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EDITORIAL

MATERNAL OBESITY AND THE RISK OF HYPERTENSIVE DISEASE IN PREGNANCY

Hypertensive disease in pregnancy complicates about 10% of pregnancies[1] and remains a major cause of maternal morbidity and mortality as well as perinatal mortality. At the Korle Bu Teaching hospital (KBTH) annual statistical reports (2016 and before) have demonstrated that it has overtaken haemorrhage as the leading cause of maternal death for over a decade It contributed 30 % of all maternal deaths in 2016[2]. In most of the teaching and tertiary hospitals in Ghana it is the leading cause of institutional maternal death.

The cause and the prevention of hypertensive disease in pregnancy especially preeclampsia is not exactly known. There have been several theories. The current theory is that preeclampsia is a two –stage disorder with maternal and fetal interactions linking the 2 stages. The first stage is reduced placental perfusion from abnormal placental development, and the second stage is the maternal syndrome which develops in a subgroup of women with some genetic, behavioral and environmental characteristics in response to factors produced by the poorly perfused placenta[3]. Obesity is one of the maternal characteristics that plays a role in the maternal syndrome, and therefore an important risk factor for the development of this condition. Other known risk factors include primigravidity, primipartenity, family history, hypertensive disease in previous pregnancy, extremes of reproductive age, multiple pregnancy, chronic hypertension, renal disease, and autoimmune disease etc. Many of these are, however, not modifiable. Obesity, together with overweight, is one of the modifiable risk factors. It is therefore imperative that clinicians and health workers managing pregnant women don't overlook this. This has become even more crucial today than in time past, as the prevalence of obesity has increased in the last 15 years in west Africa, especially among women[4]. In Ghana, data from the 2008 Demographic& Health Survey(GDHS) indicate that 29% of women are overweight and 12% are obese[5]

Buckman and colleagues write in this issue that body mass index (BMI) before 20 weeks gestation is a strong independent risk factor for development of hypertensive disease in pregnancy. They demonstrated that the risk of hypertension in obese pregnant women at the 37 Military hospital was double that in the women with normal BMI. They also found an increased risk of developing hypertension with increase in BMI within each BMI category. In their cohort, the proportion of patients developing hypertension in the obese and overweight category was 14% whilst that for normal BMI was 9%. Their recommendation that health workers attending to obese pregnant women, monitor blood pressure carefully especially in the 2nd trimester is very laudable. Ideally, there should be education of our women to reduce weight before embarking on the pregnancy to optimize their general outcome.

In another related article[6], on blood pressure patterns and body mass index among antenatal attendants at the KBTH, Amoakoh-Coleman and co demonstrated that obese pregnant women had a threefold increased risk of hypertensive disease in pregnancy, compared to those with normal BMI. From the foregoing, if we are going to achieve some reduction on the prevalence and impact of hypertensive disease in pregnancy, we may have to include in our antenatal and prepregnancy protocols some interventions, for preventing or early detection and management of obesity.

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COMMENTARY

SLEEP!

Persistent scientific enquiry is steadily stripping away some of the mystery associated with sleep, a universal behaviour which consumes one third of our lives. Indeed, we have to thank God for the efforts of these scientists, most of whose writings suggest that they might be atheists. A recently published book by Matthew Walker[1], a neuroscientist, titled - Why We Sleep: The New Science of Sleep and Dreams, summarises some of this fascinating, evidence-based information. This book is highly recommended for everyone – insomniacs, those who look after insomniacs, those who want to maximise their health and productivity, and those who desire little pearls for interesting conversations.

Subjectively, we know that during sleep, our brains lose contact with the outside world, and on wakening there is a feeling of a time cavity. Dream-time is often prolonged relative to real time but at a non-conscious level, time continues to be catalogued by the brain with incredible precision.

The loss of consciousness in sleep bears a superficial resemblance to death, and there is no shortage of sayings linking the two phenomena: such as the popular Twi utterance, loosely translated, "is it because we will die that we shall not sleep?"

Sleep is, however, not just the absence of wakefulness but an exquisitely complex, metabolically active, and deliberately ordered series of unique stages with different benefits. These stages include light non-rapid eye movement (NREM), deep NREM and REM sleep.

Considering the associated loss of time and living activities, as well as the vulnerability to predators when asleep, it is clear that sleep must serve an absolutely vital function. Could sleep have evolved by natural selection or is it evidence of intelligent design? Perhaps a question for another time.

