

LAPAROSCOPIC SURGERY FOR RECTOVAGINAL ENDOMETRIOSIS:
A RETROSPECTIVE DESCRIPTIVE STUDY FROM A SINGLE CENTRE

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DECLARATION

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ABSTRACT

Background

Rectovaginal endometriosis accounts for 5-10% of cases of endometriosis and constitutes one of the forms of deep infiltrating endometriosis. Deep infiltrating endometriosis involving the bowel is most frequently encountered in the rectovaginal septum and is considered to be the most severe form of the disease and the most difficult to treat surgically owing to its invasive nature. There are currently no studies on this topic pertaining to a South African context

Study Objective

To document the outcomes in 112 patients undergoing laparoscopic surgery for rectovaginal endometriosis.

Methods

A retrospective audit of 112 women undergoing laparoscopic surgery for rectovaginal endometriosis at Vincent Pallotti's Aevitas Fertility Clinic was undertaken. Eligibility was established by identifying women from a surgical database based on medical aid coding as well as a review of individual case notes. Patients were telephonically contacted to gather any missing information and to assess further outcomes.

Design Classification

Study number S11/11/036. This study was approved by the Health Research Ethics Committee at Stellenbosch University and was conducted according to ethical guidelines and principles of The International Declaration of Helsinki, South African

Guidelines for Good Clinical Practice and the Medical Research Council (MRC) Ethical Guidelines for Research.

Setting

Vincent Pallotti's Aevitas Reproductive Medicine Clinic

Patients

112 consecutive patients suffering from rectovaginal endometriosis

Interventions: Laparoscopic surgery for treatment of deep infiltrating, namely rectovaginal endometriosis.

Measurements and Main Results

Primary outcome: Complications of laparoscopic surgery for rectovaginal endometriosis included one patient requiring a blood transfusion (0,9%), three cases of rectovaginal fistula (2,7%), two bowel injuries (1,8%)-detected and managed intra-operatively , one ureteric injury (0,9%), one pelvic abscess (0,9%) and the need for three urgent re-operations (2,68%).

Secondary outcome: Of the 71 patients desiring fertility 39 (54,9%) fell pregnant of which 27 (69,2%) were spontaneous.

Conclusion

To our knowledge this is the first study assessing surgical outcomes in the management of deep infiltrating endometriosis from South Africa. These outcomes are in keeping with complication rates quoted in the international literature. Most of the surgery was performed using the shaving technique, in keeping with international trends, whilst fourteen cases required the performance of a segmental resection owing

to extensive disease. In trained hands laparoscopic surgery is a valid management option in the management of rectovaginal endometriosis.

ABSTRAK

Agtergrond

Vyf tot tien persent van alle endometriose gevalle kan toegeskryf word aan rektovaginale endometriose. Dit word beskou as een van die vorme van diep infiltrerende endometriose. Diep infiltrerende endometriose van die darm kom meestal in die rektovaginale septum voor en word as die ernstigste vorm van die siekte beskou. Dit is die moeilikste om chirurgies te behandel weens sy indringende aard. Daar is tans geen studies beskikbaar oor hierdie onderwerp in die Suid-Afrikaanse konteks nie.

Doel van die studie

Om die uitkomste te dokumenteer van 112 pasiënte wat laparoskopiese chirurgie vir rektovaginale endometriose ondergaan het.

Metodes

'n Retrospektiewe oudit is by Vincent Pallotti se Aevitas Fertiliteitskliniek gedoen van 112 vroue wat laparoskopiese chirurgie vir rektovaginale endometriose ondergaan het. Geskikte pasiënte is geïdentifiseer vanaf 'n chirurgiese databasis gebaseer op mediese kodering, sowel as vanaf 'n oorsig van pasiënt notas. Pasiënte is telefonies genader om ontbrekende inligting in te samel en verdere uitkomste te evalueer.

Klassifikasie Ontwerp

Studie nommer S11/11/036. Hierdie studie is deur die Gesondheids Navorsing Etiese Komitee van die Universiteit van Stellenbosch goedgekeur en uitgevoer volgens die

etiese riglyne en beginsels van die Internasionale Verklaring van Helsinki, Suid-Afrikaanse Riglyne vir Goeie Kliniese Praktyk en die Mediese Navorsingsraad (MNR) se Etiese Riglyne vir Navorsing.

Instelling

Vincent Pallotti se Aevitas Reproduktiewe Medisyne Kliniek

Pasiënte

112 agtereenvolgende pasiënte met rektovaginale endometriose.

Ingrepe: Laparoskopiese chirurgie vir die behandeling van diep infiltrende, rektovaginale endometriose.

Resultate

Primêre uitkoms: Komplikasies van laparoskopiese chirurgie vir rektovaginale endometriose het ingesluit: een pasiënt wat 'n bloedoortapping benodig het (0,9%), drie gevalle van rektovaginale fistels (2,7%), twee dermbeserings (1,8%) - intraoperatief gediagnoseer en herstel, een ureter besering (0,9%), een bekkenabses (0,9%) en drie dringende herhaal operasies (2,68%).

Sekondêre uitkoms: Van die 71 pasiënte wat fertilitet verlang het: 39 (54,9%) het swanger geraak, waarvan 27 (69,2%) spontaan was.

Gevolgtrekking

Sover ons kennis strek, is dit die eerste Suid-Afrikaanse studie waar daar na die chirurgiese uitkomste in die behandeling van diep infiltrerende endometriose gekyk is. Hierdie uitkomste stem ooreen met internasionale literatuur in terme van komplikasie syfers. Die meeste van die operasies is uitgevoer met behulp van die skeer-tegniek,

in ooreenstemming met internasionale tendense, terwyl veertien gevalle segmentele reseksies vereis het weens uitgebreide siekte. In goed opgeleide hande is die laparoskopiese behandeling van rektovaginale endometriose 'n geldige behandelingsopsie.

BACKGROUND AND LITERATURE REVIEW

Endometriosis is defined as the presence of endometrial glands and stroma outside of the uterus. The pathogenesis and natural history of endometriosis are poorly understood and numerous mechanisms of disease have been proposed. These include the classic description of retrograde menstruation by Sampson in 1927, in which it was believed there was 'menstrual dissemination of endometriotic tissue in to the peritoneal cavity'. The coelomic metaplasia theory suggests that endometriosis arises as a result of spontaneous metaplasia in mesothelial cells of coelomic origin. Lymphatic and vascular spread have also been postulated as possible mechanisms for transplantation of endometrial tissue to extra-uterine sites. Other theories include transplantation of disease secondary to inadvertent iatrogenic dissemination during pelvic procedures. There is a definite genetic component as endometriosis is seven times more prevalent among first degree relatives of affected females than in the general population [1].

Endometriosis is a common disorder affecting up to 10% of women of reproductive age [2] [3]. Rectovaginal endometriosis consists of endometriotic nodules, in which the fibrotic component is prevalent, within the connective tissue between the anterior rectal wall and the vagina [4]. In 1997 it was suggested that rectovaginal endometriosis be considered a different disease from peritoneal endometriosis and should rather be referred to as rectovaginal adenomyosis or rectovaginal adenomyoma in the case of a solitary lesion. Donnez and Nissole described the rectovaginal endometriotic nodule as an adenomyotic nodule whose histopathogenesis is not related to the implantation of regurgitated endometrial cells but due to metaplasia of Mullerian remnants located

in the rectovaginal septum [5]. Rectovaginal endometriosis accounts for 5-10% of cases of endometriosis and constitutes one of the forms of deep infiltrating endometriosis [2]. Deep infiltrating endometriosis is defined as endometriosis penetrating more than 5mm under the peritoneal surface and is strongly associated with severe chronic pelvic pain, dyspareunia and dysmenorrhoea [6]. In cases of bowel involvement, patients may experience debilitating symptoms including, painful defaecation (dyschezia), tenesmus and rarely cyclical rectal bleeding. Deep infiltrating endometriosis involving the bowel is most frequently encountered in the rectovaginal septum and less so in the sigmoid [7]. Endometriosis resulting in complete obliteration of the posterior pelvic cul-de-sac is considered to be the most severe form of the disease and the most difficult to treat surgically owing to its invasive nature [8].

Classification

Several classification systems used to describe deep infiltrating endometriosis exist, namely those by Adamyan, Koninckx and Martin, and Donnez and Squifflet [9] [10] [11]. These categorise the disease into numerous subtypes based on their clinical, surgical and radiological appearance. They intend to aid clinicians in standardising diagnosis and management decisions. Widespread implementation of these systems, however is still lacking and their use in predicting clinical outcomes remains unclear. The Revised American Fertility Society Score (rAFS) is a system that has been used for the past two decades, however it lacks correlation between the stage of disease and degree of symptoms. Furthermore the rAFS does not include extra-peritoneal endometriosis therefore limiting its use in cases in which there is rectovaginal involvement. The Endometriosis Fertility Index (EFI) proposed by Adamson and Pasta is an externally validated system that can be reliably used to develop treatment plans and predict conception rates following endometriosis surgery [12]. The EFI is useful

only for infertility patients who have had surgical staging of their disease and does not predict any aspect of endometriosis-associated pain. The AAGL (formerly American Association of Gynecological Laparoscopists) Special Interest Group (SIG) intends to propose a new classification system based on surgical difficulties. It comprises four categories and it has been suggested that this system will correlate with pain intensity and level of surgical difficulty. Its ability to predict pregnancy rates is, however unknown [13].

