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Editorial

Gynecologic Cancer Research at a Crossroads

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Gynecologic cancer research is currently at a crossroads. Recent changes in the NCI’s approach to clinical cancer research have resulted in a complex makeover of the federal clinical research community. This was prompted by perceived inefficiencies in the existing model, as well as the realities of stagnant (or declining) funding for the foreseeable future.

Perhaps more than any other discipline, gynecologic cancer research has been dramatically affected by these changes. The Gynecologic Oncology Group (GOG) was founded in 1971, an outgrowth of President Nixon’s “War on Cancer” and the growing recognition in that era of gynecologic oncology as a separate and distinct subspecialty. In the 43 years since, the GOG has been responsible for virtually every step forward in the treatment of gynecologic cancers. The following represent just a handful of the GOG’s findings: the efficacy of combination chemotherapy with paclitaxel and cis- or carboplatin for ovarian cancer, along chemotherapy with paclitaxel and cis- or carboplatin for ovarian cancer, with intraperitoneal administration of those drugs; the modern concept of surgical staging for endometrial cancer, which was adopted by the International Federation of Gynecology and Obstetrics (FIGO) in 1988, and revised in 2010; the use of chemotherapy in combination with radiation to improve the survival of women with locally advanced cervical cancers; the feasibility of minimally invasive surgery for gynecologic cancers; and most recently, identifying agents such as bevacizumab, which can be targeted at the molecular level of gyn cancers.

However, as of March, 2014, the GOG will no longer exist. The NCI has consolidated the nine existing cooperative group organizations in its’ clinical research portfolio into five new groups. The GOG has been combined with the Radiation Therapy Oncology Group (RTOG) and the National Surgical Adjuvant Breast/Bowel Program (NSABP) to form the NRG, which will have responsibility for all the studies formerly handled by those three so-called “Legacy” groups. NRG leadership will be a rotating co-Chairmanship made up of the chairs of the three legacy groups. The former GOG office in Philadelphia and statistical office in Buffalo will take over management of the NRG as a whole.

This reorganization was based on the Institute of Medicine’s (IOM) 2010 analysis of NCI clinical research. This report was highly critical of the inefficiency of the process by which the cooperative groups carry out their trials. Historically, relatively few U.S. oncologists have even participated in clinical research, mostly from academic institutions. Community oncologists, who see the great majority of American cancer patients, have generally been reluctant to participate in federal clinical research due to the bureaucratic burden and low reimbursement. As a result, more than half of the trials initiated by the NCI’s cooperative groups do not meet their accrual goals and are closed, generating no data. Further, the attendant bureaucracy ensures that each new Phase III trial startup costs well over a million dollars, which becomes a total loss when a trial closes early. The IOM made a number of recommendations for improving and streamlining that process, including the consolidation of the groups.
The GOG was, however, an exception to this poor showing. The GOG has a much higher rate of participation by gynecologists, such that nearly 90% of American women with a gynecologic cancer are seen by physician/investigators involved with the GOG. As a result, the GOG completes a much higher percentage of its trials, compared to the other groups. GOG leadership argued for the right to “stand alone” in the reorganization based on its’ very specific target population and its’ success, much like the Children’s Oncology Group (COG) was allowed to do. Unfortunately, that argument was not accepted.

So, we enter a new era of gynecologic cancer research, in which limited resources must be shared with other disciplines. The reasons for the GOGs’ historic success (widespread participation, adequate number of trials for the population) will receive less support. Committee membership in the NRG will be scrutinized and limited. Seats must be reserved on each committee for members from the other legacy groups. The Cancer Prevention and Control Committee for example, must accommodate former NSABP and RTOG members, replacing gynecologists and gynecologic oncologists for a limited number of seats. It has also become clear that the threshold for approving a new trial will be much higher than in the past, resulting in fewer total trials. Fewer questions will be asked or answered. These changes will require that investigators become more efficient in the design of new trials. They must generate precise questions that are simultaneously intended to have broad impact. And, all new questions must truly be answerable in the clinical trial format—there must be high likelihood that accrual will be completed.

Those are tall orders. As a result there is much uncertainty among investigators about the future. No one can predict whether gynecologic cancer research will proceed with the level of success it has become known for. Grumbling and discouragement are the order of the day among many former GOG (now NRG) researchers.

In view of these events, it’s more important than ever for gynecologic cancer patients, their families and friends to get involved. The federal government works for you, but it must hear your collective voices, and historically gynecologic cancer patients have been among the quietest of cancer interest groups. Now is the time to change that. Approach local and national advocacy groups, including the Foundation for Women’s Cancer (http://www.foundationforwomenscancer.org), the Gynecologic Cancer Awareness Project (http://www.thecap.org), No Evidence of Disease (http://www.nedtheband.com) and/or many others and volunteer. Never hesitate to personally contact your representative (http://www.house.gov/representatives/find/) -nothing is more effective than direct communication from a constituent. Don’t allow your government to decrease its’ commitment to prevent and treat gynecologic cancer at this critical time. Make sure your representatives know that you demand no less than the continuation of our past success. Our wives, mothers and daughters deserve no less.