The documented benefits of sleep are numerous. It enhances memory, and the various stages, occurring at different times of night, offer different benefits. For example, during deep NREM sleep, which predominates early in the night, unnecessary neural connections are removed, making it easier for the brain to retrieve information. During the dreaming stage of REM sleep, which prevails later in the night, the neural connections that have not been removed are strengthened. Therefore, following a night of sleep you regain access to memories that you could not retrieve before sleep. Dreaming also provides benefits including mollifying of painful memories, and increased creativity by the provision of a virtual reality space in which the brain melds past and present knowledge. Sleep moves recently acquired fact-based memories, stored in the hippocampus, to a more permanent, long-term storage location in the cortex, thereby freeing up short-term memory stores. Sleep therefore restores the brain's capacity for learning, making room for new memories, and cementing newly learned information, preventing it from fading away.

Another benefit of sleep (stage 2 NREM) is the improvement of motor performance speed and accuracy without further practice. This is achieved by the transfer of motor memories to brain circuits that operate below the level of consciousness, so that the newly learned skills can be performed with less conscious effort. In other words, practice, followed by a night of sleep, leads to perfection.

Sleep helps in healing emotional wounds and in providing solutions to challenging problems. Various psychiatric conditions have been shown to benefit from improvements in sleep. After physical activity, sleep accelerates recovery from inflammation, stimulates muscle repair, and helps restock cellular energy in the form of glucose and glycogen.

Further benefits of sleep include healthier physical appearance, reduced food cravings, protection from cancer and dementia, resistance to colds and flu, reduced risk of cardiovascular disease and diabetes, emotional stability and better decision-making.

Therefore, along with a balanced diet and exercise, sleep should be considered a cornerstone of good health.

What are the effects of insufficient sleep?

The human mind cannot accurately sense how sleep-deprived it is when sleep-deprived. Objective impairment in brain performance is evident after sixteen hours of being awake. Sleep deprivation reduces the ability of the brain to retain new facts, and the learning restoration benefit is diminished when sleep lasts six hours or less. After a week of short sleeping, performance levels are not restored by three full nights of recovery sleep. The ability to concentrate is impaired by the slightest sleep deprivation. After being awake for nineteen hours, people who were sleep-deprived were as cognitively impaired as those who were legally drunk. Furthermore, the effects of the combination of sleep loss and alcohol are worse than additive. The under-slept brain is extremely emotionally labile; studies of adolescents have identified a link between sleep disruption and suicide. When sleep deprived, patients with epilepsy are more likely to have seizures.

Routinely sleeping less than seven hours a night demolishes the immune system and increases the risk of cancer. Less than eight hours of sleep a night, and

especially less than six hours a night, impairs exercise capacity and even sweating.

There are many ways in which insufficient sleep can literally kill. First, there is a very rare genetic disorder that starts with a progressive insomnia, emerging in midlife, and resulting in death after twelve to eighteen months of no sleep. Secondly, drowsy driving causes more vehicular accidents than alcohol and drugs combined. Drunken driving causes delay in braking and in making evasive maneuvers. But drowsy driving results in momentary lapses in concentration called microsleep during which the driver does not react at all. During a microsleep, the brain becomes unaware of the outside world for a brief moment, and the driver may have no awareness of the event. Less common but even more serious is when a driver completely falls asleep at the wheel.

There is currently no drug, device or any amount of psychological willpower that can replace the benefits derived from a full night of sleep. There are many tips on promoting sleep in Dr. Walker's book. They include sticking to a sleep schedule and getting rid of anything in the environment that might interfere with sleep, such as noises. Mere disruption of the depth of sleep, such as that caused by infrequent sounds, even without waking up the individual, may have similar effects on brain function as a whole night of sleep deprivation.

What are the implications for people in Ghana? There is much scope for research on the effects of our very noisy environment and early waking (for long commutes) on the sleep, health and behaviour of Ghanaians[2]. Perhaps, therein lies a possible solution to some of the problems in this country – if the recommendations can be enforced.