Diagnosis

The initial diagnosis of rectovaginal endometriosis is clinical, based on symptoms that are highly suggestive of disease, namely dyschezia, deep dyspareunia and cyclical rectal bleeding. In addition to these findings, diagnostic imaging modalities including trans-vaginal ultrasound (TVUS) and magnetic resonance imaging (MRI) provide further information regarding the size, location, extent and degree of infiltration of lesions. These tests also aid in detecting the presence of hydronephrosis, which, if present necessitates pre-operative ureteric stenting. Abrao et al. found TVUS superior in all aspects to both digital vaginal examination and MRI in the pre-operative assessment of deep infiltrating endometriosis, quoting a sensitivity rate of 99% when diagnosing rectocervical disease and 97% when diagnosing rectosigmoid disease [14]. A systematic review and meta-analysis evaluating the role of TVUS for the detection of deep infiltrating endometriosis involving the rectosigmoid estimated sensitivity and specificity rates of 91% and 98% respectively [15]. This study confirms the valuable role of TVUS as a reliable, non-invasive diagnostic tool when diagnosing deep infiltrating endometriosis of the rectosigmoid. In view of its accuracy, availability and relatively non-invasive nature, TVUS should be considered the first-line imaging technique for all cases of suspected deep pelvic endometriosis [16]. It should, however

be remembered that as with other forms of ultrasound scanning TVUS is operator dependent. Other pitfalls include its inability to detect the depth of rectal wall invasion, its failure to determine the distance of rectal lesions to the anal margin and its poor predictive value when evaluating the degree of difficulty encountered during surgery. Van der Wat and colleagues have proposed the use of modified virtual colonoscopy (MVC) to predict the severity of disease, approaches to surgery and treatment outcomes when managing endometriosis [17]. Modified virtual colonoscopy (MVC) also known as computerized tomography colonography is a non-invasive form of computed tomography (CT) in which multi-slice CT scanning is performed following the insufflation of CO₂ in to the rectum. MVC is safe and has the advantage over other scanning modalities in that it not only provides information regarding the extent of disease in the bowel lumen and mucosal surface but details the degree of rectovaginal septum and urogenital involvement too.

CT scanning is accessible and available in most hospitals and the modified version uses a lower dose of radiation than conventional virtual colonoscopy and barium enema. Van der Wat's group have devised a classification system based on the findings of MVC aimed at standardizing the radiological reporting of rectogenital, bowel and disseminated endometriosis. Despite the appeal of this technique its accuracy and utility will only become apparent after use on a greater number of patients. Despite the valuable information that can be gained from the above-mentioned modalities, none of them can accurately predict the degree of technical difficulty that will be encountered at the time of surgery.

Fertility prognosis

The relationship between rectovaginal endometriosis and infertility remains controversial. Spontaneous pregnancy rates following rectovaginal surgery have been estimated to be in the region of 50-60% [18]. There is, however, a paucity of data assessing the effect of surgical resection of rectovaginal disease on subsequent fertility outcome. Only one randomised control trial exists in which laparoscopic resection and expectant management of rectovaginal endometriosis-associated infertility were compared. This study by Vercellini and co-workers found that surgery had no benefit in terms of reproductive outcome but did significantly reduce the rate of disease recurrence [19]. Laparoscopic surgery for minimal or mild disease has been shown to improve fertility and pregnancy outcome and whilst several studies have established laparoscopic resection to be an effective method of managing pain symptoms associated with rectovaginal endometriosis, its efficacy in the treatment of endometriosis-associated infertility in the presence of severe disease is uncertain[3] [20] [21].

Management

Whilst medical therapy has shown to be effective for superficial disease, it appears to provide symptom relief for the short term only when used for deep rectovaginal endometriosis. In view of the chronic nature of endometriosis, long term use of medication is required. Approved therapies include gonadotropin-releasing hormone (GnRH) agonists, the androgen, danazol and progestins. There is, however, concern regarding the safety profiles and tolerability associated with long-term use of these agents. The GnRH agonists are characterised by symptoms consistent with oestrogen deficiency and bone demineralisation limiting their usage to six months in the absence of add-back therapy, whilst danazol is complicated by unwanted androgenic effects and lipid profile abnormalities [22]. Medroxyprogesterone acetate has shown equal

efficacy to leuprolide acetate but has the drawback of delayed ovulation following discontinuation of use and adverse effects on bone mineral density [23]. Dienogest is a selective progestin combining 19-norprogestins and progesterone derivatives that is reported to have less of an effect on ovulatory suppression and no clinically relevant androgenic side effects [24]. In a recent randomised control trial, Strowitzki et al reported Dienogest to have equal efficacy to leuprolide acetate at relieving pain associated with endometriosis, in addition, preferable safety profiles and improved tolerability were observed [24]. The applicability of dienogest in the management of deep infiltrating endometriosis is yet to be seen and long term data on its efficacy in this regard are eagerly anticipated. Most authors recommend surgery as the primary treatment modality [2] [3] [21]. There are currently no randomised control trials comparing the efficacy of medical treatment with surgical treatment in the management of rectovaginal endometriosis. The outcome of laparoscopic surgery in the management of rectovaginal endometriosis, whether by conservative or radical means is not well documented in the South African literature thus necessitating a study of this nature. When obtaining informed consent one should not only provide information relating to immediate complications of a procedure but the long term morbidity of the procedure too. Incomplete lesion resection does not appear to be of any benefit, whilst radical resection is associated with major complications including bowel and ureteric injuries [20]. The complication rate after laparoscopic surgery for deep endometriosis is estimated to be 3,4%, rising to 10-22% when colorectal resection is necessary [6]. The debate continues as to which surgical approach is the most appropriate. Level 1 evidence is lacking as to which technique will achieve the greatest symptom relief, with the lowest morbidity rates without negatively impacting on future fertility.

Although there have been several studies looking at this particular subject, the majority of them originate from Europe and North America. There are currently no studies on this topic pertaining to a South African context.

OBJECTIVE

To document the outcomes following laparoscopic surgery in the management of rectovaginal endometriosis, including intra and post-operative complications as well as fertility rates.

DESIGN

A retrospective descriptive study of women undergoing laparoscopic surgery for rectovaginal endometriosis at Vincent Pallotti's Aevitas Clinic between March 2005 and March 2012 was undertaken. Eligibility was established from identifying women from a surgical database based on medical aid coding as well as a review of individual case notes. The cohort was restricted to women with histologically confirmed rectovaginal endometriosis. To ensure anonymity and confidentiality each patient folder was allocated a number. Collected data included age, symptoms, previous medical and surgical history, reproductive history, physical examination findings, type of surgery performed, operative complications, post-operative complications, histopathology, symptoms at follow-up, post-operative reproductive outcomes and duration of follow-up. Patients were contacted telephonically and via an email questionnaire to enquire about any outstanding and follow-up data. Ethics approval

was obtained from the Health Research Ethics Committee at Stellenbosch (S11/11/036) and the study was conducted in accordance with the ethical principles underlying the Declaration of Helsinki.

SETTING OF THE STUDY

The study took place at the Life Vincent Pallotti Aevitas Reproductive Medicine Clinic. The clinic is a private institution affiliated to the Department of Obstetrics and Gynaecology at Stellenbosch University. The team includes four full time reproductive medicine specialists and the clinic serves as a referral centre for infertility treatment and advanced endoscopic surgery.

MATERIALS AND METHODS

The study group included women who were operated on laparoscopically at the Life Vincent Pallotti Aevitas Reproductive Medicine Clinic for rectovaginal endometriosis. A data analysis was performed on all data collected from all the laparoscopic surgeries for rectovaginal endometriosis performed at the Vincent Pallotti Life Aevitas Clinic during the specified time period. General data collected from the patient notes included:

- Patient age
- Gravidity and parity
- Date of surgery
- The presence of dysmenorrhoea prior to surgery
- The presence of dyspareunia prior to surgery

- The presence of non-cyclical pelvic pain prior to surgery
- The patient's fertility status
- The presence of a rectovaginal nodule to palpation
- The past surgical history
- The previous use of medical treatment for endometriosis
- The surgical technique employed
- The histological diagnosis
- The need for conversion to open surgery
- The need for a blood transfusion
- The need for a colostomy
- The occurrence of a ureteric injury
- The development of a rectovaginal fistula
- The occurrence of a bowel injury
- The development of a post-operative pelvic abscess
- The development of urinary retention
- Post-operative fertility outcomes
- Time from surgery to conception
- The need for assisted reproductive technology
- Post-operative symptoms, including dysmenorrhoea, dyspareunia and pelvic pain.

INTERVENTION

Preoperative assessment

The diagnosis of rectovaginal endometriosis was suspected based on history and physical examination. Preoperative imaging consisted of transvaginal ultrasound and in patients with symptoms of dyschezia and cyclical rectal bleeding, a barium enema was performed. MRI was not routinely performed. Informed consent was obtained and included a detailed discussion on the potential complications of bowel surgery, including the possibility of a protective ileostomy. In cases in which a large rectal nodule was detected, a multidisciplinary team including two gynaecological laparoscopists and a colorectal surgeon was involved.

Preoperative bowel preparation

All 112 patients had mechanical bowel preparation (Sodium sulphate 5,685g, polyethylene glycol 59g, potassium chloride 0,7425g, sodium bicarbonate 1,685g, sodium chloride 1,465g/68,96g). This was performed to avoid potential stool soiling of the abdominal cavity following entry in to the bowel lumen. The need for this procedure is debatable and was performed in accordance with individual surgeon's preference. Most of the data concerning mechanical bowel preparation has been extrapolated from randomized trials involving patients undergoing elective colorectal surgery. A review by Cohen and Einarrson suggests that the morbidity is increased when mechanical bowel preparation is used, resulting in increased post-operative infections, extra-abdominal complications and lengthened hospital stay [25]. Furthermore, the Canadian society of Colon and Rectal Surgeons recommends that mechanical bowel preparation is avoided due to a lack of benefit and increased adverse effects, including

electrolyte disturbances with no reduction in anastomotic leakage or surgical site infection [26].