In view of these events, it’s more important than ever for gynecologic cancer patients, their families and friends to get involved. The federal government works for you, but it must hear your collective voices, and historically gynecologic cancer patients have been among the quietest of cancer interest groups. Now is the time to change that. Approach local and national advocacy groups, including the Foundation for Women’s Cancer (http://www.foundationforwomenscancer.org), the Gynecologic Cancer Awareness Project (http://www.thecap.org), No Evidence of Disease (http://www.nedtheband.com) and/or many others and volunteer. Never hesitate to personally contact your representative (http://www.house.gov/representatives/find/) -nothing is more effective than direct communication from a constituent. Don’t allow your government to decrease its’ commitment to prevent and treat gynecologic cancer at this critical time. Make sure your representatives know that you demand no less than the continuation of our past success. Our wives, mothers and daughters deserve no less.
Etiology of Infection, Femoral Nerve and Splenic Injury by Abdominal Retractor

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ABSTRACT

The aim of this work is to identify the underlying factors of infections in surgical wounds, as well as injury to the femoral nerve and spleen. Medical literature dating between the years 2000 and 2013 was reviewed using PubMed's electronic service. The structure and shape of semi-automatic retractors used for abdominal surgical procedures were studied. The results we obtained showed that the etiology of infection in surgical wounds and injury to the femoral nerve and spleen are due to semi-automatic retractors. We conclude that prophylactic antibiotic therapy is not sufficient in eradicating these surgical wound infections or injury to the femoral nerve and spleen. This reorganization was based on the Institute of Medicine's (IOM) 2010 analysis of NCI clinical research. This report was highly critical of the inefficiency of the process by which the cooperative groups carry out their trials. Historically, relatively few U.S. oncologists have even participated in clinical research, mostly from academic institutions. Community oncologists, who see the great majority of American cancer patients, have generally been reluctant to participate in federal clinical research due to the bureaucratic burden and low reimbursement. As a result, more than half of the trials initiated by the NCI’s cooperative groups do not meet their accrual goals and are closed, generating no data. Further, the attendant bureaucracy ensures that each new Phase III trial startup costs well over a million dollars, which becomes a total loss when a trial closes early. The IOM made a number of recommendations for improving and streamlining that process, including the consolidation of the groups.

KEYWORDS: Infection of surgical wounds; Abdominal-cutaneous nerve injury; Abdominal surgery; Surgical retractors.

METHODS AND LITERATURE

Medical literature dating between the years 2000 and 2013 was reviewed using PubMed’s electronic service. The structure and shape of semi-automatic retractors used for abdominal surgical procedures were studied.
RESULTS

Infection of Surgical Wounds

This affection occurs in all hospitals around the world, but significantly more in developing countries. In research undertaken by Giri, it was observed that obesity, anemia, the duration of the surgical procedure and the surgeon’s experience were all underlying factors of wound infections.1

To reduce the incidence of infection in patients who underwent abdominal hysterectomies, Young implemented training programs for medical and nurse staff where they would use povidone-iodine or chlorhexidine gluconate as antiseptics, which reduced the incidence of infection from 10% to 2%.2

Machado noted that in patients suffering from obesity who underwent cesarean sections, the incidence of surgical wound infection has higher, when compared to patients whose weight was normal.3 Memon, in a comparative study, detected that prior to cesarean sections being practiced, asepsis and antisepsis of the vagina decreases infections.4 Kamyla communicated that the administration of antibiotics as a prophylactic reduced the incidence of infections.5

Próspero reported that when three doses of antibiotics were administered as prophylaxis for postoperative infection in a sample of 21,351 patients, 12,558 (58.8%) presented no infection. Statistically speaking, the difference was not significant.6

In a retrospective research, Khalifa analyzed reports from the 1970s through to 2011 regarding the resistance of bacteria to antibiotics. That work resulted in that Staphylococcus aureus, Klebsiella, Pseudomonas and E. coli are the most common bacteria found in infected surgical wounds. Ampicillin resistance reached 78% and amikacin resistance 2%.7 Hendricks emphasized that the lack of prophylaxis increased morbidity and mortality in surgical patients as well as the cost of care.8

The World Health Organization, based on research on the resistance of Gram-positive and Gram-negative bacteria to antibiotics, implemented programs to improve aseptic and antisepctic techniques in order to reduce their use.9

Femoral Nerve Injury

Femoral nerve injuries occur during abdominopelvic surgery due to the blade part of semi-automatic retractors being used to have a better view of the surgical area. The poor design and structural characteristics such devices present make it prone to compress the nerves in the abdominal wall.

Infantino analyzed these injuries in patients who underwent surgical procedures and published that femoral nerve injuries can occur during obstetric, gynecologic or oncologic surgeries via the abdomen. In order to diagnose those injuries an electromyography of the pelvic limbs must be done.10

Moore reviewed medical literature on femoral nerve injury dating from 2000 through to 2010 and reported that symptoms of this neurological complication include paresthesia, decreased strength in the lower limbs, difficulty standing and walking, sometimes not being able to walk at all. These symptoms persist indefinitely, ranging from a few days to several months. Medical treatment is needed and the patient needs to follow physiotherapy for the rehabilitation aspect of this ailment.11

On the other hand, Irving reviewed medical literature from 1960 to 2002 regarding the same type of injury and reported that the side blades on retractors, the intraoperative position of the patient and the radical dissection are all contributing factors to damage.12

The incidence of neurological injuries attributed to the use of semi-automatic retractors was underestimated due to information regarding this iatrogenic effect not being spread, perhaps due to forgetfulness or for fear of legal repercussions.

In 2013, Clarke-Pearson reported that in the United States 600,000 hysterectomies are performed yearly, of which 12,000 patients suffered femoral nerve injury.13

Many studies on femoral nerve injury agree in that it is due to the side blades on retractors.10,11,12,13

Abdominal Cutaneous Nerve Injury

Some of Ehler’s research focused on clinical manifestations of other post-surgery (via the abdomen or vagina) neurological iatrogenic effects and published that injury inflicted on the genitofemoral nerves produce pain in the crural and vulvar areas; injury to the lateral femoral cutaneous nerve causes paresthesia on the anterolateral thigh; and injury to the obturate nerve is due to the weakening of thigh muscles, with a decrease in strength of the foot and while walking. When the injury affects the pudendal nerve, functional anatomical changes include urinary and fecal incontinence as well as pain the perineum. These injuries are produced with the compress-
ion of the hooks and side blades of retractors. In order to decrease this type of injury, blades should not exert excessive pressure on the abdominal wall. Electromyography is used to diagnose injuries, and in some cases CT scans or MRIs are used.14

Tonneti studied the mechanism through which abdominal-cutaneous nerves are damaged on corpses. He identified that these injuries are caused by the compression of nerves from the use of retractor hooks.15

Splenic Injury

Cassar reviewed literature on iatrogenic splenic injury and reported that 40% of splenectomies are performed for this type of injury, an injury caused by compression from side blades in semi-automatic retractors.16 Mettke published that in 42,802 patients who underwent colorectal surgery, 640 (1.40%) suffered splenic injury.17 The Bookwalter retractor also causes injuries to the spleen; its use in surgery requires ten joint movements which promotes infection.18

Retractor features and design, operating time and excessive traction force used to ensure optimal surgery area visibility are all factors associated to infection in surgical wounds, abdominopelvic nerve compression and splenic injury.

