magos BSc MD FRCOG
Consultant Gynaecologist
G.P. Information Sheet

Evaluation of Diagnostic Culdoscopy in Women with Infertility

Background As you know, it can take many months to investigate couples referred to hospital with subfertility. In addition to blood tests, pelvic ultrasound and semen analysis, in-patient admission for diagnostic laparoscopy is often required. We have introduced culdoscopy as an alternative to laparoscopy. Culdoscopy is done using a narrow telescope which is passed through the vagina into the pelvis; there are no external scars, and the procedure can be done under local anaesthesia in the out-patient department.

This new technique was introduced into clinical practice by gynaecologists in Leuven, Belgium a few years ago. Having gained experience in culdoscopy, we are now trying to find out which is the better investigation for couples complaining of infertility, laparoscopy or culdoscopy? As you have referred a couple to the Royal Free Hospital with subfertility, we have mentioned our study to them.

What are we trying to find out? Broadly speaking, we have three aims:

(a) To evaluate culdoscopy as diagnostic technique which could be performed under local anaesthesia in an outpatient clinic, as a first-line and an alternative to diagnostic laparoscopy for investigation of female infertility;
(b) To evaluate the diagnostic accuracy and cost of this technique in comparison to in-patient laparoscopy; and
(c) To assess the acceptability of the procedure as an outpatient technique as part of a ‘One-Stop Fertility Clinic’ for the investigation, diagnosis and management of the infertility in comparison with in-patient laparoscopy.

Your patient can choose which of these areas she wishes to help with. She will be fully counselled and consented, and it will be made clear to her that she is under no obligation to take part in our studies, and she can withdraw from the studies at any time. Neither action will in any way prejudice her further care.

Ethical approval The studies have been approved by the Royal Free Hospital and Medical School Ethics Committee.

Further information If you require any further information regarding this study, please contact:

Mr. Adam Magos BSc MD FRCOG, Consultant Gynaecologist
Dr. Amena Al Khouri MB Bch, Clinical Research Fellow
Who's who in the clinic

Adam Magos BSc MD FRCOG
Consultant Obstetrician and Gynaecologist

Peter Scott BSc MB BS DCH MRCGP MRCOG
Clinical Research Fellow

Amina Khouri MB BS
Visiting Clinical Fellow

Rosanne Spry RGN
Clinic Sister

Address for enquiries and referrals

One Stop Fertility Clinic
Minimally Invasive Therapy Unit & Endoscopy Training Centre
University Department of Obstetrics and Gynaecology
The Royal Free Hospital
Pond Street
Hampstead
London NW3 2QG

Telephone: 020 7830 2495 and ask for Sister Spry
Facsimile: 020 7830 2504

Where to find us

The clinic is held in the Community Gynaecology Clinic (entrance on Pond Street). The nearest underground stations are Belsize Park and Hampstead on the Northern Line. Buses C11, 24, 46, 168 and 268 also stop close to the Clinic. Trains on the North Thames Link stop at Hampstead Heath station.

The Royal Free Hospital

THE ONE-STOP FERTILITY CLINIC

A new clinic to improve the investigation of infertility

♦ Consultation
♦ Ultrasound scan
♦ Hysteroscopy
♦ Culdoscropy

at one outpatient appointment

This booklet has been written to explain what to expect when you attend the clinic

For further information, please visit our website at www.infertility.uk.net
Why attend a one-stop clinic?

This clinic allows all the special investigations for infertility to be performed at one attendance as an out-patient.

- Ultrasound scan
- Diagnostic hysteroscopy
- Culdoscopy

Coming to the clinic will mean that you will usually have only one hospital appointment rather than several hospital visits, and often an in-patient admission and surgery under general anaesthesia which is the traditional alternative.

What is ultrasound?

You have probably had an ultrasound before as it is a very common investigation. We will do a vaginal ultrasound scan using a small probe. The procedure is painless and gives us a very useful image of your womb and ovaries.

What is a hysteroscopy?

A very narrow telescope is inserted into the womb via the vagina and cervix. We can see the cavity of the womb and check that it is normal for pregnancy. A local anaesthetic may be used if you wish.

What is culdoscopy?

Here, another narrow telescope is used via the vagina to check the outside of your womb, fallopian tubes and ovaries. We use a dye to see if your fallopian tubes are not blocked. Other problems can be looked for such as endometriosis and scar tissue which can affect your fertility. We will give you a local anaesthetic for this.

How long will it take?

The whole visit should take less than 2 hours. You will be able to go home afterwards and we would recommend that you are accompanied by a friend or relative. You should rest during the evening.

What should I expect afterwards?

You may experience some slight discomfort and bleeding after the procedure requiring a sanitary towel. Tampons should not be used and you should not have sexual intercourse for 1 week.