Operative procedure

Following induction of general anaesthesia and placement in the Lloyd-Davies position a Foley catheter was inserted in to the bladder and a uterine manipulator was inserted in to the uterus. A carbon dioxide pneumoperitoneum was achieved via a Verre's needle placed at the umbilicus. High flow insufflation at 20L/min was used. A 10mm port was inserted through a vertical intra-umbilical incision. In patients in whom a previous laparotomy had been performed, an initial subcostal incision and port placement was used. Three further ports were used, including a 5mm port at the right anterior superior iliac crest, a 5mm port at the left anterior superior iliac spine and a further 5mm port in the midline between the pubic symphysis and the umbilicus. Inspection of the abdominal cavity using a step-wise systematic approach was then performed. Dissection was then carried out at the level of the pelvic brim, allowing for adhesiolysis of the ovaries, fallopian tubes and any other visible endometriotic tissue. This was followed by identification of both ureters and assessment for hydronephrosis, which if present was an indication for ureteric stenting. The pararectal spaces were subsequently identified and opened allowing for exposure and isolation of the nodule. Sharp dissection of the nodule was then performed using dissecting scissors .The nodule was separated from the bowel, and then dissected free from the rectovaginal septum with a partial vaginectomy being performed in cases in which infiltration of the posterior fornix was present. In the case of a rectal wall defect, closure was performed laparoscopically with a double layer of vicryl sutures. This was followed by copious irrigation of the pelvis. The anastomosis/suture line was checked using an underwater air leak test.

The performance of a bowel resection was deemed necessary under the following circumstances: cases involving the recto-sigmoid, cases in which there was extensive rectal wall involvement too large for conservative techniques. A covering ileostomy was performed if the colorectal surgeon had any concern regarding the integrity of the anastomosis. It is debatable as to whether this step is seen as a complication or a requirement to avoid unnecessary morbidity in cases demanding complex dissection.

DATA COLLECTION

The files and records (clerking sheets, theatre notes, histology reports, prescription charts and doctor's notes) of all patients suffering from rectovaginal endometriosis, who had undergone laparoscopic surgery for rectovaginal endometriosis between April 2005 and May 2012, were reviewed with permission of the relevant clinic head and hospital superintendent. In addition to this the patients were telephonically contacted and enquiries were made regarding post-operative outcome and outstanding data in the form of a telephonic questionnaire (see Addendum A). A data capturing form was completed containing all the above-mentioned information (see Addendum B).

STATISTICAL ANALYSIS

The data collected was transcribed onto a Microsoft Excel spreadsheet by the principle investigator. The data transcription was then checked by one of the co-authors to ensure accuracy.

Data cleaning was performed on an ongoing basis and again at the end of the study.

Our analysis methods were descriptive in nature and incorporated:

- Frequency tables/distributions with counts and percentages
- 95% confidence intervals for proportions/prevalence rates
- Measures of central location and spread (means and standard deviations if the data was normally distributed, otherwise medians and interquartile ranges if data was not normally distributed)
- 95% confidence intervals for means.
- Data was graphically presented using histograms for continuous data and bar charts for categorical data
- Proportions with small numbers were compared using Fisher's exact test.
- A *p*-value of <0,05 was considered to be significant.

ETHICAL ASPECTS

Approval to conduct this retrospective review was obtained from the Health Research Ethics Committee of Stellenbosch University's Faculty of Medicine and Health

Sciences (S11/11/036). Approval for the audit was also obtained from hospital management at Vincent Pallotti Hospital.

- The study was a retrospective audit.
- There was no deviation from standard patient management.
- Patient confidentiality was not compromised in any way.
- The data was collected personally by the researcher

BUDGET

There was no need to make any budget provision for this study by the Western Cape Department of Health, Aevitas Clinic or Stellenbosch University.

RESULTS

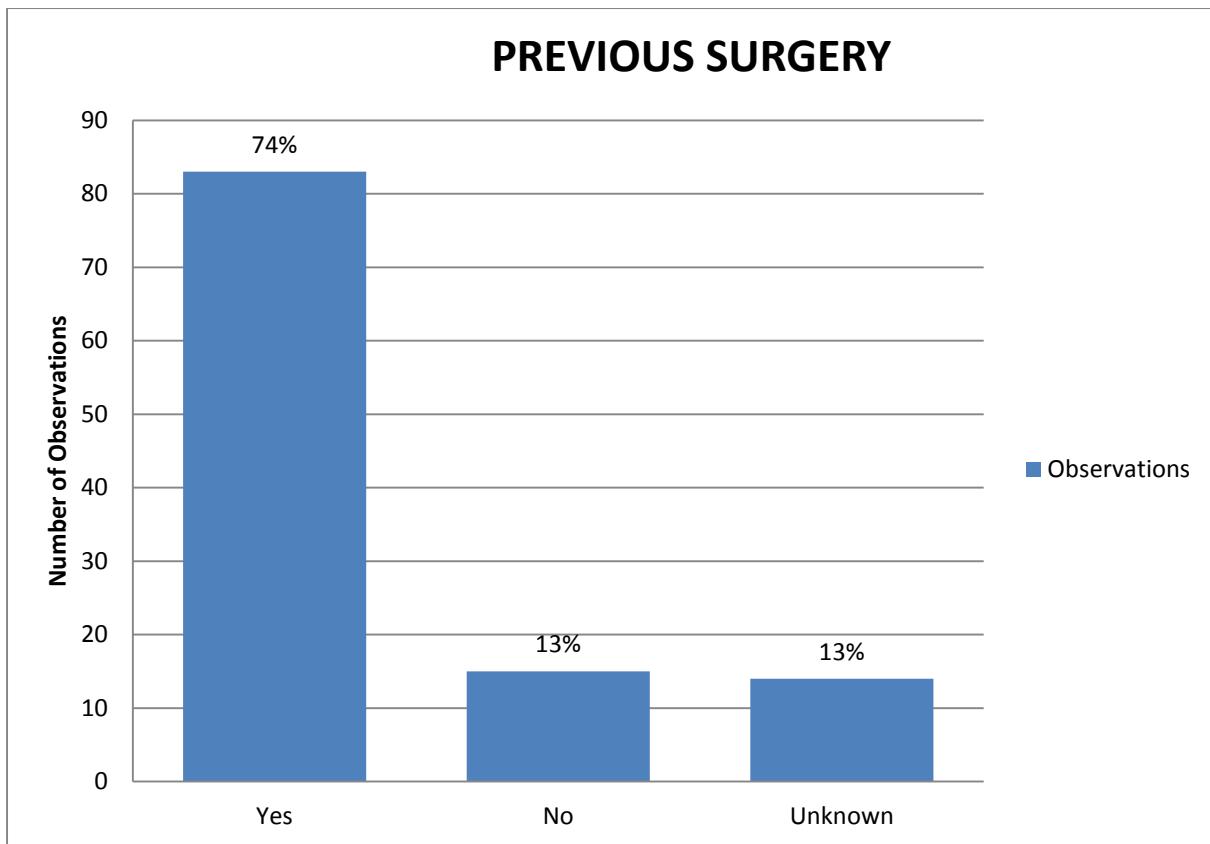
From April 2005 and May 2012 112 women underwent laparoscopic surgery for histologically confirmed rectovaginal endometriosis. The patient characteristics and surgical data including mean operating time and duration of follow-up are shown in Table 1.

Table 1: Table of patient characteristics, surgical data and follow up.

Table 1: Patient characteristics, operating time and follow up	
Age [years; median (range)]	32,7 (20-46)
Mean parity [n (range)]	0,3 (0-3)
Nulliparas [n (%)]	83 (74,1)
Dysmenorrhoea [n (%)]	105 (93,8)
Sexually active in preceding year [n (%)]	108 (96,4)
Dyspareunia [n (%)]	83 (74,1)
Haematochezia [n (%)]	36 (32,7)
Infertility [n (%)]	71 (63,4)
Primary [n (%)]	65 (91,5%)
Secondary [n (%)]	6 (8,5%)
Palpable rectovaginal nodule [n (%)]	58 (51,8)
Previous endometriosis surgery [n (%)]	73 (65,2)
Mean operating time [minutes]	186
Mean follow up time [months]	60

The past surgical history of the study group is depicted in Figure 1. Of the 83 patients that had undergone previous pelvic surgery, 73 (65,2%) had a prior surgical diagnosis of endometriosis. Sixty eight (60,7%) of these were diagnosed at laparoscopy and 5 (4,5%) at laparotomy. Prior total abdominal hysterectomy had been carried out in 5(4,5%) patients in the cohort. A total of 37 (33,0%) patients had received previous medical therapy, consisting of either gonadotrophin-releasing hormone (GnRH) analogues or medroxyprogesterone acetate.

