

AOGS LETTERS TO THE EDITOR

Successful treatment of massive deep vein thrombosis using catheter-directed thrombolysis and inferior vena cava filter in a puerperal woman

Sir,

Venous thromboembolism is one of the major causes of maternal mortality and morbidity in the western world and has in Denmark been estimated at around 1.3 per 100 000 live births (1). Systemically and locally administered thrombolytic agents have been used with success in extreme situations in pregnant and in puerperal women (2). It is important to emphasize the favorable outcome of these methods in the event of extreme life-threatening situations. We therefore wish to call attention to a woman with puerperal bilateral massive deep venous thrombosis, treated with catheter-directed thrombolysis and a temporary inferior vena cava filter.

A 32-year-old woman presented with a history of lumbar pain and a painful and swollen right leg. Two weeks earlier, she had delivered vaginally at term without complications. She had several risk factors for thromboembolism, such as smoking, a pre-pregnancy body mass index of 39 kg/m², gestational diabetes mellitus and a current urinary tract infection. Duplex ultrasound and CT scan with contrast demonstrated iliofemoral deep venous thrombosis of her left leg, as well as massive thrombosis of her right leg (Figure 1). The patient was initially treated with low-molecular-weight heparin in therapeutic doses. A temporary inferior vena cava filter was inserted through her right jugular vein. Catheter-directed thrombolysis of her left iliofemoral deep venous thrombosis was initiated with recombinant tissue plasminogen activator and heparin. After 117 hours, all thrombus was resolved. An underlying stenosis of her left common iliac vein was treated with stenting. Although the patient did not fulfil the inclusion criteria for catheter-directed thrombolysis of her right leg (3), this was attempted and completed after 66 hours, with all thrombus material having resolved. The inferior vena cava filter was removed and anticoagulation initiated. The patient was discharged after 14 days. One year later, duplex ultrasound demonstrated patent deep veins in the left lower limb, and some residual thrombus in the right common femoral vein. No signs of post-thrombotic syndrome were present. She was found to carry Factor V Leiden and prothrombin mutations, both in heterozygous form, and anticoagulation therapy was recommended indefinitely.

Treatment of venous thromboembolism during pregnancy and in the puerperal period is challenging. The indication for thrombolysis must be considered as a risk–benefit evaluation and is usually only chosen on vital indications. The advantages of catheter-directed thrombolysis include a high local concentration of thrombolytic agents, resulting in rapid lysis and decreased risk of systemic bleeding complications (4). Major bleeding complications have only

rarely been described. The use of an inferior vena cava filter in pregnant or puerperal women has likewise only been described in a few cases. The main risks of such filters are migration, perforation and thrombosis, but the latter two risks can be reduced with a retrievable filter. In a retrospective audit of prospectively collected data, including 560 inserted filters in 507 non-pregnant patients, major complications were seen in two cases (0.4%) (5).

It is important to be aware of the different treatment modalities mentioned above, but the choice of modality must be individualized, based on risk factors, clinical presentation, diagnostic findings, local resources and experiences.



Figure 1. CT scan. Arrows demonstrate iliofemoral deep vein thrombosis. 118 mm × 171 mm (300 × 300 d.p.i.).

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Postpartum rectal adenocarcinoma in a 26-year-old woman

Sir,

Colorectal carcinoma developing during pregnancy is uncommon, estimated to affect <0.002% of pregnant women. Most patients present late in pregnancy, and more than 80% have rectal tumors (1). The presenting signs/symptoms, such as rectal bleeding, nausea, vomiting, and constipation, are often attributed both by the patient and physician to the pregnancy itself. We wish to call attention to the case of a 26-year-old woman (para1) who presented in the first trimester of gestation, at the emergency department with abdominal pain, vomiting, and fatigue, which was attributed to the pregnancy. These symptoms persisted throughout her pregnancy, but she gave birth to a healthy baby, delivered by cesarean section.