Semi-automatic Retractors

The most frequently used retractors in gynecologic surgery are O’Sullivan-O’Connor, Balfour and Collins. All of these have permanent hooks, and blades that can be used if so wished. The hooks are curved and “fit” into the inner part of the abdominal wall, exerting pressure on abdominal-cutaneous nerves.

These retractors need bolts, screws and an opening system. The complete cleaning of these areas is very difficult and asepsis of the opening system is impossible. When retractors are dismantled, blood detritus and secretions are found on the screws, bolts and openings. Rust can also be found there. Detritus is an underlying factor in surgical wound infections.

Infection begins at the center and ends of incision sites, where there is direct contact with the retractor and where hooks and blades exert pressure. Table 1 shows surgical procedures with information regarding retractors, joints, screws and bolts used, all of these on which detritus is lodged.

**Sites Where Blood, Detritus and Pathogen Microorganisms Are Lodged**

<table>
<thead>
<tr>
<th>Name</th>
<th>Type of Surgery</th>
<th>Joints</th>
<th>Screws</th>
<th>Bolts</th>
<th>P.D.L.S.</th>
</tr>
</thead>
<tbody>
<tr>
<td>O’Sullivan</td>
<td>Gynecological</td>
<td>43 in each</td>
<td>4</td>
<td>4</td>
<td>13</td>
</tr>
<tr>
<td>Balfour</td>
<td>Cesarean</td>
<td>23</td>
<td>3</td>
<td>3</td>
<td>6</td>
</tr>
<tr>
<td>Collins</td>
<td>Cesarean</td>
<td>32</td>
<td>3</td>
<td>3</td>
<td>6</td>
</tr>
<tr>
<td>Soriano</td>
<td>Cesarean</td>
<td>22</td>
<td>0</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>Vaginal-gynecological</td>
<td></td>
<td>11</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
</tbody>
</table>

P.D.L.S. = Potential Detritus Lodging Sites

Table 1: Surgical procedures using retractors with joints, screws and bolts where detritus is lodged

**O’Sullivan-O’Connor Retractor**

The retractor’s opening and closing system is a rack-that uses a metal band or spring. Its semi-hermetic characteristic makes it difficult to access as well as the parts contained therein. This retractor’s upper and lower blades are hinged, see Figure 1. For an image of detritus in the rack, see Figure 2. Spaces between the joint and curved side blade are shown in Figure 3.

**Balfour Retractor**

Two screws are placed at the ends of the two rods that are inserted in the openings, each one measuring 5 mm. The “slider” is rectangular and measures 28 x 30 x 10 mm; with two openings each with a length of 28 mm and diameter of 8 mm.
The “slider” glides along the length of the each rod (28 cm), see Figure 4. There is a screw fixed on one end of the slider. Detritus is lodged both in the openings and this fixed screw, as seen in Figure 5.

Collins Retractor

In this retractor biological agents can be lodged in three permanent joints, two side blades and in one site where arms bend.

Soriano Retractor

The Soriano retractor’s use was tested on female patients and the results showed no postsurgical infections and no femoral nerve injury thanks to the structure and design of the instrument as a whole and its individual parts. The suprapubic or deep blades are a complementary part of this retractor. This instrument does not need screws or bolts and can be used in abdominal and/or vaginal surgeries on patients with normal weight or who are morbidly obese. The dismantled instrument is composed of the following parts: the main part; four deep blades; and three suprapubic blades. The articulation system requires no screws or bolts (Figure 6). Detritus can be lodged - in this instrument - in two sites, the joint of the Main Part and that of the Complementary Part.

Viral Infections

Hepatitis is a viral diseases transmitted through blood be it orally, via blood transfusion, the use of contaminated needles and sex. Preventive measures are intended to prevent contact with blood from patient to patient, patient to doctor or nurse, or vice versa.

In spite of programs created by the World Health Organization, the number of patients with hepatitis worldwide is increasing gradually. The morbidity and mortality rate was determined in pregnant women. Forty percent of patients with Hepatitis C (HC) have no history of blood transfusions or drug addiction, but rather the infection was acquired through surgical instruments used on them. Hospital-acquired infection is the most important underlying factor in HC transmission.

Another deadly disease is AIDS, a major public health problem worldwide. Obstetric patients are not exempt from this disease and transmission to the fetus is inevitable. In research about AIDS-transmission mechanisms conducted by Onuga, it was stated that the virus survives several days in dry conditions, and up to four weeks in a humid environment. Compared with men, there is a higher incidence of hepatitis or AIDS from abdominal surgical procedures in women. This type of infection includes hospital-acquired infections.

CONCLUSIONS

The WHO’s preventive programs focusing on reducing the incidence if infection in surgical wounds have lowered this rate. However, hospital-acquired infections persist and are a constant threat.

Femoral nerve and abdominal-cutaneous nerve injury along with splenic injury are caused by the structure and shape of semi-automatic retractors.

To help reduce infections and neurological injuries, retractors must be anatomically designed and joints must not have spaces in order to prevent detritus from lodging there.