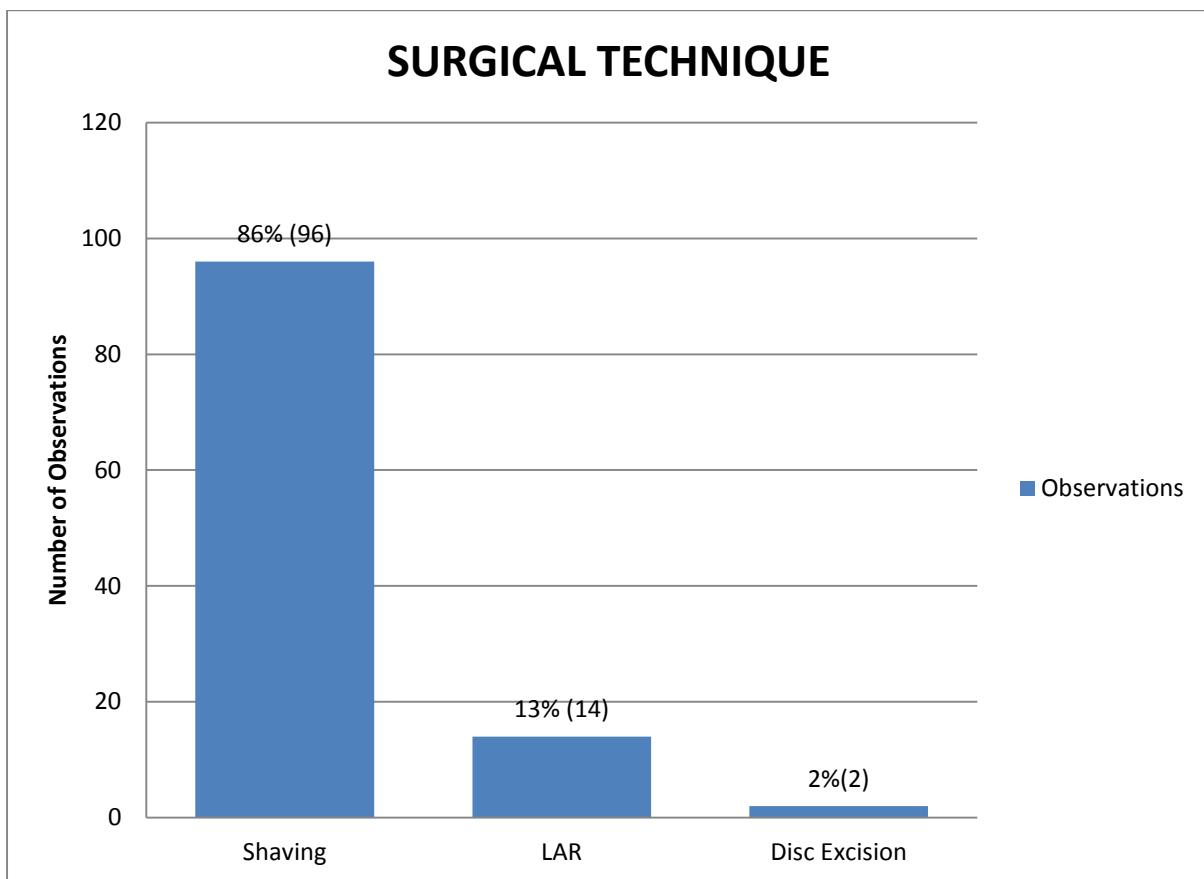
Figure 1: Histogram depicting past surgical history



Surgery:

All of the surgeries were performed laparoscopically and no conversions to an open laparotomy were required. The different surgical techniques are shown in figure 2 below.

Figure 2: Histogram of different surgical techniques employed



*LAR: Lower Anterior Resection

A covering ileostomy was performed in 2 (1,8% of total, 14,3% of bowel resection cases and none of the shaving cases; $p=0,0151$) patients. A partial vaginectomy with subsequent laparoscopic closure was performed in 15 (13,4%) cases. Ureteric stents were placed in 8 (7,14%) cases in which hydronephrosis and extensive ureteric involvement were present. There was 1 (0,9%) case requiring resection of a concomitant endometriotic nodule of the bladder. The uterosacral ligaments were excised during 15 (13,4%) of the surgeries.

Complications

The overall complication rate was 7,1%, with a total of 8 complications in 112 women and is depicted in Table 2.

Table 2: Total complications in 112 women undergoing laparoscopic resection of rectovaginal endometriosis.

Complication	Total	Percentage
Rectovaginal fistula	3	2,68%
Vesicovaginal fistula	0	0%
Abscess formation	1	0,89%
Need for emergency surgery	3	2,68%
Ureteric injury	1	0,89%
Total	8	7,14%

The complication rate varied according to the surgical technique employed as is shown in Tables 3, 4 and 5.

Table 3: Complications in patients operated on using the shaving technique.

Complications from shaving technique	Number of complications (n)	Percentage [n/96=%]
Rectovaginal fistula	0	0.00%
Abscess	1	1.04%
Emergency Re-Operation	2	2.08%
Ureteric Injury	1	1.04%
Bowel Injury	2	2.08%
Total	4	4.17%

Table 4: Complications in patients undergoing bowel resection

Complications from bowel resection	Number of complications (n)	Percentage [n/14=%]
Rectovaginal fistula	3	21.43%
Abscess	0	0.00%
Emergency Re-Operation	1	7.14%
Ureteric Injury	0	0.00%
Total Complications	4	28.57%

Table 5: Comparison of complications according to surgical technique employed

Complications of patients undergoing removal of rectovaginal endometriosis (n = 112)			
Complication	Shaving [n = 96] (%)	Bowel resection [n = 14] (%)	p-value
Pelvic Abscess	1 (1,04)	0	0,87
Rectovaginal fistula	0	3 (21,4)	0,0017
Blood transfusion	0	1 (7,1)	0,13
Ureteric injury	1 (1,04)	0	0,87
Need for emergency surgery post-op	2 (2,08)	1 (7,1)	0,2998

There were no cases of anastomotic leakage, postoperative urinary retention or venous thrombo-embolism in this series.

Symptom recurrence

Repeat surgery was required in 39 (34,8%) patients due to persistence of symptoms. Histologically confirmed endometriosis was only present in 6 (15,4%) of these 39 patients. The need for repeat surgery due to persistent symptoms is shown in table 6.

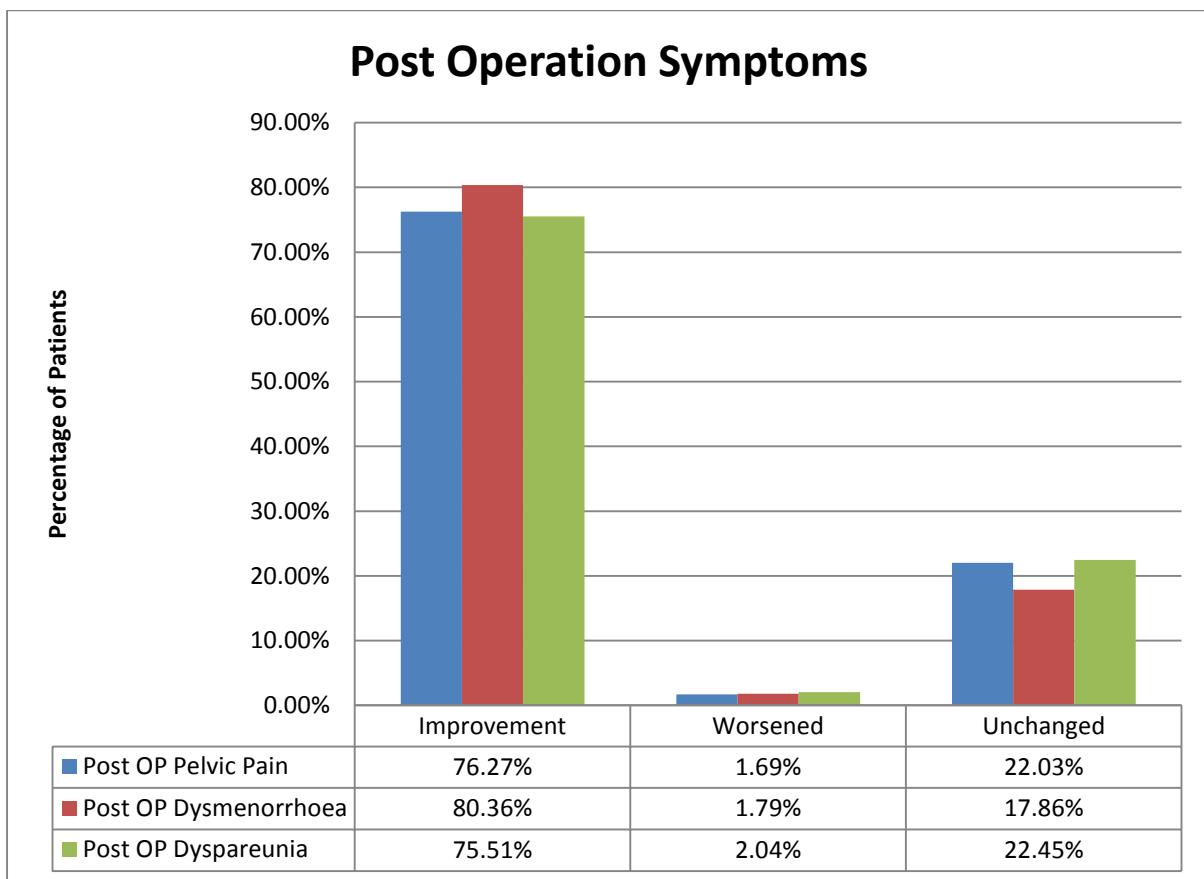
Table 6: Table comparing need for repeat surgery based on initial technique used

Technique employed	Repeat surgery required
Shaving (n=96)	32 (33,3%)
Bowel resection (n=14)	6 (42,9%)
$p=0,34$; OR=0,67 (95% CI: 0,19-2,55)	

Of the two patients that underwent disc excision, 1 (50%) required further surgical intervention due to the persistence of disease.

A total of 66 (58,9%) of the patients responded to the telephonic and electronic questionnaires submitted to them. Of these 66 patients 17 (25,8%) required repeat surgery due to persistent disease.

A total of 60 (90,9%) of the 66 telephonic respondents had experienced non-cyclical pelvic pain prior to surgical intervention. Fifty six (84,8%) of the patients who responded to the questionnaire had reported dysmenorrhoea prior to surgery. Of the respondents, 49 (74,2%) patients had reported suffering from dyspareunia prior to surgery. Figure 3 shows the change in these symptoms following surgery.