As abdominal and lumbar pain recurred with fever (38°) in the postpartum period, a CT-Scan was performed but showed only inflammatory features of the rectosigmoid area. Endoscopic evaluation revealed a 5-cm ulcerated mass, and the biopsy demonstrated a moderately differentiated adenocarcinoma. As the metastatic work-up was negative, she underwent rectosigmoid colon resection with low anterior anastomosis. Pathologic examination of 5-cm polypoid and ulcerated tumor confirmed the diagnosis of adenocarcinoma, invading all layers of the rectosigmoid wall, without lymph node metastasis. The patient did not receive adjuvant therapy and she is alive and well after 10 months of follow-up.

Colorectal carcinoma in pregnancy represents a serious, difficult malignancy to manage for a number of reasons, including delayed presentation, difficulties in diagnosis, staging, and problematic decisions on the timing of surgical intervention (1). Unlike in the general population, 86% of colorectal carcinoma found during pregnancy occurs below the peritoneal reflection and is detectable by flexible sigmoidoscopy, without a need for sedation and radiation exposure. Tumor staging in pregnancy by MRI is a satisfactory substitute for CT

scanning, which is contraindicated due to radiation teratogenicity, particularly in the first trimester (1,2). Management of this condition can be difficult, as the twin goals of curing the disease and preserving the pregnancy are divergent. In general, women diagnosed in the first 20 weeks of pregnancy can have surgical excision without undue risk to the fetus, albeit with limitations in pelvic access secondary to the pregnant uterus. If colorectal carcinoma is diagnosed after 20 weeks, consideration can be given to postponing treatment until after delivery (1,3). Prognosis is better for rectal tumors than for colonic tumors, which might be partly explained by the advanced stage at presentation of colonic cancers, often with peritoneal dissemination (1). Despite the absence of a long follow-up in our case, the prognosis will probably be good, as there was no lymph node metastasis. In a large review of the literature, Bernstein et al. found that even if patient survival is poor, stage-for-stage survival is similar to patients with colorectal carcinoma in the general population (4).

Colorectal carcinoma in pregnancy presents a diagnostic and therapeutic challenge. Pregnant woman with suspicious symptoms should be evaluated for this possibility even in the absence of any other gastrointestinal symptoms, and undergo rectal examination and sigmoidoscopy.

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Laparoscopic bilateral oophorectomy – feasible migraine management?

Sir,

Migraine is a huge health issue and the prevalence is higher among women. One type of migraine is menstrual or catamenial migraine. Women who experience menstrual migraine have attacks of longer duration and the attacks are more resistant to treatment than other migraine attacks. Exclusively menstrual episodes, anywhere from two days prior to onset of menses to three days following onset of flow in at least two of three cycles, may occur in 15% of women with migraine (1,2). If women also experience attacks non-menstrually, their migraine is classified as a menstrually related migraine. There is a link between female sex hormones and migraine (3). Many women obtain complete relief from their migraine headaches at menopause. We wish to call attention to the possibility of surgical treatment for women suffering from severe and frequent menstrual migraine attacks.

We encountered a 40-year-old G4P1 Caucasian woman in generally good health with more than 20 years' history of migraine attacks related to menstruation. The attacks were initially infrequent, lasting a few hours, and were relieved with non-steroidal anti-inflammatory drugs and rest. Later on, the attacks became more frequent and severe, occurring monthly three days before her period. Heraldng auras consisted of spots or tunnel vision and feeling sick and tired, with the headache starting behind the left eye and radiating to the back of the head ipsilaterally. She had accompanying phono- and photophobia as well as touch sensitivity. Sometimes she also developed neurologic deficits including hemi-face drooping and aphasia. During her pregnancy and breastfeeding in 2003 she experienced substantial relief, followed by three miscarriages and severe attacks following each of these failed pregnancies. She has a strong family history for migraine. The patient has kept a detailed headache diary since the birth of her child in 2003. She had several imaging studies, both CT (computerized tomography) and MRI (magnetic resonance imaging). She utilized several treatment options including non-steroidal anti-inflammatory drugs, narcotics, tryptans, anti-epileptic drugs, botox, acupuncture, nerve blocks, stress reduction, oral contraceptives, cyclic estrogen supplement, large doses of corticosteroids and lastly, a GnRH agonist (LUPRON