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ORIGINAL ARTICLES

MATERNAL BODY MASS INDEX AND THE RISK OF HYPERTENSIVE DISEASE IN PREGNANCY - A STUDY OF AN URBAN POPULATION OF GHANA

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Abstract

Background: Hypertensive disease in pregnancy accounts for about 10-15% of maternal deaths in sub-Saharan Africa and Asia. The relationship between maternal BMI and Hypertensive disease in pregnancy has received limited attention especially in these low- and middle-income settings. This study aimed to quantitatively describe the relationship between maternal BMI in the first half of pregnancy and the risk of developing hypertensive disease later in pregnancy.
Methodology: A prospective cohort of pregnant women attending antenatal clinic at 37 Military Hospital, Accra between 15 June 2015 and 22nd March 2016 was conducted. A total of 196 consenting expectant mothers in the first half of pregnancy who met the inclusion criteria were recruited based on their BMI classification as normal or abnormal. They were followed up at regular antenatal visits till delivery. At these visits, repeated measurements of weight and blood pressure were taken. Univariate and multivariate statistical analysis taking into account the other risk factors for hypertensive disease in pregnancy was performed. Level of significance was set at $p<0.05$.
Results: Maternal BMI in the first half of pregnancy was significantly associated with developing hypertensive disease in pregnancy in second half of pregnancy. About 10 % of normal BMI mothers and 14% of abnormal BMI mothers developed hypertensive disease respectively. An increase in BMI within each BMI category was associated with an increased risk of developing Hypertensive disease in pregnancy.
Conclusion: Promoting a healthy maternal BMI in the first half of pregnancy may help reduce the risk of hypertensive disease later in pregnancy.

Keywords : hypertension, pregnancy, body mass index

Introduction

Background to the study

All over the world, pregnancy is usually a time when most couples share a lot of joy as they go through the various stages of this new state awaiting the arrival of the new family member. The joy of motherhood is the expectation of every pregnant woman and all expectant couples.

However, in most developing countries, the unacceptably high rates of maternal mortality makes couples envisage pregnancy with great uncertainty. Globally an estimated 289 000 women died during and following pregnancy and childbirth in 2013 alone and almost all these maternal deaths occurred in developing countries with sub-Saharan Africa accounting for more than half of these deaths[1]. In Ghana, maternal mortality was measured at 350 per 100,000 live births in 2010[1] and this is far greater than recent average maternal mortality ratio of 230 per 100,000 live births in developing countries[1] indicating that there is the need for continued concerted efforts to further reduce maternal mortality in Ghana. In these low-resource settings, it is well established that complications of hypertensive disease in pregnancy is one of the top 4 leading causes of maternal deaths[1]. Hypertensive disease in pregnancy however, complicates about 10% of all pregnancies[2], and in sub- Saharan Africa and Asia, contributes to 10-15% of maternal mortality[3].

Obesity and overweight on the other hand have also been identified as risk factors for various obstetric complications including Hypertensive disease in pregnancy[4,5]. However, the risk of developing hypertensive disease in pregnancy in the various BMI categories continues to be a subject area for research.

Significance of the study

A study to quantify the risk of developing hypertensive disease in the various BMI categories in a developing country like Ghana is imperative. This is because of the high prevalence of obesity among females in Ghana, and more so a higher prevalence in Greater Accra Region which is the subject region of the study. This is of immense public health value since the ramifications are huge and with advocacy and education, maternal mortality reduction, which is the

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Conflict of Interest : none declared

fifth Millennium Development Goal of the WHO, could be supported.

Aim of the study

To determine and quantify the relationship between maternal body mass index in the first half of pregnancy and the risk developing hypertensive disease in pregnancy in the second half of pregnancy.

Objectives and Hypothesis

Objectives of the study

The specific objectives of this study include

1. To describe the socio-demographic characteristics of expectant mothers seeking antenatal care in an urban area.
2. To determine the prevalence of obesity disease amongst expectant mothers attending antenatal clinic at the Military hospital.
3. To determine the prevalence of hypertensive disease in pregnancy amongst expectant mothers attending antenatal clinic at the Military hospital.
4. To determine and quantify the risk of Body Mass Index on hypertensive disease in pregnancy whilst controlling for other important confounders.

Hypothesis

Null hypothesis:

HO: 1. Having a BMI greater than 25 at the booking visit has no effect on the risk of developing Hypertensive disease in pregnancy.

HO: 2. Increased maternal weight gain in each BMI category has no effect on developing Hypertensive disease in pregnancy.

Alternate hypothesis:

H1: 1. Having a BMI greater than 25 at the booking visit increases the risk of developing Hypertensive disease in pregnancy.

H1: 2. Increase in weight gain within each BMI category increases the risk of developing hypertensive disease in pregnancy.

Methodology

Study design

This study was a prospective cohort study, which was conducted at the Department of Obstetrics and Gynaecology at the 37 Military Hospital, in Accra.

Study site and setting

The 37 Military Hospital situated in Accra, Ghana, is a tertiary hospital and a referral centre for the Greater Accra Region, and also a centre for postgraduate training in various disciplines including obstetrics and gynaecology. Although it is primarily a Military Hospital, it provides services to both military personnel and the general civilian population. It is also the second biggest hospital in the city situated almost at the centre of Accra, which is the capital city of Ghana. The hospital has a 600-bed capacity with the Obstetrics and Gynaecology Department having 58 Beds.