Figure 3: Change in symptoms following surgery

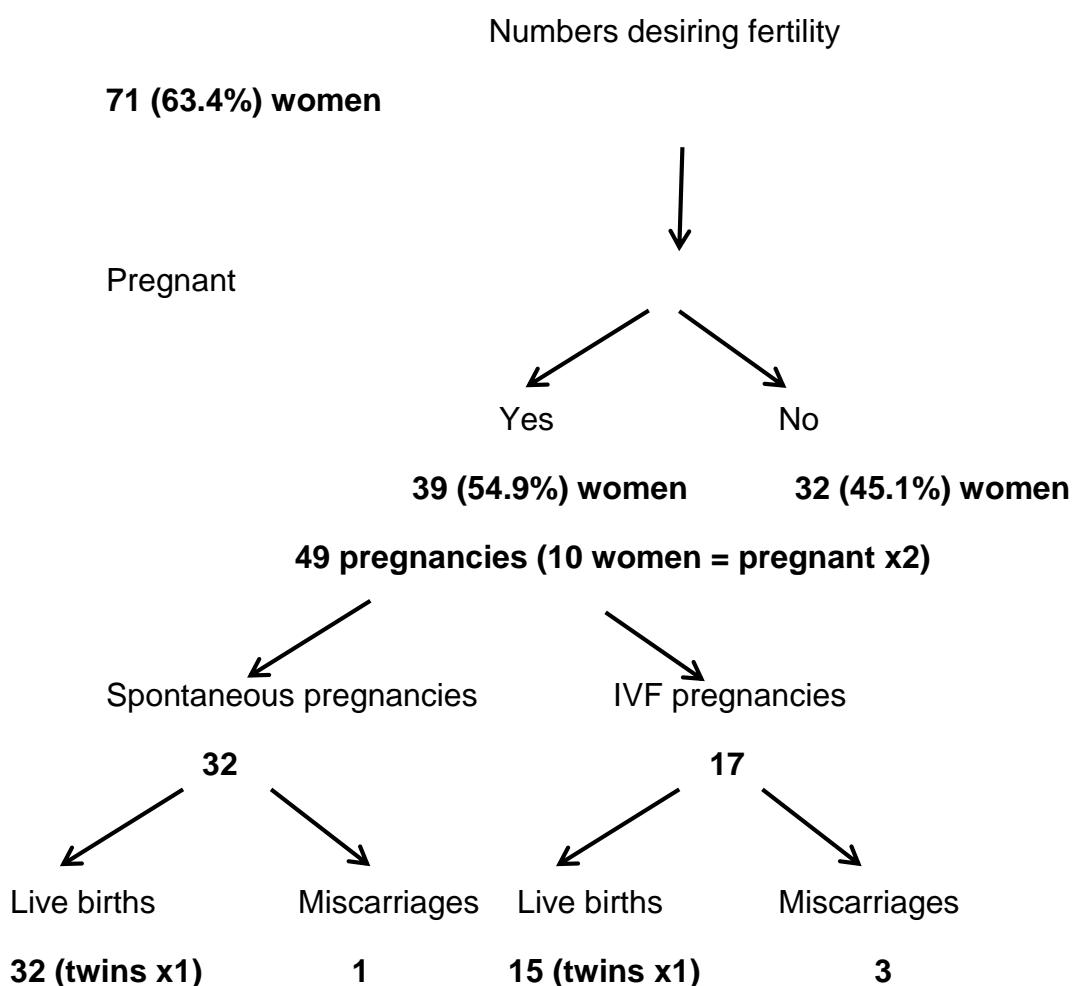
Fertility Outcomes

Of the 112 women operated on during the designated time period, 71 (63,4%) were suffering from infertility and wished to conceive. Of these 71 patients, 65 (91,5%) had primary infertility and 6 (8,55) had secondary infertility. Table 7 shows the fertility outcome based on the type of infertility the patient was experiencing before surgery.

Table 7: Table of fertility outcomes dependent on the pre-operative fertility status of the patient.

Fertility Status	Conceived
Primary infertility (n=65)	37
Secondary infertility (n=6)	2
$p=0,25$; OR=2,64 (95% CI: 0,35-30,75)	

Among the 39 patients who fell pregnant, 27 (69,2%) did so naturally, whilst 12 (30,8%) required IVF procedures. In the cohort of women with primary infertility that fell pregnant (n=37), 26 (70,3%) did so naturally whilst 11 (29,7%) required IVF. Of the 2 women with secondary infertility who fell pregnant, 1 (50%) did so naturally and 1 (50%) did so following IVF. The mean age of the patients that fell pregnant spontaneously was 32,0 years and the mean time to conception in this group was 18,96 (SD 18,4) months. Of the 12 patients falling pregnant following IVF, the mean age was 33,7 years and the mean time to conception was 30,1 (SD 23) months. In total there were 49 pregnancies resulting in 47 live births including 1 set of monochorionic diamniotic twins and 1 set of dichorionic diamniotic twins. There were 33 spontaneous pregnancies and 16 pregnancies as a result of IVF. Figure 7 provides a flow diagram representation of the fertility outcomes following surgery.

Figure 7: Flow diagram of fertility outcome**Table 8:** Fertility outcome according to surgical technique used.

Surgical technique employed	Conceived
Bowel resection (n=8)	4
Shaving (n=63)	35
<i>p=0,527 ; OR=0,8 (95% CI: 0,14-4,72)</i>	

DISCUSSION

Surgical technique: shaving versus bowel resection

Despite numerous publications on the subject of rectovaginal endometriosis there are no generalised guidelines related specifically to its management. Many authors have described the complications associated with the laparoscopic resection of rectovaginal endometriotic lesions; however there is still no consensus regarding which particular surgical technique should be used in the treatment thereof [27].

The surgical management of rectovaginal endometriosis is complex due to the anatomical location, significant inflammatory response and resultant fibrosis characteristic of the disease. Three different surgical techniques have been described in the management of deep infiltrating endometriosis. The so-called shaving technique, which was first described by Donnez, involves separation of the anterior rectum from the loose areolar tissue of the rectovaginal septum, with subsequent excision or ablation of the endometriotic lesion. Rectal resection is never performed and it is believed that the avoidance of deep, lateral dissection allows for preservation of nerves and organs thereby minimising long term bladder, bowel and sexual dysfunction [28].

Full thickness disc excision involves selective resection of the endometriotic lesion with concomitant opening and subsequent closure of the bowel wall. The performance of a bowel resection involves resection of the affected bowel segment followed by anastomosis [29]. Proponents of radical surgery, comprising bowel resection, base

their approach on the belief that incomplete lesion resection may increase the risk of disease recurrence [6]. This, however, has been disputed by authors favouring less aggressive techniques [18]. Those advocating the shaving technique state that evidence supporting complete lesion resection is lacking, whilst radical surgery is associated with unacceptably high morbidity. Anaf found that in cases in which a bowel resection was performed, the margins were not free of disease more than 10% of the time [30].

Multiple attempts at performing systematic reviews allowing for direct comparison between the two surgical techniques have failed due to the heterogeneity of the data within each study [7] [31] [29]. These authors found that the number of different procedures and techniques described in the published reports of the treatment of rectovaginal endometriosis made it difficult to compare the results obtained. Maytham and colleagues were unable to perform an accurate meta-analysis as most of the reports they reviewed lacked sufficient detail describing which complications were associated with a particular procedure [31].

Owing to the variable nature of deep infiltrating endometriosis and the fact that evaluation of outcomes is dependent on both the technique used and the ability of the surgeon it is difficult to perform a truly randomised control trial comparing different surgical approaches and hence much of the literature relies on expert opinion, not necessarily backed up by high quality evidence. Recently Meuleman and co-workers have proposed a checklist in order to standardise clinical and surgical data in an attempt to provide accurate reporting of surgical approaches and outcomes [32]. This

is intended to clarify which approach is the safest and most effective with regards to symptom control and fertility outcomes.

This retrospective study included 112 women operated on for rectovaginal endometriosis using a variety of surgical techniques. The study focused on complications and outcomes after surgery, namely symptomatology and pregnancy rates. The technique employed was decided upon during surgery according to the level of the lesion and the extent of disease. In cases in which a large rectal nodule was detected preoperatively on clinical examination, a multidisciplinary team including a gynaecologist and an experienced colorectal surgeon was involved. It is important to acknowledge that the patients in this series underwent different surgical techniques due to varied disease presentation and the particular technique employed was that deemed appropriate for the individual patient. The performance of a bowel resection was considered necessary in cases where there was concern about the integrity of the bowel following resection of extensive disease. The two cases of covering ileostomy were not viewed as complications but deemed necessary by the attending colorectal surgeon due to the close proximity of the anastomosis to the anal margin. The performance of a protective ileostomy is recommended when there is concern regarding anastomotic leakage and is based on data extrapolated from rectal cancer [33]. Both stomas were closed 3 months postoperatively.

Complications

In this series the overall complication rate was 7,1%, with a total of 8 complications occurring in 112 women.

The two (1,8%) reported cases of breaching of the rectal mucosa both occurred when the shaving technique was performed. This is consistent with rates reported in the literature. This injury is considered to have occurred when the bowel lumen is entered. Both of these injuries were identified and managed intra-operatively using a full thickness laparoscopic suture. The integrity of the repair was then tested using the underwater air leak test. Both Slack et al and Donnez reported that no complications developed nor were any further surgeries were required following this complication [2] [34]. Donnez et al reported this complication to have occurred in 7(1,4%) patients in his series of 500 women undergoing shaving of deep rectovaginal endometriotic nodules [34]. This group of authors believe that injuries limited to the rectal muscular layer in which no breach of the lumen has occurred are not considered to be a complication of the surgery but part of the procedure.