DEPOT[®], 3.75 mg i.m. Abbott Laboratories, Abbott Park, IL) to induce medical menopause. Two weeks into that treatment, she had one of the worst headaches she had ever experienced, lasting two weeks. Estrogen add-back therapy was then implemented and her migraine attacks became less severe in the following months. Daily intra-vaginal progesterone gel treatment was added as she still had her uterus. The progestogen triggered a severe attack, so she discontinued it. A continued medical menopause trial with GnRH agonist and estrogen add-back therapy for a total of 14 months demonstrated successful resolution of her migraine attacks. She subsequently underwent total laparoscopic hysterectomy with bilateral salphingo-oophorectomy to enable the estrogen add-back treatment to continue and induce a surgical menopause. She has remained headache free now, two years after surgery.

On searching the literature for articles on oophorectomy or ovariectomy, headache or migraine, only one article was found suggesting surgical oophorectomy after successful treatment of migraine with GnRH agonists, but without mentioning the postoperative migraine results (4). Women who experience menstrual migraine seem to have several things in common; their attacks are of longer duration and are more resistant to treatment and they may suffer from dysmenorrheal and premenstrual syndrome (5). The ICHD-II (International Classification of Headache Disorders) diagnosis of menstrual migraine (2) requires that attacks occur without aura, but in clinical practice it is common that women complain of aura symptoms in relation to their menstrual headache (6). Our patient had a pattern of migraine that qualified for the designation of menstrual migraine but with aura. Many treatment modalities have been recommended but outcome has been variable. Preventative efficacy has been demonstrated for the GnRH analog, leuprolide acetate, in women with medically refractory menstrual migraine (4) but the effects of long-term use are not known.

If a medical menopause trial with GnRH agonist demonstrates successful resolution, the present case raises the possibility that surgically induced menopause and hysterectomy with estrogen add-back therapy may represent an alternative treatment option for severe refractory menstrual migraine.

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Fetal growth and gestational hypertension in women classified as gestational diabetes mellitus defined by the new consensus criteria only

Sir,

Since the new consensus criteria for gestational diabetes mellitus (GDM) were proposed by the International Association of Diabetes and Pregnancy Study Groups based on the results of the Hyperglycemia and Adverse Pregnancy Outcomes (HAPO) study, several studies have demonstrated that women with GDM by the new criteria are at high risk of large for gestational age (LGA) and gestational hypertension (GH) (1–4). For instance, O'Sullivan et al. demonstrated the clinical feature of the new consensus criteria in a predominantly European population (3). However, it remains to be determined whether similar perinatal complications are achieved in clinical practice as much as in research settings. In particular, data on perinatal outcomes in women who were classified as having normal glucose tolerance (NGT) by the previous criteria, but as having GDM by the new criteria (i.e. the new criteria only-defined GDM), are limited. In addition, the majority of participants in the HAPO study were of non-Asian ethnicity, making it difficult to interpret the results in a Japanese population. With this background, we have investigated the clinical impact of the new criteria on perinatal outcomes in a Japanese setting.

A retrospective review of medical records was performed for 5749 sequential Japanese women who were cared for at our hospital between 1996 and 2010. Each woman underwent a two-step screening for GDM: universal early testing in women with high-risk characteristics and a standard one hour, 50 g oral glucose challenge test between 24 and 27 weeks of gestation for all women not previously

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found to have glucose intolerance. Women with positive screening underwent a two hour 75 g oral glucose tolerance test. On the basis of the criteria proposed by the Japan Society of Obstetrics and Gynecology (JSOG), GDM was diagnosed if two or more values reached or exceeded the following thresholds: fasting, 5.6 mmol/L; one hour, 10.0 mmol/L; and two hours, 8.3 mmol/L (5). All women with GDM were treated with a strict glycemic protocol.