REFERENCES


Bilateral Bullous Retinal Detachment in a Case of Preeclampsia

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CASE REPORT

A 30-year-old caucasian primigravida was diagnosed with arterial hypertension at 34 weeks of gestation. At 36th week, labor induction was performed for severe preeclampsia. During labor, blood pressure was controlled with labetalol and convulsion prophylaxis was performed with magnesium sulfate. She had a vaginal delivery without complications and forty-eight hours later complained of intense fronto-occipital headache, blurred vision and metamorphopsia with a sudden decrease in visual acuity. Blood pressure during the postpartum period was 170/110 mm Hg. Blood samples showed no abnormalities. The previous ocular history was unremarkable. The patient was transferred from a secondary to a tertiary hospital in order to have an adequate ophthalmologic evaluation that revealed visual acuity of 2/10 and 4/10 in the right and left eye, respectively. Fundoscopy, retinography (Figures 1A and 1B) and Optical Coherence Tomography (OCT) showed bilateral bullous retinal detachment of the posterior pole with no hemorrhage or retinal exudates and also contributed to exclude the presence of a macular hole in both eyes. There was no retinal tear on peripheral retina examination. Neurological examination was normal and cranial computed tomography scan showed no lesions. Blood pressure was controlled with 48 hours of labetalol. Magnesium sulfate was performed in accordance to the Department’s protocol for the management of severe preeclampsia. Ophthalmologic re-evaluation on days 2 and 4 improved significantly, without specific therapy. She was discharged asymptomatic on day 7 with controlled blood pressure. Follow-up examination 2 weeks later showed complete resolution of the retinal detachment (Figures 1C and 1D). Visual acuity remained 8/10 for both eyes.

Figure 1: Retinography: images A) B) at admission, there is a bullous retinal detachment of the posterior pole involving the macula (arrows) and extending superiorly beyond the limits of the superior temporal vascular arcade. The area of retinal detachment is smaller on the left (OS) than on the right eye (OD). Images C) D) at 2 weeks follow up, normal retinography showing complete resolution of the bilateral bullous retinal detachment.
COMMENT

Retinal detachment is an unusual cause of visual loss in pregnancy, being observed in 1% of preeclamptic patients and up to 10% of eclamptic patients.\(^1\)

According to a review of all case reports of retinal detachment associated with preeclampsia/eclampsia published between January 1990 and December 2010, it is usually bilateral (89%), more frequent in nulliparous women (60%), women with a cesarean delivery (76%) and tends to be diagnosed in the postpartum period (69%).\(^1\) There is no specific treatment for serous retinal detachment associated with preeclampsia. In these cases the only recommended treatment should target preeclampsia, requiring magnesium sulfate for seizure prophylaxis and anti-hypertensive drugs for severe hypertension. Bed rest and fluid restriction, an ophthalmologic and neurologic examination as well as neuroimaging could be also helpful in the management of preeclampsia with important visual symptoms. Unless there is an associated retinal tear, surgery is never necessary for resolution of serous retinal detachment. Visual disturbances are transient and visual acuity is completely and spontaneously recovered within weeks to months.\(^2\)

There is no confirmed link between teratogenic effects of fluorescein angiography and breastfeeding. Furthermore, fluorescein angiography is useful as a screening method for diffuse choroidal ischemia. Despite the possibility of identifying a retinal detachment based on the clinical picture and fundus examination, OCT is important for disclosing a macular hole in the differential diagnosis.\(^3,4\)

During the first 48 hours postpartum, symptoms associated with aggravated preeclampsia usually develop before hospital discharge and are promptly diagnosed and managed. However, in the subsequent days, they are more frequently diagnosed at the emergency room if puerperal women return for medical help. In our Department, in accordance to what is suggested by Barton, et al.\(^5\) we insist on giving both verbal and printed instructions on which symptoms should bring immediately the puerperal women to the emergency room. The aim of this measure is to diagnose the earliest an imminent worsening of the preeclampsia.

With this case report, we aim to highlight the importance of prodromal symptoms, mainly headaches and visual disturbances, which may raise our index of suspicion for complicated preeclampsia in the postpartum period.

ACKNOWLEDGEMENTS

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REFERENCES


A Case Report of Solitary Adrenal Metastasis from Early Stage Endometrial Carcinoma

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ABSTRACT

Although Type I endometrial cancers are generally associated with a good prognosis, specific histopathological features portend worse outcomes. Compared to type II tumours which have increased metastatic potential, this phenomenon is seldom seen in type I counterparts at presentation. Moreover, adrenal metastatic sites are rarer still with only one case report describing this pattern of dissemination to date. To our knowledge this is the first case report of an isolated adrenal metastasis from early stage type I endometrial cancer and highlights the heterogeneity which exists in this disease.

KEYWORDS: Endometrial cancer; Endometrioid adenocarcinoma; Adrenal metastasis.

INTRODUCTION

The worldwide prevalence of endometrial carcinoma was 280,000 cases in 2008.1 Clinico-pathologic and molecular data suggests the existence of two distinct types of endometrial carcinomas. Type I endometrial carcinoma comprise the endometrioid adenocarcinomas, which are often preceded by premalignant disease and express the oestrogen receptor and progesterone receptor.2 Furthermore, they are predominantly low grade and rarely metastasise. The prognosis of type I cancers are favourable if diagnosed at an early stage, with a 5 year survival of >97% in stage I and >80% in stage II.3 Type II endometrial carcinomas are those of non-endometrioid histology, in particular serous or clear-cell morphology. These tumours are considered to be of high histological grade, arise in the background of atrophic endometrium and are not driven by oestrogenic signalling.4 Despite the higher prevalence of type I cancers, type II tumours account for a high proportion of endometrial cancer-related deaths (44%), as they have a higher proclivity for extra uterine spread, are associated with poor prognosis and, if treated at an early stage, carry a higher risk of recurrence.5 Although type I cancers generally have a good prognosis, deaths do occur with these tumours, hence tumour heterogeneity must have a significant part to play.