The development of a rectovaginal fistula is a well-recognised complication that usually occurs following resection of nodules in the lower part of the rectum. The development of a rectovaginal fistula occurred in 3 (2,7%) of the total cohort, where all 3 occurred following the performance of a bowel resection equating to a 21,43% rectovaginal fistula rate associated with this particular technique. There were no rectovaginal fistulae arising in the group undergoing a shaving procedure. The difference in incidence of fistula between the two surgical techniques reached statistical significance ($p=0,0017$). The first patient was a 26 year old nullipara who

had undergone a segmental bowel resection with re-anastomosis using a 28 French EEA stapler. This patient had a large rectovaginal nodule, with associated endometriotic deposits on both ureters and obliteration of the Pouch of Douglas. The patient presented on day 17 post-operatively with an offensive yellow-brown vaginal discharge. Further investigation by barium enema revealed the presence of a fistula. The patient was managed conservatively with oral ciprofloxacin and metronidazole and follow-up imaging two months later showed the fistula to have closed. A sigmoidoscopy two months after the surgery showed an intact, well healed anastomosis suture-line. The second case involved a 38 year old nullipara who had experienced severe dysmenorrhoea and cyclical dyschezia of a longstanding duration. A lower anterior resection and anastomosis using a 29 French EEA stapler was performed following the finding of an extensive rectovaginal nodule with near-complete circumferential involvement of the rectum in close proximity to the anal margin. This patient presented 2 weeks post-operatively with stool draining per vagina. Further surgical intervention was delayed for 3 months to allow for the inflammatory process to subside. An attempt to close the fistula 6 months after the initial surgery was unsuccessful and a defunctioning colostomy was performed. Unfortunately numerous further procedures to close the fistula have failed and the colostomy is still required. The development of a rectovaginal fistula occurred in a third patient who had undergone a bowel resection for a low rectal nodule. This complication ensued despite the performance of a protective ileostomy. All three cases that arose in this series developed in patients in whom large rectal nodules were present, where resection and opening of the vagina had occurred. These findings support the view held by some authors that when colorectal resection and vaginal opening are undertaken concomitantly, a protective temporary ileostomy or colostomy should be performed [6]

[29] [35] [36]. Donnez et al reported a 0,06% rate of rectovaginal fistula in 3298 patients that were operated on using the shaving technique only [28]. Meuleman et al found that rectovaginal fistulae developed in 55 (2,7%) women out of 2036 undergoing bowel resection whilst this complication was reported to have occurred in 12 (0,7%) of the 1799 patients in whom a mixed surgical approach was used [29]. In a study by Kondo et al including 568 patients, 9 (1,6%) patients developed rectovaginal fistulae including 3 (17,6%) following disc excision, 3 (1,6%) following shaving and 2 (8%) following a bowel resection [6]. Slack reported four (3%) major complications in a retrospective cohort study including 128 women undergoing laser excisional surgery, three of which were rectovaginal fistulae [6] [2]. All three of these patients required temporary colostomies. They concluded that where possible a conservative approach and avoidance of rectosigmoid resection be attempted. In a study by Ruffo and co-workers 14 rectovaginal fistulae occurred in 436 women undergoing laparoscopic bowel resection for deep infiltrating intestinal endometriosis, amounting to an overall incidence of 3,2%. They recommend that intestinal surgery is performed in all cases in which bowel stenosis is present and when lesions larger than 2cm are suspected, but emphasise that the approach is individualised according to the patient's symptoms and desires [36]. In Darai's evaluation of complications associated with laparoscopic colorectal resection, a 10% (rate for) major complication rate was reported [37]. This included the development of three (7,5%) rectovaginal fistulae and one (2,5%) pelvic abscess. The fact that no rectovaginal fistulae occurred following the use of the shaving technique in this cohort is consistent with international data [28]. The rate of fistula development after bowel resection seen in this series is higher than that quoted in previously mentioned studies, however, a possible explanation for this could be the small sample (n=14) in which radical bowel resection was undertaken[6] [28] [29].

One (0,9%) case of ureteric injury was noted in this series and there was no statistical difference in its occurrence related to the technique used ($p=0,87$). The patient, who had undergone a shaving procedure and partial vaginectomy for a large rectovaginal nodule with bilateral uterosacral involvement, presented 5 days after surgery draining urine via a peritoneal drain that was inserted following extensive dissection. Initial management involved the insertion of a JJ stent, however the patient continued to leak urine in to her peritoneal cavity. A subsequent vesico-ureteric reimplantation was performed and a good outcome was achieved. This case was one of the three emergency repeat procedures reported in the results section. In the aforementioned study by Donnez, 4 (0,8%) cases of ureteric injury and no cases of rectovaginal fistula occurred [34]. Three of the cases of ureteric injury occurred secondary to thermal damage and presented 6-8 days after surgery with lower abdominal pain. This complication is particularly associated with extensive adhesiolysis in cases where widespread ureteric involvement exists. Kondo et al reported 6 (1,0%) cases of post-operative ureteric fistulae, all managed by cystoscopic stent placement for a period of three to six months [6]. In Maytham's prospective study two patients suffered intra-operative ureteric injuries, which were both diagnosed and repaired at the time of surgery [31].

The development of one post-operative abscess seen was not related to anastomotic dehiscence or a rectal perforation but secondary to the concomitant drainage of an ovarian endometrioma during a shaving procedure for a deep rectovaginal nodule. This patient, who comprised one of the three patients in whom emergency post-

operative surgery was required, presented 10 days after surgery with pyrexia and lower abdominal pain. After a poor response to intravenous antibiotics a laparoscopy was performed. This revealed an abscess collection adjacent to the ovary. The collection was drained and the patient made an uneventful recovery. Although this cohort did not have any cases of anastomotic leakage, an anastomotic leak is an early post-operative complication associated with significant morbidity and requires the performance of a protective stoma as part of its management. According to a review by De Cicco et al this potentially life-threatening complication occurs in 4,7% cases in which a colorectal resection is performed [7]. Ret Davalos and co-workers found that the incidence of anastomotic leakage increases to 15% when low rectal resection is carried out [38]. In the light of these findings an expert panel have recommended that discoid excision be attempted for all rectosigmoid and rectal nodules [18].

Emergency postoperative surgery was required in two patients that underwent a shaving procedure and one in whom a bowel resection was performed. This difference did not reach statistical significance ($p=0,2998$). Two of these cases are those alluded to in the text above, whilst the third emergency post-operative procedure was performed for post-operative bleeding. The patient who had undergone a bowel resection developed a tachycardia and hypotension associated with a reduction in her haemoglobin level within hours of surgery. At repeat laparoscopy a bleeding vessel on the pelvic sidewall was identified and cauterised. No further intervention was needed and the patient made an uneventful recovery. Ford and colleagues assessed quality of life and complications following radical resection of rectovaginal endometriosis [39]. Five (10,4%) of the patients quoted in their study required blood transfusions.

Kondo found that complication rates were significantly increased when any form of rectal surgery was undertaken (9,3% overall) with a statistical difference observed between complication rates following bowel resection and those seen after a shaving procedure ($p < 0,01$) [6]. Of note this study quoted a 24% major complication rate following bowel resection, however, this group included only 25 patients with wide confidence intervals ranging from 7-40%. Despite being a retrospective study, this data may provide an accurate reflection of the true incidence of complications arising after laparoscopic surgery for deep infiltrating endometriosis when a variety of techniques are used. In Donnez's study including 500 patients operated on by the shaving technique, an overall major complication rate of 3,2% was reported, however, patients who had undergone previous surgery for endometriosis were excluded from this study so it is difficult to comment on the applicability of this data to our setting where 67% of patients had undergone some form of prior surgery for endometriosis [34]. These low complication rates do, however, make a compelling argument in favour of less aggressive techniques and the authors emphasise the point that endometriosis surgery is not oncology surgery and hence does not require the same radical approach. Whilst the decision to perform colorectal resection is supported by the findings of significantly improved postoperative pain symptoms and quality of life, the performance of a nodule excision only appears to be a valid approach too as surgical morbidity is higher following colorectal resection and the evidence that it results in microscopic complete resection and absolute prevention of post-operative pain recurrence is lacking [27]. Although the numbers in our cohort are too small to allow for direct comparison of the different surgical techniques, it would appear that shaving is associated with fewer complications, however, this should be viewed in the light that

bowel resections were performed in cases involving more extensive and severe disease. Consistent with this is a recent expert opinion statement that “disc excision should at least be attempted for all rectosigmoid and rectal nodules”, furthermore “bowel resection should be contemplated whenever a defect of >50% of its circumference is present or when the muscularis defect is >7-8cm long” [18].

Symptom recurrence

The primary aim of surgery for deep infiltrating endometriosis is aimed at pain relief and improvement in quality of life factors. It is thus prudent to report on the response of symptoms to surgery. A total of 66 (58,9%) patients responded to the telephonic questionnaire enquiring about changes in symptoms experienced after surgery. This questionnaire comprising questions on non-cyclical pain, dysmenorrhoea and dyspareunia was not based on a visual analogue scale or grading system but purely on the patient's subjective experience of pain symptoms. It can be argued that one of the shortcomings of this study could be the fact that pre-operative pain symptoms were not objectively quantified according to any validated grading system. It is, however, important to consider that pain is subjective and influenced by many external factors and any improvement in this symptom can be considered a successful outcome for the effected individual. Furthermore, even when visual analogue scales are used to rate pain symptoms, in a retrospective study recall bias is a significant factor influencing the patient's response.

The median follow-up time in this study was 60 months which provided sufficient time to determine long term outcomes following surgery, however, the poor response rate to the telephonic questionnaire is concerning. Numerous reasons for the poor

response and difficulty in contacting patients include emigration, change of contact details, and the fact that as a referral centre many patients came from varying parts of Southern Africa and their contact details were limited to a contact address and number for the time of treatment. There is also the possibility that patients whom experienced a worsening of symptoms or post-operative inability to conceive were less willing to respond to our attempts at contact. Conclusions such as these are merely suppositions and not based on any sound evidence.