Using the new criteria (1), 349 (6.1%) women were reclassified into hyperglycemia in pregnancy (overt diabetes 3; GDM 346), compared with 132 (2.3%) by the JSOG criteria. Compared with the 'new criteria-defined NGT', those with GDM by the new criteria had a higher incidence of LGA births (12.2 vs. 6.2%, $p < 0.001$) and GH (4.1 vs. 1.8%, $p < 0.01$). The 'new criteria only-defined GDM' corresponding to untreated mild hyperglycemia ($n = 217$) showed a significantly higher incidence of LGA and GH, compared with the 'new criteria-defined NGT' (Table 1). After adjustment for maternal age, pre-pregnancy body mass index, previous GDM, a family history of diabetes and the glucose intolerance status using a multiple linear regression model, the 'new criteria only-define GDM' was correlated with LGA and GH (adjusted odds ratio 1.76 and 2.20; 95% confidence interval 1.14–2.71 and 1.13–4.28, respectively). Our results suggest that women with GDM defined by the new consensus criteria only are at high risk of subsequent development of GH as well as LGA.

Currently, a number of healthcare associations in the world are contemplating the adoption of the new criteria. Based on our

Table 1. Clinical characteristics of women reclassified into gestational diabetes mellitus defined by the new consensus criteria only.

Parameter	Units	The new criteria-defined NGT (n=5400)	The new criteria only-defined GDM (n=217)	p-Value
Age	(years)	33±5	36±4	<0.0001
Body mass index	(kg/m ²)	20.3±2.5	21.2±3.0	<0.0001
Overweight (body mass index ≥25 kg/m ²)	(%)	4.9	9.7	0.002
Underweight (body mass index <18.5 kg/m ²)	(%)	21.3	15.8	0.053
Parous	(%)	30.1	31.3	0.704
Previous GDM	(%)	0.48	1.38	0.100
Family history of DM	(%)	6.48	17.05	<0.0001
GW at delivery	(week)	39±2	38±2	0.020
Birthweight	(g)	2954±464	2956±522	0.960
Macrosomia	(%)	0.63	0.92	0.649
GH	(%)	1.86	4.61	0.008
Pre-eclampsia	(%)	1.83	1.38	1.000
LGA	(%)	6.22	11.52	0.002
SGA	(%)	9.04	8.76	0.887

Abbreviations and definitions: DM, diabetes mellitus; GDM, gestational diabetes mellitus defined by the former criteria; GH, gestational hypertension; GW, gestational week; macrosomia, defined as birthweight >4000 g; LGA, large for gestational age, defined as birthweight >90th percentile for gestational age; NGT, normal glucose tolerance defined by the new criteria; and SGA, small for gestational age, defined as birthweight <10th percentile for gestational age. Continuous variables are given as means±SD. Statistical analysis: Student's *t*-test for continuous variables and the chi-squared or Fisher's exact test for categorical variables.

findings, the new criteria appear to be acceptable to a Japanese clinical setting with regard to LGA and GH. As discussed in several articles (3,4), however, further studies are warranted to determine the cost-effective therapeutic strategies for treatment of GDM defined by the new criteria.

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Advanced Life Support in Obstetrics (ALSO) and post-partum hemorrhage: a prospective intervention study in Tanzania

Sir,

We express our profound appreciation to the authors for reporting on the evaluation of the ALSO course in Kagera region, Northwestern Tanzania. That study evaluated the impact of the training on the major cause of direct maternal deaths. Oxytocin has been the uterotonic of choice in Tanzania but this has challenges in terms of storage which may limit its effectiveness, so the registration of misoprostol for the prevention and treatment of post-partum hemorrhage in Tanzania in September 2007 and this training of health care workers is welcomed (1).