Endometrial cancer recurrence is frequently loco-regional with distant metastases usually found in lungs, liver, and more rarely, bone and brain. Metastatic spread to the adrenal gland is common with carcinomas of the lung, breast, kidney, gastrointestinal tract in addition to melanoma. However, the dissemination of endometrial cancer to the adrenal gland is a rare occurrence. To the best of our knowledge, only four such cases have been reported in the literature. Here we report a case of a solitary adrenal metastasis from early stage type I endometrial...
adclear cell carcinoma).6

**CASE REPORT**

We report the case of a 62-year-old female who presented with twelve months of progressively worsening post-menopausal per-vaginal bleeding in November 2011. Physical examination was within normal limits. She initially underwent a pelvic ultrasound scan which was unremarkable. Subsequently a dilatation and curettage procedure was performed which revealed grade 3 endometrial adenocarcinoma (Type I).

A CT thorax, abdomen and pelvis performed in December 2011 showed no evidence of metastatic disease. A laparoscopic modified radical hysterectomy; bilateral salpingo-oophorectomy and peritoneal lymph node dissection were performed. Histopathological diagnosis revealed an endometrioid adenocarcinoma invading 5mm of the myometrium with focal lymphovascular invasion considered to be FIGO Stage 1B disease. She went on to have brachytherapy.

A progress CT scan performed in March 2012 revealed a new left adrenal nodule measuring 17mm in size which was monitored. A subsequent CT adrenal gland performed in May 2012 showed an increase in the size of the adrenal nodule to 20mm. A laparoscopic adrenalectomy was performed in September 2012 and subsequent histology revealed malignant cells in keeping with endometrial adenocarcinoma to the adrenal gland and focal squamous metaplasia was evident. The tumour cells were positive for cytokeratin (CK) 7 and negative for TTF1, napsin A, CK20, CDX2 and villin. Immunohistochemistry on tumour cells revealed strong expression for oestrogen receptors and weak to moderate staining of progesterone receptors (Figure 1).

![Figure 1: Immunohistochemical staining confirming strong oestrogen receptor (A) and weak to moderate progesterone receptor expression (B) in approximately 70% of tumour cells.](image)

**DISCUSSION**

Women with early (FIGO stage 1) type I endometrial cancer have a low risk of recurrence of their disease. This risk is significantly higher for some women with risk factors including high grade, deep myometrial invasion (>50%), extraperitoneal spread, lymphovascular invasion and certain histological subtypes (e.g. papillary serous carcinoma, endometrioid carcinoma and clear cell carcinoma).6

Adrenal metastasis following endometrial carcinoma is rare. To date, four cases have been reported describing adrenal metastasis from endometrial cancer. The first case described a 76-year-old women with FIGO stage 4, well differentiated endometrial cancer and pathological right acetalubar fracture.

The patient underwent transabdominal hysterectomy (TAH), bilateral salpingo-oophorectomy (BSO) with pelvic lymph node dissection followed by post-operative pelvic radiation. Surveillance CT performed 9 months later revealed a 50mm right suspicious adrenal mass. Laparotomy and partial resection was performed due to direct extension to adjacent organs. The patient was given medroxyprogesterone 500mg daily. She subsequently developed lung recurrence and died two years after initial surgery.7

The second case was a 62-year-old female with well-differentiated adenocarcinoma with no evidence of metastasis. The patient was given uterovaginal brachytherapy and underwent TAH/BSO and pelvic node dissection with cleared resection margins. At 7 years follow up the patient was found to have localised lung metastasis confirmed by biopsy. The patient received 6 cycles of adriamycin and cisplatin followed by medroxyprogesterone 500mg daily. After 2 years of remission she was found to have disease recurrence with lung metastasis and bilateral adrenal masses, as well as presumed malignant ascites. The patient died 2 months later, 9 years after initial diagnosis.7

The third case involved a well-differentiated, stage 3C endometrial cancer involving pelvic lymph nodes, treated with TAH and BSO followed by adjuvant carboplatin and paclitaxel for seven cycles. Fourteen months later she developed a 30mm right adrenal tumour which was laparoscopically resected, and a further 3 cycles of adjuvant carboplatin and paclitaxel were administered. There was no evidence of recurrence 5 years later.8

The fourth case involved a patient with progesterone positive, moderate-poorly differentiated stage 3C endometrial carcinoma who underwent a laparoscopic hysterectomy/BSO and pelvic lymphadenectomy and subsequently received six cycles of adjuvant cisplatin. A 60mm left adrenal mass was detected on PET-CT ten months later and was laparoscopically resected. Several months later the patient developed a new liver lesion.9

Laparoscopic adrenalectomy is considered to be the treatment of choice in solitary adrenal metastasis. The local-regional recurrence rate after laparoscopic adrenalectomy of primary adrenal cancer is 60%, usually occurring 1-2 years after resection.10 In a 12-year series of 30 patients undergoing surgery for adrenal metastasis from all cancers, the overall median survival was 23 months with a 5-year survival rate of 23%. Other studies reported similar survival rates.11-13 In gen-
eral, the prognosis of patients with metastatic disease is poor, with few survivors at 5 years.

According to the literature, metastatic spread to the adrenal glands tends to occur in advanced stage endometrial carcinoma. Metastatic spread from a type I early stage endometrial cancer is rare. Although the second aforementioned case report potentially describes a type I cancer, in view of well-differentiated histopathological features, the disease free survival was several years. This is in stark comparison to our case whereby the patient had a type I cancer that relapsed within 6 months of definitive surgery. Hence, highlighting that there is indeed a significant degree of heterogeneity, which exists in a subtype that is usually deemed to have an excellent prognosis.

There is increasing evidence that stage IC endometrial carcinoma patients should be regarded separately due to an increased risk of pelvic and distant metastases with lower survival rates. The 5-year vaginal and pelvic relapse rate of this particular cohort has been reported at 13%, substantially higher than the other stage I patients who had excellent pelvic control rates after pelvic radiotherapy (97-99%). The overall survival at 5 years was 58% for the IC grade 3 patients, compared to 74% for those with IB grade 3, and 83-86% for IB grade 2 and IC grade 1 and 2 disease (p<0.001).