Of the 66 patients who did reply, it was found that 45(76,3%) experienced a subjective improvement in non-cyclical pain symptoms whilst only 1 (1,7%) patient reported worsening of this symptom. The same improvement in symptoms was found with regard to dysmenorrhoea and it was the same patient who experienced a worsening of her dysmenorrhoea. This patient had undergone previous surgery for endometriosis and was found to have severe disease extending from an obliterated Pouch of Douglas to the pelvic sidewalls and round ligaments bilaterally. She also had bilateral uterosacral ligament involvement and despite the surgery and post-operative use of 3 monthly medroxyprogesterone acetate injections ended up having a hysterectomy due to unbearable pain.

Dyspareunia as a symptom showed a poorer response to the surgery than the other two symptoms. The reasons for this are unclear but may in part be attributed to the fact that 51 (77,3%) of the respondents had undergone prior endometriosis surgery. Of the ten patients who reported no improvement in their dyspareunia and the 1 who reported worsening, only 1 (9,1%) had not had prior endometriosis surgery. The role

of adhesion formation secondary to repeat surgeries and its impact on pain is a possible explanation for this phenomenon. Meuleman et al reported a significant improvement in post-operative symptoms at follow up (median follow up time of 27 months; p value <0,0001) following segmental bowel resection and reanastomosis [32]. They also reported an improvement in all the aspects of the Quality of Life assessment (p -value <0,0001). De Cicco and colleagues reported relief from overall pain in 81,5% of patients undergoing bowel resection, with 37,8% reporting an improvement in dysmenorrhoea, 33,3% experiencing improvement in deep dyspareunia and 43,8% reporting an improvement in chronic pain [7]. Dubernard found a significant improvement in dysmenorrhoea, dyspareunia and painful defaecation. They also reported that no difference was observed between women with or without post-operative complications [40]. These results were supported by a recent study by Bassi evaluating the quality of life of patients undergoing laparoscopic resection of the rectosigmoid for treatment of deep infiltrating endometriosis [41] in which greater than 90% of patients experienced an improvement in pain symptoms and quality of life scores after surgery.

Finally, the placebo effect of surgery on pelvic pain should not be underestimated. Based on the findings of two randomised control trials comparing the effect of diagnostic laparoscopy alone with that of therapeutic laparoscopy it was found that there was a significant placebo effect in the region of 30%-40% when this surgery was performed [42] [43]. Medical therapy has also been found to have a similar effect, however, the details of this phenomenon are beyond the scope of this discussion. This observation should be borne in mind when counselling patients regarding the pros and cons of surgery and when discussing the patient's expectations of the surgery.

Thirty nine (34,8%) patients required repeat surgery due to persistent or recurrent symptoms. Interestingly, 17 (25,8%) of the 66 respondents required repeat surgery due to persistent pain, which may provide a more accurate indication of the long term response to surgery. Of the 46 patients who were lost to follow up, it is unclear how many may have undergone repeat surgery in different centres.

Numerous different criteria have been used to define disease recurrence, namely symptom recurrence based on history, recurrence on imaging, recurrence based on visual inspection during surgery and histological diagnosis. In only 6 (15,4%) cases of repeat surgery was there histologically confirmed disease recurrence which again lends support to the previously mentioned belief that symptom recurrence could possibly be secondary to the severe adhesions that develop after repeated surgeries in deep infiltrating disease. This aspect of surgery for deep infiltrating endometriosis appears to be poorly documented in the literature and according to Koninckx et al, a randomised controlled trial currently under preparation has found adhesions to be more severe than expected in most women [18]. The contribution of intra-abdominal pelvic adhesions to pelvic pain is controversial and there is a paucity of well- designed trials concerning the effect of adhesions on chronic pelvic pain. Whilst adhesions may be a cause of pain due to the resultant anatomical distortion and peritoneal stretching they cause, the few prospective trials involving controls have not displayed any difference in the incidence of adhesions in patients with pelvic pain compared to those without it [44]. In contrast to this, a recent meta-analysis by ten Broek and colleagues found that in patients with chronic post-operative pain following previous surgery,

adhesions were identified as the most likely cause of the pain in 57% [45]. Despite this, the evidence supporting adhesiolysis is lacking. A randomised control trial comparing the outcome of laparoscopic adhesiolysis with diagnostic laparoscopy only, found no significant difference in the two interventions at providing pain relief [46]. A possible explanation for this could be the development of new adhesions following adhesiolysis. Swank's findings have provided much of the data for practitioners abandoning routine adhesiolysis for chronic pelvic pain. Critics have, however, suggested that this study had inherent design flaws and should therefore not be viewed as the definitive reason to stop considering adhesiolysis in patients with chronic pelvic pain [43].

A further factor to consider in patients with endometriosis, is whether the pain experienced is caused by the endometriosis itself, due to adhesions secondary to the presence of endometriosis or due to other factors such as neuropathic pain or physiological changes. In view of the high rate of post-operative adhesion formation and the conflicting data surrounding its effect on pelvic pain, it appears that there is a growing body of research investigating ways to reduce and prevent the development of adhesions [44].

There was no statistical difference in the need for repeat surgery between women undergoing shaving and those undergoing bowel resection ($p=0,34$, $OR=0,67$; $CI:0,19-2,55$). Donnez and Squifflet reported an overall recurrence rate of 7,8% following the shaving technique whilst De Cicco quoted clinical recurrence, surgical recurrence and histological recurrence rates after bowel resection of 23,8%, 19,4%

and 13,9% respectively [7] [34]. In series containing longer follow up periods, higher rates of disease recurrence were observed [29]. Kavallaris, however, reported that there were significant reductions in pain and dysfunctional symptoms at 94 month follow up [47]. Fedele reported a re-operation rate at 5 years of 36% [4]. It is evident from a number of sources that in women not desiring further fertility and in those not concerned by amenorrhoea, the use of post-operative hormonal treatment, either in the form of progesterone or the combined oral contraceptive, is advocated [48] [34] [49]. This was difficult to apply to our study due to the large number of women (63,3%) desirous of conception. It also remains to be seen what impact dienogest will have on the progression of post-operative symptoms.

Pregnancy outcomes

The 54,9% overall pregnancy rate seen in this study is in keeping with the 50-60% spontaneous pregnancy rate quoted in a recent authority-based review on the subject[18]. What is reassuring is the fact that 27 (69,2%) of these patients fell pregnant spontaneously. Twelve (48%) of the 25 patients that underwent IVF/ICSI following surgery fell pregnant. Unfortunately 15 (21,1%) of the 71 (63,4%) patients desiring future fertility were lost to follow-up. The reasons for this dropout rate have been discussed in the previous section. There was no statistical difference in conception rates between women undergoing shaving and those undergoing bowel resection ($p=0,527$; OR=0,8; CI: 0,14-4,72). Women with primary infertility prior to surgery had a 2,64 greater chance of successful fertility outcomes following surgery than those with secondary infertility. This difference, however, was not statistically significant ($p=0,25$; CI: 0,35-30,75).

In a prospective study evaluating pregnancy rates after bowel resection, a significantly higher pregnancy rate occurred amongst women undergoing laparoscopic bowel resection than in those operated on by laparotomy (57,6% versus 23,1%) [50]. This is further supported by the findings of a prospective study by Darai et al from Paris [51]. They found that the route of surgery was the sole factor affecting spontaneous pregnancy rate and that spontaneous pregnancy rates were higher in the laparoscopy arm of the study.

Donnez's group reported that 221 (57%) out of 388 patients desiring fertility conceived naturally over a 2-6 year follow up period [34]. Sixty four percent of the patients that underwent IVF became pregnant giving an overall pregnancy rate of 84%. When analysing surgical outcomes for deeply infiltrating endometriosis, Meuleman et al reported varying pregnancy rates ranging between 23,5 and 57,1% of which 45% followed spontaneous conception [29]. It is the view of these authors that the fertility wishes of patients suffering from deep infiltrating endometriosis is often underestimated. Interestingly, of the 71 patients suffering from infertility in our series, 67 (94,4%) experienced either cyclical pelvic pain, dyspareunia or both and the primary indication for surgery was for pain management. Darai and colleagues reported a 45,5% overall pregnancy rate in a series of 34 women undergoing laparoscopic colorectal resection for endometriosis [52]. There were 9 (75%) pregnancies arising from spontaneous conception. The major determinant for a successful outcome was patient age, hence their recommendation that immediate IVF be considered in women older than 35 undergoing colorectal resection. A recently published systematic review by Vercellini et al found that 1 in 4 patients undergoing

radical resection conceived spontaneously [53]. They quote a mean post-operative conception rate of 39%, which decreased to 24% in infertile patients desiring spontaneous conception. This, however, according to the authors is believed to be an overestimate as the literature was not always clear in terms of pre-operative fertility status and post-operative mode of conception. The authors highlight the fact that there is a lack of good quality trials comparing the effect of surgery and expectant management on fertility rates. To reiterate, the overall pregnancy rate of 54,9% seen in the study is comparable with larger international studies.

STUDY LIMITATIONS

This was a retrospective cohort study and thus has certain, associated intrinsic limitations. The investigator has no control over exposure or outcome assessment and relies on the record keeping of others. There is a lack of a control group.

One other limitation included the poor response to the telephonic questionnaire meaning that the section on symptom recurrence and pain relief lost some of its impact.

Furthermore, the surgical technique employed did not follow strict criteria but was adapted to each individual case. It must be borne in mind that deep infiltrating endometriosis has a wide range of clinical and anatomical presentations which can explain the varying therapeutic approaches used in its management.