Emergency Obstetric Care (EOC) training is the most frequent component of interventions (52–65% of the 54 interventions reviewed) that improved maternal health in low income countries in a recent systematic review, the other components were placement of providers, refurbishment of existing infrastructure and improved supply of drugs, supplies and equipment (2).

Most low resource countries have a high burden of maternal deaths and use in-service EOC training programs to improve the quality of skilled attendance at birth (3). Most of these programs are not reported or evaluated in detail and those evaluated have weak study designs (4). The direct obstetric case fatality rate can be used as a crude index of quality of EOC services after implementing interventions to improve EOC and skilled birth attendance (5). Such process indicators reflect impact on health care outcomes and are relatively cheap to collect. They also provide a wider range of assessment for the EOC training being evaluated. Including a control group through a cluster randomized approach will also strengthen the design but is likely to increase the costs associated with the study.

EOC training programs are usually funded by donor organizations in low resource countries and are usually not linked to any system of routine in-service training/updates. One contributing factor may be the cost associated with organizing training. The cost of the ALSO course taught by Tanzanian trainers was reported as \$125, which may restrict its access by midwives and middle cadre health care workers. The use of evidence-based training methods of short duration linked to certification to practice midwifery which are partly funded by government and the health care provider will likely result in sustainable in-service EOC training programs in low resource settings.

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REPLY

Postpartum hemorrhage and Advanced Life Support in Obstetrics (ALSO)

Sir,

We thank Drs. Mdelega and Ameh for their interest in our article reporting the short-term impact of Advanced Life Support in Obstetrics (ALSO) training on postpartum hemorrhage at Kagera Regional hospital in Tanzania and the very relevant related questions that they raise. Before commenting on this I would like to take the opportunity to thank you wholeheartedly for the admirable and most inspiring work you are leading for promoting emergency obstetric care training in developing countries through the RCOG Life Saving Skills in Obstetrics Course based at Liverpool School of Tropical Medicine.

You raise a very important question about how to evaluate the impact of the various emergency obstetric care training interventions that exist. Using a process indicator like case fatality rate (CFR) seems feasible when conducting randomized, controlled trials; however, the concern could be that the quality of routine data registration often leads to severe underestimation of the true incidence of obstetric complications. After interventions to improve the quality of emergency obstetric care, such as an audit of skills training, the registration of complications tends to improve and so the CFR can be seen to decrease without a decline in absolute maternal mortality. The data registration seems to be a crucial problem for any research program in this field to yield valid evidence. At the Copenhagen School of Global Health we are considering community-based RCTs on the impact of emergency care obstetric training and we are trying our best to think up 'strong' study designs that are still feasible for the often difficult conditions that research is conducted under in developing countries.

Regarding sustainability of interventions it is a very true observation that many programs live as long as there is external funding. The ALSO program in Tanzania is still continuing and the hope is that it will be financed within public health budgets. The ALSO course is much cheaper than longer courses that are on the national health budget and the price has come down to 80–90 USD per participant, as there is no need any more for external instructors. However, there is a logistic problem reaching the health workers at peripheral health facilities. In November, an ALSO program will be initiated at Zanzibar's College of Health Sciences to teach all graduating health workers ALSO before they are posted to village health

centers and dispensaries. This program is intended to be on the national health budget after the initiation phase at costs around 60 USD per participant. Another possible way of extending emergency obstetric care training and quality assurance to peripheral settings is the use of smart phones distributed to health workers that can be used for emergency consultations, data collection, audit and training by animated video instructions. Such a 'wired mothers' program has proven to be effective in Zanzibar and we are now planning an adapted and more extensive programme in Western Ethiopia.

The Copenhagen School of Global Health has a small but very dedicated group of researchers working within the field of reproductive health. We would indeed welcome any future discussion and exchange of ideas and perhaps a collaboration with the Maternal and Newborn Health Unit at Liverpool School of Tropical Medicine.

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