Whether or not surgical staging has been performed, pelvic radiotherapy is generally recommended for grade 3 tumours with deep myometrial invasion. In view of the increased risk of distant relapse and cancer related death, adjuvant chemotherapy is currently being investigated in the PORTEC-3 study (Clinicaltrials.gov Identifier NCT00411138).

CONCLUSION

The notion that type I tumours have a predominantly good prognosis is for the most part true. However, more scrutiny is required for treatment of endometrial cancers with poor histological features. This paves the way to develop novel biomarkers to predict type I tumours with poor prognosis that may potentially benefit from adjuvant chemotherapy or targeted agents.

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The Road to Fatherhood Using Assisted Reproductive Technology: Decision Making Processes and Experiences Among Gay Male Intended Parents and Gestational Surrogates

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ABSTRACT

Background: With the progression of the gay rights movement, including increased legalization of same sex marriage and parenting options through joint adoption and Assisted Reproductive Technology (ART), there is support of access to ART regardless of marital status or sexual orientation. As an increasing number of gay men are now seeking biological parenthood through gestational surrogacy, there is limited data on the decision making processes and experiences for gay male couples and their Gestational Surrogates (GS) using ART in order to identify potential needs for programmatic improvement.

Materials and Methods: Retrospective qualitative survey was sent to 102 gay men in a committed relationship and 51 GS. Data from responses of 22 gay male intended parents and 11 GS who underwent ART was analyzed regarding their decision making processes and experiences. Statistical analysis including descriptive and Kappa correlations were completed.

Results: All gay men had considered different options for having children. Their families were more supportive of this process than when the men had disclosed their sexual orientation. When selecting GS, men prioritized surrogates’ attitudes towards gay men. All GS felt comfortable carrying for gay men. Twenty-two percent of GS reported postpartum depression despite considerable ante- and postpartum support and lack of separation difficulty from the infant(s). Sixty four percent reported they would carry for the same couple again, while only 38% of gay men expressed a desire to use the same GS. Both groups reported an overall lack of support from ART programs, attorneys, obstetricians and pediatricians.

Conclusion: There are identified areas for needed improvement for the ART process for both gay men and GS, including the need for increased sensitivity and support from those providing care/services to the intended parents and GS. Meticulous detail to pre- and post-ART treatment is essential to coordinating the medical, emotional and legal needs of gay men couples undergoing ART and their GS.

KEYWORDS: Gay men; Fatherhood; Gestational surrogacy; Assisted reproductive technology.
INTRODUCTION

The family, traditionally understood as a husband, wife and their biological children, is undergoing a transformation. The number of children living with 2 parents has fallen from 88% in 1960 to 68% in 2012. Additionally, there has been an increase in the number of non traditional families, which may consist of a single parent, unmarried heterosexual couples, heterosexual couples with non-biological children, gay or lesbian couple. No national registry provides exact numbers of gay and lesbian parents, but recent reports estimate up to 6 million children in the United States are parented by gay or lesbian families. The American Community Survey suggests that 26.5% of female-female unmarried couple and 13.9% of male-male unmarried couple households contain children.

Simultaneous with this transformation is a progression of the gay rights movement, including increased legalization of same sex marriage and parenting options through joint adoption and ART. In 2009, the American Society for Reproductive Medicine (ASRM) Ethics Committee published a report entitled, “Access to fertility treatment by gays, lesbians and unmarried persons,” supporting access to ART regardless of marital status or sexual orientation. Furthermore, this report and several others find no data suggesting that children are harmed or disadvantaged based on non traditional family compositions. Since the early 1980s when donor insemination became more readily available, there has been an increase in the number of babies born to lesbian couples. There are several studies that have evaluated this social trend including issues related to the prospective lesbian mothers, the use of donor insemination and IVF and the outcomes of their children. An increasing number of gay men are also seeking biological parenthood through gestational surrogacy. There is a paucity of literature, however, examining gay male couples, and to our knowledge, there is no published data regarding their gestational surrogates (GS). The purpose of our study was to report the decision making processes and experiences for gay male couples using ART and their GS in order to identify potential needs for programmatic improvement.

MATERIALS AND METHODS

This was an institutional review board approved retrospective qualitative survey. Questionnaires were distributed by the University of Cincinnati Center for Reproductive Health and The Surrogacy Center in Madison, Wisconsin. All potential candidates for the study were identified through a database maintained at the Surrogacy Center. Questionnaires were sent to gay men (n=102) and GS for gay men (n=51) who had completed or were currently undergoing ART in the United States. All participants reviewed and signed informed consent documents. Questionnaires were self-administered.

The questionnaire was designed to assess the respondent’s background, ART experience (including medical, psychological, legal and financial) and insights gained from the experience. Questionnaires included both closed and open-ended questions that allowed for comments. Questions regarding the level of “support” felt at various times during the process utilized a likert scale (1=extremely supportive, 5=not at all). Questionnaires included parallel themes on: sexuality, ART, the legal process, the pregnancy, postpartum and plans for the future. Questionnaires for men also included: family support, the decision to become a father, selection criteria of the egg donor, the selection of the GS and psychological evaluation. GS questionnaires also inquired about: motivation and compensation. The questionnaires were completed by gay male who were in a committed relationship with a total of 22 responses (22%) and 11 (22%) from GS.

Preparation for the cycle, including explanation of the medical, legal and psychological aspects, were reviewed at the initial consult with the ART team and surrogacy center. In addition, an information packet with internet resources and ASRM links were provided. Members of the ART team were also available throughout the cycle to answer any questions or concerns that presented at a later time. The Surrogacy Center has a specific checklist for GS and Intended Parents (IPs) that is comprehensively reviewed. This process is complex, therefore it may require further explanation and support throughout the process.