CONCLUSION

To our knowledge this is the first study assessing surgical outcomes in the management of deep infiltrating endometriosis from South Africa. These outcomes are in keeping with complication rates quoted in the international literature. Most of the surgery was performed using the shaving technique, in keeping with international trends, whilst fourteen cases required the performance of a segmental resection owing to extensive disease. Deep infiltrating endometriosis is a complex disease and its management is challenging. In trained hands laparoscopic surgery is a valid treatment option in the management of rectovaginal endometriosis, however patients should be fully counselled and aware of the inherent risks associated with this type of surgery. Due to the technical nature of this type of surgery it should be performed by experienced surgeons in centres carrying out high volumes of these procedures. Patients who are desiring fertility and suffering from the debilitating effects of this disease should be advised not to delay surgery until after their reproductive years.

There is a real need for a randomised controlled trial to evaluate which surgical approach is optimal in managing rectovaginal endometriosis. An investigation on the impact of adhesions on symptom recurrence is also warranted.

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ADDENDUM A: Ethics Approval



Approval Notice New Application

08-Mar-2012
GOODING, Mattew Simon

Protocol #: S11/11/036

Title: Laparoscopic surgery for rectovaginal endometriosis: Is it safe? A retrospective South African review from a single unit.

Dear Dr Mattew GOODING,

The New Application received on 14-Nov-2011, was reviewed by members of Health Research Ethics Committee 2 via Expedited review procedures on 27-Feb-2012 and was approved.

Please note the following information about your approved research protocol:

Protocol Approval Period: 27-Feb-2012 -27-Feb-2013

Please remember to use your **protocol number** (S11/11/036) on any documents or correspondence with the REC concerning your research protocol.

Please note that the REC has the prerogative and authority to ask further questions, seek additional information, require further modifications, or monitor the conduct of your research and the consent process.

After Ethical Review:

Please note a template of the progress report is obtainable on www.sun.ac.za/rds and should be submitted to the Committee before the year has expired. The Committee will then consider the continuation of the project for a further year (if necessary). Annually a number projects may be selected randomly for an external audit.

Translation of the consent document in the language applicable to the study participants should be submitted.

Federal Wide Assurance Number: 000001372

Institutional Review Board (IRB) Number: IRB0005239

The Health Research Ethics Committee complies with the SA National Health Act No.61 2003 as it pertains to health research and the United States Code of Federal Regulations Title 45 Part 46. This committee abides by the ethical norms and principles for research, established by the Declaration of Helsinki, the South African Medical Research Council Guidelines as well as the Guidelines for Ethical Research: Principles Structures and Processes 2004 (Department of Health).

Provincial and City of Cape Town Approval

Please note that for research at a primary or secondary healthcare facility permission must still be obtained from the relevant authorities (Western Cape Department of Health and/or City Health) to conduct the research as stated in the protocol. Contact persons are Ms Claudette Abrahams at Western Cape Department of Health (healthres@pgwc.gov.za Tel: +27 21 483 9907) and Dr Helene Visser at City Health (Helene.Visser@capetown.gov.za Tel: +27 21 400 3981). Research that will be conducted at any tertiary academic institution requires approval from the relevant hospital manager. Ethics approval is required BEFORE approval can be obtained from these health authorities.

We wish you the best as you conduct your research.

For standard REC forms and documents please visit: www.sun.ac.za/rds

If you have any questions or need further help, please contact the REC office at 0219389207.

Included Documents:

Application

ICF

Declaration

Protocol

Synopsis
CVs

Sincerely,


Merinda Davids
REC Coordinator
Health Research Ethics Committee 2

LAPAROSCOPIC SURGERY FOR RECTOVAGINAL ENDOMETRIOSIS: IS IT SAFE?

SAMPLE DATA COLLECTION FORM

STUDY NO._____

DATE OF INTERVIEW ____/____/201____

INTERVIEWER:

PATIENT INFORMATION:

- **Age**_____
- **Gravidity** _____ **Parity** _____
- **Date of surgery** ____/____/____
- **Indication for surgery**_____

- **Previous pelvis surgery? Yes/No**
If yes, when & why?_____

- **Previous medical treatment for endometriosis? Yes/ No**
If yes, what?_____

- **Surgical technique** 1. **Shaving**_____
 2. **Excision**_____
 3. **Segmental resection**_____

- **Histology findings:**_____

- **Difficulty with dissection/nature of disease:**_____

PRIMARY OUTCOMES

INTRAOPERATIVE

- **Conversion to laparotomy? Yes/No**_____

- **Need for blood transfusion? Yes/No**_____

- If yes, no. of units _____
- Need for colostomy? Yes/No
If yes, why? _____
- Ureteric injury? Yes/No
- Bowel injury? Yes/No _____

POSTOPERATIVE

- Need for re-operation? Yes/No
- If yes, why?

- Rectovaginal fistula formation? Yes/No
- Pelvic abscess formation? Yes/No
If yes, how managed?

- Vesico-vaginal fistula formation? Yes/No
- Urinary retention? Yes/No
If yes, how managed?

- Febrile morbidity? Yes/No

SECONDARY OUTCOMES

- Pregnant within 1 year of surgery? Yes/No
If yes: spontaneously__ or assisted reproductive technology__

- Average length of hospital stay (days)_____
- Average duration of surgery (hours)_____
- Symptoms on followup: 1). Improved post-surgery?
2). Unchanged?
3). Worsened?

TELEPHONIC INFORMATION AND CONSENT FORM:

TITLE OF RESEARCH PROJECT: Laparoscopic Surgery for rectovaginal endometriosis: Is it safe and effective? : A retrospective South African review from a single unit

REFERENCE NUMBER: S11/11/036.

ADDRESS: Department of Obstetrics and Gynaecology, Tygerberg Hospital, Francie van Zyl Drive, Parow 7505

TELEPHONE NUMBER: 082 330 3211

Good day Mrs/Miss X.

My name is Matthew Gooding and I am currently a registrar/trainee in Obstetrics and Gynaecology at Stellenbosch University.

I am conducting a study in to the complications, symptom relief and pregnancy rates following laparoscopic/keyhole surgery for rectovaginal endometriosis in patients operated on at The Vincent Pallotti Hospital between the period of 2005-2011.

Your participation is **entirely voluntary** and you are free to decline to participate. If you say no, this will not affect you negatively in any way whatsoever. You are also free to withdraw from the study at any point, even if you do agree to take part.

This study has been approved by the **Health Research Ethics Committee at Stellenbosch University** and will be conducted according to the ethical guidelines and principles of the international Declaration of Helsinki, South African Guidelines for Good Clinical Practice and the Medical Research Council (MRC) Ethical Guidelines for Research. Study number S11/11/036.

You have been chosen as you were operated on for rectovaginal endometriosis at Vincent Pallotti in 200?. I am telephonically interviewing all the women that were operated on for rectovaginal endometriosis at Vincent Pallotti between 2005-2011.

There are no personal benefits for you to be gained from this research, but this research may be of benefit to future patients.

There are no risks involved in your participation.

All the information collected will be treated as confidential and your identity will remain anonymous. Myself and Prof Igno Siebert will be the only people with access to the information.

You will not receive any financial reward for participating and equally there will be no costs involved for you, if you do take part.

Should you have any questions or would like to know more about this research, you can contact me on 082 330 3211.

You can contact the Health Research Ethics Committee at 021-938 9207 if you have any concerns or complaints that have not been adequately addressed by your study doctor.

You will receive a copy of this information and consent form for your own records.

Declaration by investigator

I (name) declare that:

- I explained the information in this document to
- I encouraged her to ask questions and took adequate time to answer them.
- I am satisfied that she adequately understands all aspects of the research, as discussed above
- I did/did not use an interpreter.

Signed at (place) on (date)
2011.

Study patient no._____

Questions directed to patient

1). Following the surgery, did you find your pain symptoms had improved, worsened or stayed the same? _____

2). Regarding painful intercourse, after the surgery did this improve, worsen or remain the same?

3). Regarding pain during your menstruation/periods. Has this improved, worsen or remain the same?

4). Did you fall pregnant within the first year following the surgery? And if so, was this a spontaneous pregnancy or was assisted reproductive technology/fertility treatment used?

DRS AEVITAS

Ingelyf / Incorporated



Professor TF Kruger
MBChB, MPharMed, MMed (O+G)
FCOG (SA), FRCOG (London), MD.

Dr TI Siebert
MBChB, MMed (O+G)
LKOG / FCOG (SA)

Dr JP van der Merwe
MBChB, MMed (O+G)
LKOG / FCOG (SA)

Fertiliteits Spesialiste & Ginekoloë / Fertility Specialists & Gynaecologists

PR No 1605925 / 7700539 VAT 4410145801

26 January 2012

University of Stellenbosch

Dear Colleague

Aevitas Clinic is an accredited training unit with an accredited training posts for reproductive gynaecologist. We also train scientists and are also an accredited unit for the training of the registrars in obstetrics and gynaecology of the University of Stellenbosch. We do about 5 – 6 endometriosis cases per week which adds up to about 20 – 30 operations per month. We are a referral unit for patients throughout South Africa with severe rectal endometriosis.

Matt Gooding is a registrar rotating through our unit and doing research with me.

Kind regards

Prof TI SIEBERT

ACKNOWLEDGEMENTS

I would like to express my gratitude to my supervisor, Prof Igno Siebert for his helpfulness in gathering data, his academic advice and his friendly support. To Prof Thinus Kruger, Dr Kobie van der Merwe, Dr Thabo Matsaseng and Prof Hennie Botha for their invaluable help. I would also like to thank Dr Cathy Cluver for guidance in the initial stages of the study.

To both Roger Spencer and Dr Justin Harvey for helping with the statistical analysis and to Prof Wilhelm Steyn for last minute statistical support.

I would also like to thank the helpful administrative staff at the Aevitas Clinic for helping to find and access patient folders.

I am very grateful to the patients who responded to my questionnaires. This study would not have been possible without them.

Finally, I would like to thank my wife, Caroline, for her unwavering support and to my daughter Olivia for sleeping through the night!