The city lies in the savannah belt between the Central and Volta regions with its population being essentially a melting pot of diverse ethnic groups with a dominance of the Ga–Adangbe tribe. The population in the city is about 5 million and the major occupation ranges from marketing goods and services, civil service and fishing. The educational levels of the populace are mainly secondary and tertiary levels for the white collar working population, but a large proportion who work in the informal sector have only basic education.

The antenatal clinic is held at the maternity outpatient department during the working week days of Mondays to Wednesdays and Fridays. Each of the four teams has a fixed day to run the antenatal clinic. Activities on each clinic day include booking of new patients; follow up of old patients, HIV counselling and testing and patient education. Thursdays are used to see patients reporting for the booking visit. At the booking visit the identification particulars of the patient and a full history are taken. Each patient undergoes a thorough physical examination including general examination, respiratory, cardiovascular and gastrointestinal systems, nervous system and musculoskeletal systems. The obstetric examination is done and this information and any subsequent information are recorded in specially designed patient hand-held "Maternal Health Record Book". Most other medical institutions in Ghana use these booklets.

At the booking visit, the patient is weighed, her height is measured and the urine is tested for proteins and sugar with a dipstick. Investigations requested for on the first visit are haemoglobin estimation and sickling test (if positive haemoglobin electrophoresis), blood group and rhesus factor, VDRL test, G6PD enzyme activity, urine for microscopy and biochemistry and stool for microscopy. Referred patients who had these tests done prior to referral do not have to routinely repeat them. Other tests or repeat tests are ordered as indicated.

Patients are seen monthly up to twenty-eight weeks gestation, then fortnightly until thirty-six weeks gestation and then weekly until delivery. In complicated pregnancies, patients are seen more frequently, or as the Obstetrician in charge may determine. Patients who require admission are admitted to the maternity lying-in wards.

Study period

From 15th June 2015 to 22nd March 2016

Sample size determination

The sample size calculation was done with the help of Epi-info 7 Statistical software. The sample size was calculated for an unmatched cohort using Fleiss method with the correction factor[6] at a power of 80% and a 95% confidence interval to detect the minimum Odds ratio of 3.4 between normal and abnormal BMI mothers based on literature. Similarly, a prevalence rate of hypertension in pregnancy of 10% was adapted from literature. The calculated sample size for the study was

178. However, adding a 10% non-response/ attrition rate, a sample size of 196 was used with 98 participants in each category.

Inclusion criteria

All antenatal attendants with normal blood pressure and with BMI within 18.5-24.9 were classified as normal BMI, and BMI equal to or greater than 25 was classified as abnormal BMI.

Exclusion criteria

- Foetal complications including multiple pregnancy and molar pregnancy
- Anomaly scan showing any foetal anomaly
- Patients with chronic medical conditions for example pre-existing hypertension before 20 weeks, renal disease and diabetes mellitus.

Data collection: Tools and methods

The primary tool used for data collection in this study was a structured questionnaire, which was administered by the principal investigator, and five research assistants who were trained at the beginning of the study to ensure standardisation of reporting.

The questionnaire was pretested at the antenatal clinic of the military hospital over 4 working days to improve the quality of data collection. Another meeting was scheduled after the pretesting was done and this helped to address issues and questions that came up during the pretesting period.

The participants who fitted the inclusion criteria and gave their informed consent, were recruited between 12 and 17 weeks, and were seen 2 weeks afterwards with their laboratory results, so as to be enrolled in the study. The dating of the pregnancy was done using a first trimester ultrasound scan. The scales that were used were Seca electronic scales and the patients were made to remove their shoes and have minimal clothing on. For the BP check, the patient had to be seated, and the right arm was used with a mercury sphygmomanometer with appropriate cuff for each patient, placed at the level of the heart.

At the initial visit, the patients were recruited based on their BMI into two groups, and those that consented to participate were given their laboratory requests and were seen 2 weeks afterwards, to be enrolled in the study. At the enrolment visit, at less than 20 weeks of pregnancy, a personal history was obtained and demographic data was collected. Also the BMI and blood pressure of patients were taken. This was important, so that patients with chronic Hypertension can be identified and excluded. The two groups based on normal BMI and abnormal BMI were then be followed up by trained research staff at clinic visits scheduled every 4 weeks, after 20 weeks of gestation, then every 2 weeks after 28 weeks to 36 weeks, and weekly thereafter till delivery.