What are the risks?

You may find the hysteroscopy or culdoscopy slightly uncomfortable but you will be given the option of a local anaesthetic. We will also give you a fast acting pain killer before these procedures as well as an antibiotic to reduce the risk of infection.

Problems resulting from using the telescopes is unusual; if there is a complication, you may be asked to stay in hospital over night and rarely may need a further operation.

What happens afterwards?

Once you have had the investigations, we will review all the results and recommend treatment. For instance, we might suggest medical treatment with tablets or surgery. We will give you a printed summary of all the results to take home with you.

Are you suitable for this clinic?

You must be referred to this clinic by your general practitioner. We will then send you a brief questionnaire, and once returned, an appointment to an appropriate clinic will be given.
The One Stop Fertility Clinic

Name ___________________________________________ Date of birth

Address __________________________________________ Telephone (daytime)

________________________________________ Telephone (evening)

________________________________________

Your partner's name _____________________________ His date of birth

Would you like an appointment for the One Stop Fertility Clinic? ☐ Yes ☐ No

If you would like an appointment to the Clinic, please answer all the following questions

How long have you been trying to get pregnant? ________ months

What is the average length of your menstrual cycle (eg. 28 days)? ________ days

Are your periods regular (you can usually predict the start date of your next period to within 4 days)? ☐ Yes ☐ No

Have you been told you have endometriosis? ☐ Yes ☐ No

Have you been told you have large fibroids? ☐ Yes ☐ No

Have you been told you have adhesions (scar tissue) in your pelvis? ☐ Yes ☐ No

Have you had a serious pelvic infection? ☐ Yes ☐ No

Have you had major abdominal surgery (eg. laparotomy)? ☐ Yes ☐ No

Have you had an ectopic pregnancy (pregnancy in the tube)? ☐ Yes ☐ No

How painful are your periods usually? ___________ Pain free ___________ Mildly ___________ Moderately ___________ Very

How uncomfortable do you find sexual intercourse usually? ___________ Pain free ___________ Slightly ___________ Moderately ___________ Very

How uncomfortable do you find having a cervical smear? ___________ Pain free ___________ Mildly ___________ Moderately ___________ Very

Please give details of any current medical illnesses you have (eg. diabetes, asthma, heart disease):

________________________________________________________________________________________

What is your weight? ___________ kg/stones/pounds (ring unit)

What is your height? ___________ metres/feet (ring unit)

Please return this questionnaire to the One-Stop Fertility Clinic, University Department of Obstetrics and Gynaecology, Royal Free Hospital, London NW3 2QG. We will contact you once we have received this form.
Patient survey after attendance at the One Stop Fertility Clinic:

Your name ___________________________ Date of attendance __________ / __________

Grade the main reasons for choosing to attend the One Stop Clinic (1=most important reason, 2=second most important reason, etc.)

☐ No need for in-patient admission
☐ No need for general anaesthesia
☐ Only one hospital visit for all investigations
☐ Able to see on-screen pictures of investigations
☐ Results available immediately
☐ Other reason (specify) _______________________

Please put a cross on the 10 cm lines below

What was your level of anxiety before the investigations this afternoon?

(No anxiety) 0 ___________________________ 10 (Total panic)

Please answer the following questions by ticking "Yes" or "No"

Did you receive enough information about the clinic prior to attending? ☐ Yes ☐ No

Did you have any problems getting the tests done prior to attending the clinic? ☐ Yes ☐ No

If you needed the tests repeated would you prefer a General Anaesthetic as an in-patient? ☐ Yes ☐ No

Were you pleased that you attended the clinic? ☐ Yes ☐ No

Would you recommend the clinic to other patients? ☐ Yes ☐ No

Did you receive enough information in the clinic about the investigations that you had? ☐ Yes ☐ No

Did you understand the results that were explained to you? ☐ Yes ☐ No

Please continue overleaf
Questions about the ultrasound scan - the first procedure

How much pain did you have during the ultrasound?

(No pain) 0 10 (Worst pain ever)

How acceptable was the procedure to you?

(Totally acceptable) 0 10 (Totally unacceptable)

Questions about the hysteroscopy - the second procedure

How much pain did you have during the hysteroscopy?

(No pain) 0 10 (Worst pain ever)

How acceptable was the procedure to you?

(Totally acceptable) 0 10 (Totally unacceptable)

Questions about the culdoscopy - the last procedure

How much pain did you have during the culdoscopy?

(No pain) 0 10 (Worst pain ever)

How acceptable was the procedure to you?

(Totally acceptable) 0 10 (Totally unacceptable)

We would welcome any other comments

Don't forget to return this questionnaire prior to leaving the clinic. Thank you for your help.