Data were entered into an SPSS database (version 18.0, SPSS Inc., Chicago, IL) and comments were paired as themes only after group agreement by the authors. Statistical analysis including descriptive and Kappa correlations was performed.

RESULTS

Same sex male intended parents

The average age of respondents was 41.3 years (range 30-55 years). Ninety five percent were Caucasian and 5% Asian. Countries of residence included the U.S. (64%), France (27%) and the Netherlands (9%). All of the gay men were in a committed relationship, with a mean length of 14 years (range 7-33 years). With respect to their ART outcomes, 10 of the couples had their GS successfully deliver at least once, resulting in 7 sets of twins and 4 singletons, whose mean age was 3.6 years (range 1 month to 10 years).

When asked how supportive their immediate families were when the men disclosed their sexual orientation, only 41% of men reported family support. When couples announced their intentions of becoming fathers, all reported having discussed the use of ART and gestational surrogacy with family and friends with 77% reporting family support. Ninety one percent had clear plans to disclose the nature of conception to their children, with many emphasizing age appropriate conversations.

With respect to family planning, 32% reported that the
desire to have children was an important characteristic in selecting a partner. Half reported that they desired to have children equally, while the other half reported that one partner desired fatherhood more. Thirty six percent reported difficulties within their relationships surrounding the decision to become fathers. Other difficulties regarding the ART process included costs, failed cycles and concerns about potential discrimination against offspring. Some descriptions of the difficulties experienced included, “I worried about how it would be for children having gay parents, I was afraid for them,” “I worried about societal issues that could harm our child, how to handle it,” and “the difficulties only arose after many failed attempts and high costs of continuing; it was a 5+ year journey.”

When considering ART treatment options, only 14% of respondents considered traditional surrogacy, while nearly all (91%) considered adoption. All French men reported that adoption was not possible for gay men due to French laws. American men also cited hurdles to adoption for gay men in the U.S. Sixty four percent of men were familiar with the ART process and with domestic and international laws (including adoption, parentage agreements and donor oocytes) prior to the visit with their reproductive endocrinologist and ART program. Half of the men found legal counsel by referral from a surrogacy center.

Subjects were asked to describe their priorities when selecting both an egg donor and GS (open response question). Priorities for selecting an egg donor included medical history (73%), ethnicity or appearance (41%) and intelligence (32%) (Figure 1A), which is very similar to heterosexual couples. When selecting a GS, priorities included a prior successful pregnancy (32%), medical history (27%) and working with someone who was gay-friendly (27%) (Figure 1B). Subjects were also asked to rate how well supported they felt from several professionals involved in the ART process. Ninety one percent of men found the reproductive endocrinology medical and paramedical staff supportive, and an equal number found their attorney to be supportive. One third, however, found their obstetrician and pediatrician less supportive.

In 77% of men, both partners’ banked sperm, with nearly all subjects mentioning a strong desire for each to be a biological father. With respect to the embryo transfer, 20 of 22 were counselled about transferring the best quality embryos regardless of latency. Ultimately, 55% had at least 1 embryo from each partner transferred.

The antepartum and intrapartum concerns of greatest importance for the men focused on the health of the baby and GS. Only 1 of the 22 men raised concerns regarding legal issues. During the postpartum period, concerns shifted to geographic logistics (living in different cities or countries), execution and legitimacy of legal contracts related to parentage rights and anxiety about being a new father.

Egg donors were recruited by local advertising and word of mouth. A donor was presented to the male and his partner by the ART team based on IPs preferences ascertained by questionnaire. All egg donors remain anonymous, unless arrangements for direct donation by a known donor are made by the IPs and donor. When asked about plans for maintaining contact with their egg donor, with only 1 exception, it was not expected or desired to maintain a relationship. There was agreement between partners on this point (K=0.62, p=0.03). In contrast, 55% did desire to keep in touch with the GS, however the partners did not always agree on this point (K=0.42, p=NS). If planning a future pregnancy, all men expressed a desire to use the same egg donor, yet only 38% of respondents would use the same GS.

Gestational surrogates

The average age of respondents was 37.4 years (range 34-48 years). Eighty two percent were Caucasian and 18% Hispanic. All respondents resided in the U.S. Ninety one percent of the women were heterosexual, 82% married, and all had at least one child of their own. At the time of questionnaire completion, 55% of the women had delivered a baby as a GS once, 36% twice and 9% three times. Seventy three percent reported employment outside the home. The mean number of embryos transferred was 1.9 (range 1-3), with 82% of the women successfully delivered and 18% still expecting. This resulted in 9 singletons and 5 sets of twins. Ninety two percent delivered full term and half delivered by cesarean section.

Altruistic motives were cited as the most common reason for becoming a GS (73%), and 18% stated finances as primary motivation (Figure 2). Compensation for services averaged $26,600 (range $5,200-45,000) and 82% received additional gifts, including books, jewelry, electronics, food, clothes and perfume. None had any reservations regarding carrying for a gay couple, and 27% reported a preference to carry for a gay couple (“Less neurotic than the heterosexual couples”). Eighteen percent knew the IP prior to becoming their GS. All GS disclosed the IPs’ sexual orientation to friends and 91% to their extended families. All of the GS’s significant others were supportive.
of their decision to be a GS regardless of the IP’s sexual orientation, while 18% of family members were not supportive of the decision.

Despite guidance by a surrogacy agency and ART program, women disclosed that they did not fully understand the legal issues as the process unfolded. Ninety one percent found their legal counsel by referral from a surrogacy center, and 18% found the attorney’s support inadequate. When asked about the support they received throughout the process, 36% reported a lack of support from the IVF program and 18% from the obstetrician. Top antepartum concerns for the GS were the babies’ health and maintaining their own support systems from family and friends.