A standard mercury sphygmomanometer was used to measure blood pressure with the patients in a seated position. Diastolic blood pressure was determined with the fifth Korotkoff sound unless the diastolic measurement approached zero, when the fourth sound was used. A mid-stream voided urine specimen was collected for measurement of protein by dipstick. A dipstick measurement indicating proteinuria of ≥1+ (300 mg/l) in a clean-catch, midstream urine sample was considered as positive. A dipstick measurement of zero or trace in the confirmatory sample was considered negative. BMI was categorized as normal weight (BMI 18.0– 24.9), overweight (BMI 25.0–29.9), and obese (BMI >30.0). The patients were categorised into normal BMI group (BMI 18.5– 24.9), and abnormal BMI group (BMI equal to or greater than 25).

Pregnancy Induced Hypertension was diagnosed if the systolic blood pressure is equal to or greater than 140mmHg and the diastolic blood pressure is equal to or greater than 90mmHg at two different times at least 6 hours apart, in the second half of pregnancy. Pre-eclampsia was diagnosed if there was an increased blood pressure equal to or greater than 140/90 mmHg with proteinuria, which occurs in the second half of pregnancy, after 20 weeks of pregnancy in a known normotensive non-proteinuric woman. Proteinuria in this situation is more than 300mg in a 24hour urine sample or more than 1+ on urine dipstick measurement. 1+ denotes 300mg/l of urine protein. Eclampsia was diagnosed with the occurrence of convulsion in a pre-eclampsia patient in the absence of coincidental neurologic disease. After delivery, the needed data were extracted from patient's folders, admission and discharge books at the labour and recovery wards as well as from obstetric operation entry book. Babies sent to NICU were also noted.

The information that was extracted included:

1. The socio-demographic data such as age, occupation, education level, marital status, occupation, level of income.
2. Development of hypertensive disease in a previous pregnancy and length of stay with current partner.
3. The blood pressure and the weights as determined at each visit.
4. The mode of delivery and attendance at Neonatal intensive care unit

Pregnancies were not allowed to progress beyond 42 weeks. All those who develop Hypertension were treated according to standard treatment guidelines

Data analysis

Data was originally entered using SPSS version 16 and the ensuing dataset extracted into Stata-SE version 12.0 for extensive checks and data cleaning. A descriptive analysis was performed to show the proportion of expectant mothers in each BMI classification that developed hypertensive disease in pregnancy. A general descriptive analysis of the study participants was first performed and assessed parameters compared between normal BMI group and abnormal BMI group. Simple logistic regression models

were built for of each of the independent (or exposure) variables and the dependent (or outcome) variable (hypertension in pregnancy) to understand the relationship between these variables and diabetes. The crude odds ratios (ORs) and P-values from Wald tests of these variables were noted.

Multivariate logistic regression was used to estimate the total effect of BMI at less than 20 weeks on the risk of hypertensive in pregnancy. BMI was modelled as a continuous variable rather than a categorical variable. This is because using BMI as a categorical variable assumes a constant risk within a category and a large jump in risk with the next category, which is usually not biologically plausible[8]. Variables that showed an association with the outcome variable were noted in the other of their strength of association and later included in the multivariate analysis. An explorative analysis of all independent variables that were associated with hypertension in pregnancy in the univariate logistic regression analysis (i.e. p-value<0.05) were treated as covariates and used to build a multivariate model using the backward fitting approach. The associated covariates in the univariate analysis were entered into a logistic regression model. The covariates used in the final model (multivariate) were based on literature on confounding factors that were likely to be independent risk factors for hypertensive disease in pregnancy. The factors that were strongly associated, having a p value < 0.05 therefore met the definition of confounding, and was added to the final model of a multivariate logistic regression. ORs were calculated to approximate risk ratios.

Ethical consideration

The Institutional Review Board of the 37 Military Hospital, Accra, approved the study. A written consent was obtained from all study participants after meeting the inclusion criteria.

Results

Out of the total of 196 respondents at the initial booking visit, one was lost to follow up and so was excluded from the analysis. A total of 195 respondents were obtained with 97 in the normal BMI group and 98 in the abnormal BMI group. Their baseline characteristics have been shown in Table 1.

Demographic characteristics

Majority (62/97) of the normal BMI group representing 63.92% were aged between 27 to 35 years with the minimum age for this BMI category being 19 years and the maximum being 39 years. There was a similar pattern for the abnormal BMI category with majority (69/97) in the age group of 27 to 35 years representing 70.41%, with the minimum age being 16 and the maximum age being 49 years as shown in Table 1. Majority (80/97) of the normal BMI group representing 82.47% were married whilst 68 (out of 98), also a majority, and representing 69.39% for the abnormal BMI category were married.

The level of income for the abnormal BMI category was higher with about 56 (out of 98), representing 57.14% earning 1000Gh or more whilst 32 (out of 97), representing 32.98% earned 1000 Gh cedis or more for the normal BMI category.

The level of income for the partners of respondents was higher for those with abnormal BMI, with 87 (out of 98), representing 88.77% of them earning 1000 Gh cedis or more and 62 (out of 97) representing 63.91% of the partners for the normal BMI group earning 1000 Gh cedis or more. 167 of the respondents out the 195 respondents had either secondary or tertiary education representing about 85.64%. 148 of the respondents, representing 75.90% were married.

BMI category characteristics

Majority (51/97) of the normal BMI group had tertiary education (52.58%) and 33 out of 97, representing 34.02% had secondary education. For the abnormal BMI category, 37 (out of 98), representing 37.76% had tertiary education and 46 (out of 98), representing 46.94% had secondary education as shown in Table 1. The mean weight at the booking visit for the normal BMI group was 58.33kg± 5.66. The minimum weight in this group was 44kg and the maximum was 76. The mean weight at the booking visit for those in the abnormal BMI category was 82.80kg±10.16. The minimum weight in this group was 63 and the maximum weight was 129.

The mean measured height in the normal BMI category was 1.655m±0.057. The minimum height in this BMI category was 1.53m and the maximum was 1.83m. The mean measured height in the abnormal BMI category was 1.638m± 0.067. The minimum height in this BMI category was 1.53m and the maximum was 1.83m. Majority of the normal BMI group were nulliparous (48.45%) while 39.18% were primiparous. 39.80% of the abnormal BMI group were nulliparous whiles 33.67% were primiparous. Majority (56.70%) of the normal BMI group had stayed with their current partner for between 1 and 5 years with about 17.53% having stayed for less than 1 year with the current partner. Majority (77.55%) of the respondents in the abnormal BMI group had stayed with the current partner for between 1 and 5 years with 6.12% having stayed with their partners for less than 1 year. At the booking visit, the mean BMI for nulliparous women was 25.68 with a standard deviation of 5.52. The minimum BMI for nulliparous women was 15.41 and the maximum BMI was 41.64. Multiparous women had a higher BMI, with the mean BMI being 28.47 with a standard deviation of 6.35. The minimum BMI for multiparous women was 16.14 and the maximum was 42.97. The prevalence of obesity from the study sample was 21.03%, using the weight at the booking visit. This is further illustrated in Figure 2.

Table 1. Baseline characteristics and demography of respondents

Characteristic	Exposure Status	
	Unexposed/Normal BMI (%) N=97	Exposed/Abnormal BMI (%) N=98
Maternal Age (years)		
16-26	23 (23.71)	14 (14.29)
27-35	62 (63.92)	69 (70.41)
36 0r older	12 (12.37)	15 (15.31)
Educational level of Respondents		
None	1 (1.03)	3 (3.06)
Primary	12 (12.37)	12 (12.34)
Secondary	33 (34.02)	46 (46.94)
Tertiary	51 (52.58)	37 (37.76)
Characteristic	Exposure Status	
	Unexposed/Normal BMI (%) N=97	Exposed/Abnormal BMI (%) N=98
Respondents level of income*		
<500	18 (18.56)	11 (11.22)
500-1000	32 (32.99)	26 (26.53)
1000-1500	23 (23.71)	25 (25.51)
1500-2000	4 (4.12)	19 (19.39)
>2000	5 (5.15)	12 (12.24)
Unemployed	15 (15.46)	5 (5.10)
Income level of partner *		
<500	5 (5.15)	
500-1000	29 (29.90)	10 (10.20)
1000-1500	26 (26.80)	30 (30.61)
1500-2000	16 (16.49)	23 (23.47)
>2000	20 (20.62)	34 (34.69)
Unemployed	1 (1.04)	1 (1.03)
Characteristic	Exposure Status	
	Unexposed/Normal BMI (%) N=97	Exposed/Abnormal BMI (%) N=98
Marital Status*		
Unmarried	17 (17.53)	30 (30.61)
Married	80 (82.47)	68 (69.39)
Hypertensive disease in previous pregnancy**		
No	90 (93.75)	91 (92.86)
Yes	6 (6.25)	7 (7.14)
Parity*		
Nulliparous	47 (48.45)	39 (39.80)
Primiparous	38 (39.18)	33 (33.67)
Multiparous	12 (12.37)	26 (26.53)
Length of stay with current partner*		
Less than 1 year	17 (17.53)	6 (6.12)
Between 1 and 5 years	55 (56.70)	76 (77.55)
Between 5 and 10years	24 (24.74)	12 (12.24)
More than 10 years	1 (1.03)	4 (4.08)