The number of visits by the IPs prior to delivery ranged from 0 to “countless.” Despite considerable antenatal and postpartum support from family and IPs, and all denying difficulty with separating from the infant(s), 22% of those delivered reported postpartum depressive symptoms, (either diagnosed by a physician or self-assessment). Seventy three percent have maintained contact with their IPs, ranging from weekly to once every few years. Sixty four percent reported they would agree to be a GS for the same couple again. Reasons for not wanting to be a GS again included pregnancy-related complications, age and a desire to expand their own families.

DISCUSSION

Our study describes the ART process from the perspective of gay males and their GS. Some common themes can be extrapolated from these data. All of the gay males were in stable, long-term committed relationships. They chose biological fatherhood after a great deal of consideration and contemplated several options. Options were often limited, however, due to their sexual orientation and legal limitations. They had all discussed the nature of conception with their friends and families and had not only considered, but had clear plans of having that discussion with their children in the future. Their families were much more supportive of them when announcing the decision to become fathers than when they initially disclosed their sexuality. This is possibly due to the wider acceptance of welcoming a child into the family than of an alternate lifestyle. In addition, the gay males and GS did not report universal support from the IVF programs, attorneys, obstetricians and pediatricians, indicating a need for improvement.

An increasing number of gay men view fatherhood as an expected part of their life.19 A study of young gay men reported that while one third of the males anticipated getting married, 86% expected to become fathers in the future.20 A lack of social acceptance of gay men as fathers remains. Common prejudices contributing to this include concerns that the children will be stigmatized, that the children are more likely to become homosexual and that gay males are more likely to molest their own children.21 Despite several studies discrediting these ideas,22-27 universal access to fertility treatment does not exist.

From a medical perspective, an ART cycle for a gay male couple is not unique. It is the additional legal, psychological and logistical components that make it more involved than traditional ART cycles. There are several important programmatic considerations when implementing care for this type of cycle. This starts with patient access to ART and then involves medical and psychological evaluation, selection of an egg donor, GS selection, legal contracts and checklist requirements, including those mandated by the U.S. Food and Drug Administration (FDA).28 Careful coordination with effective communication between all involved parties is imperative. One must also be mindful that while each professional may only see the patient at one step during the process, the process is ongoing from attempted conception, to antepartum, through the postpartum period.

For gay male couples seeking fatherhood, potential options include adoption, traditional surrogacy and IVF with an egg donor and GS. In certain scenarios, there are legal limitations placed on one or more of these options (i.e. depending on state or national laws). There are also substantial financial costs to these options. A recently published ASRM ethics committee document28 states that “reasonable economic compensation to the gestational surrogate is ethical.” Specific costs may vary with use of donor egg or surrogacy agencies, geographic region and egg donor or GS desirability. Costs for such a cycle may range from $80,000-160,000. There is a great amount of financial pressure on the IPs, as a failed cycle means even higher costs. There is additional pressure felt by the GS, as the majority of her compensation is based on a successful pregnancy. These financial pressures felt by each party may create an underlying tension in the IP/GS relationship.

There are a number of legal issues entrenched in this ART process, including those surrounding oocyte donation,
gestational surrogacy, adoption and parentage agreements. Selecting legal counsel familiar with these issues and educating themselves are important steps in this process. Many relied on a surrogacy center’s referral for retaining counsel. Additionally, IVF programs must be familiar with the laws of the state in which they practice as well as the FDA regulations.

The gay men in this study formed close relationships with their GS, most with continued communication postpartum. Interestingly, only approximately one third gay males would use the same GS for a future pregnancy, while two thirds of the GS were willing to carry for the same couple again. Specific reasons for this discrepancy were not elicited and further research is needed in this area. Furthermore, IVF programs and surrogacy agencies should be sensitive to the potentially-divergent needs of IPs and GS. All of the men, however, were interested in using the same egg donor if planning a future pregnancy. Perhaps the preference for the same egg donor and not the GS was to maintain genetic similarity, which would not be surprising in a sample that chose biologic fatherhood over adoption (where legal) and specifically mentioned a strong desire for each partner to be a biological father when banking sperm. Additionally, more than half of the males transferred at least 1 embryo from each partner, suggesting a priority of perpetuating their own genetics over the recommended elective single embryo transfer and reducing the risk of twins.

Consistent with existing literature, altruism was the most common reason cited for becoming a GS.29,30 All were not only comfortable carrying for gay couples, but some preferred it. The percent of GS reporting postpartum depressive symptoms was higher than the estimated prevalence of 13 to 19% in the general population.31 The current description does not indicate why this population of GS may feel more postpartum depression. Reasons behind this may be feelings of loss of identity, separation not only from the baby, but also the IPs, and pain and recovery of pregnancy with no baby in hand. Our sample size is small and our definition of postpartum symptoms/depression is broad; larger more specific studies are needed to assess this. While evaluation by a mental health professional is routine prior to entering into a treatment cycle as a GS or IP, it is not routinely provided during the cycle or postpartum. It is critical that adequate psychological support be provided to these women in the postpartum period.

This study is one of very few in the literature that investigates gay male couples and ART as well as their GS, two understudied populations with an increasing presence in third party reproduction. Our sample size is small, which limits the generalizability of our findings. The limited number of responses may be due to the length of the questionnaire and to the personal nature of the questions. That said, our study does suggest areas for needed improvement in the ART process for both gay men and GS, including the need for increased sensitivity and support from those providing care/services to the IPs and GS. Further study is needed to expand upon these results and to elicit specifics regarding how increased support may be provided.

In conclusion, while gay men and their GS reflect many of the experiences and concerns that characterize ART generally, they also bring specific needs to the process. These unique concerns can be addressed by those sensitive to the issues. Attention not only to medical, but also to emotional and legal needs of both the IPs and GS is necessary. The continuum of care from pre- to post-ART treatment must be considered at the local, national and international levels. There is a lack of a standardized process, which requires attention first at a national level. Finally, further education is needed to raise awareness to professionals including specialists in this area and beyond. The medical practice must evolve to meet the needs of increasingly diverse families in today’s society.

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