*The following had a strong association with BMI classification,

Marital status P value 0.033
Respondent's level of income P value 0.001
Income of partner P value 0.002
Parity P value 0.044
Length of stay with current partner P value 0.002
**There was one non-respondent for this variable

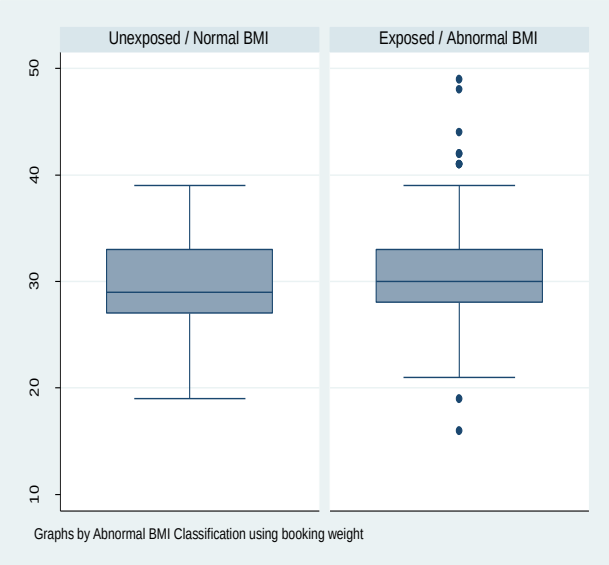

Fig 1: Box plot comparing normal BMI with abnormal BMI and ages at booking visit

BMI categories and hypertensive disease in pregnancy

4% of the normal BMI category had pre-eclampsia whilst 6% of abnormal BMI category had pre-eclampsia. 6 (6.25%) out of 96 of the normal BMI group said they had developed hypertensive disease in a previous pregnancy whilst 1 did not respond. 7 (7.14%) out of 98 in the abnormal BMI group said they had developed hypertensive disease in a previous pregnancy.

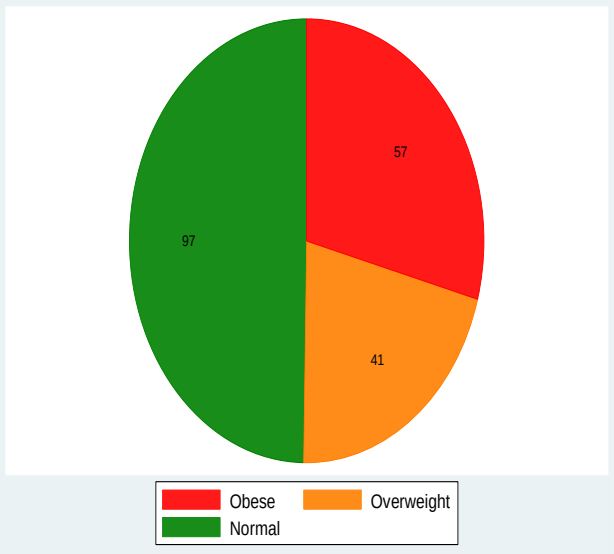

Figure 2: Pie chart showing BMI classification at the booking visit

9 women in the normal BMI group, representing 9.28% developed hypertensive disease in pregnancy whilst 14 representing 14.29% in the abnormal BMI group developed hypertensive disease in pregnancy. Also 4 women in the normal BMI category, representing 4.12% developed pre-eclampsia whilst 6 in the abnormal BMI category, representing 6.12% developed pre-eclampsia. The overall prevalence of Hypertensive disease in pregnancy was 11.79%. The overall prevalence of preeclampsia was 5.12%

Delivery and outcomes

A total of 16 of the 23 women who developed hypertensive disease had caesarean section representing 69.57%. A total of 6 women who were obese had caesarean section among the women that developed hypertensive disease in pregnancy representing about 26.09% of them.

A total of 13 of the babies delivered were sent to the neonatal Intensive Care Unit, representing 6.7% of respondent deliveries. The number of babies of respondents with hypertensive disease in pregnancy that went to NICU was 6 representing 46.15% of the babies that has been sent to NICU. Two out of the 6 babies from the hypertensive women that were sent to NICU, were from mothers in the obese group, representing 15.38%.

Crude analysis

Parity, as well as the number of years of stay with the current partner were determined to be independent risk factors for the development of hypertensive disease in pregnancy with crude analysis, both having a p value less than 0.05.

Univariate Analysis

With univariate logistic regression, the age group, parity, length of stay with current partner, hypertensive disease in a previous pregnancy and the enrolment BMI, at less than 20 weeks were independent risk factors for the development of hypertensive disease in pregnancy, all having p values less than 0.05. This is shown in Table 2 below

Table 2*:* Univariate Analysis of variables showing positive association with Hypertensive disease in Pregnancy

Characteristic	OR (95% CI)	P value
Enrolment BMI	1.0880(1.0068-1.1757)	0.0328
27-35 years	0.2057(0.0644-0.6568)	<0.0001
36 years or older	2.5210(8108-7.8388)	
Parity	0.4946(0.3013-0.7191)	0.0182
Hypertensive disease in previous pregnancy	5.6597(1.6729-19.1474)	0.0097
Length of stay with partner	0.4645(0.3013-0.7190)	<0.0001

For the age group, using univariate logistic regression, the age group between 16 to 26 years was compared with the age group between 27 to 35 years and 36 years or

greater with the risk of developing hypertensive disease in pregnancy. The OR for the age group between 27 and 35 years was 0.206 (CI 0.064-0.657). The OR for the age group 36 years or greater was 2.5 (CI 0.811-7.839) as shown in Table 2. For the variable, hypertension in previous pregnancy, the OR of developing hypertensive disease in the index pregnancy was 5.660 (CI 1.673-19.147) as shown in Table 2.

From the enrolment, which was less than 20 weeks of gestation, to delivery 9.78% in the normal BMI group developed Hypertensive disease in pregnancy whilst 13.59% in the abnormal BMI group developed Hypertensive disease in pregnancy. This result however failed to reach significance with crude analysis at a P value of 0.41. However with the application of the univariate logistic regression, the p value of the enrolment BMI at pregnancy less than 20 weeks became 0.0328, which was strongly associated with the risk of developing hypertensive disease in pregnancy. The OR was 1.0880(CI 1.0068-1.1757).

The OR for BMI group 18-24.9 (normal weight) was 0.1084 (CI 0.0545-0.2157). The OR for BMI group 25-29.9 (overweight) was 0.5764 (CI 0.1180-2.8138). The OR for BMI group 30 or greater (obese) was 1.9415 (CI 0.7678-4.9095)

Multivariate Analysis

With the multivariate logistic regression, using the independent risk factors of age, hypertension in previous pregnancy, length of stay with current partner and parity, the p value was less than 0.001 showing a strong association between abnormal BMI at less than 20 weeks of gestation and the risk of developing Hypertensive disease in pregnancy which is shown in Table 3 below.

Table 3: Multivariate analysis showing the BMI at enrolment, and risk of developing hypertensive disease in pregnancy, controlling for confounding factors. n=194*

Characteristic	Unadjusted OR (95% CI)	Adjusted OR (95% CI)
Enrolment BMI	1.08(1.0068-1.1758)	1.1356(1.0292-1.2530)
27-35 years	0.2057(0.0644-0.6568)	0.3076(0.0794-1.1916)
36 years or older	2.5210(0.8108-7.8389)	4.6661(1.0638-20.4667)
Parity	0.4946(0.2568-0.9526)	0.3637(0.1579-0.8373)
Hypertensive disease in previous pregnancy	5.6597(1.6729-19.1474)	10.3907(1.7037-63.3708)
Length of stay with partner	0.4655(0.3013-0.7190)	0.1540(0.0504-0.4709)

*There was one missing variable in the final model

Discussion

The essence of this prospective cohort study was to determine the prevalence of obesity and hypertensive disease in pregnancy, and to determine and quantify the effect of Body Mass Index on the risk of Hypertensive disease in pregnancy whilst controlling for other important confounders.

Socio-demographic characteristics of the study population

This study was done among an urban population in the city of Accra and so there might be certain differences even though the general socio-demographic characteristics reflect what pertains in the whole country of Ghana. According to the Ghana Demographic and Health Survey, 2008[9], 21% of women in the reproductive age group had no formal at all whilst 4% had tertiary education. In the study population 2.05% had no formal education whilst 45.13% had had tertiary education. The difference can be explained by the fact that the 37 Military Hospital is located in the capital city of the country where schools, colleges and universities are easily accessible compared to other parts of the country.

Also, according to the Ghana Demographic and Health Survey, 2008[9], 59% of women were married or in a union whilst it was 75.90% in the study population, largely reflecting the majority which pertains nationally.

Prevalence of Obesity

The prevalence of obesity from the study sample was 21.03%, using the weight at the booking visit. This was comparable to what was found by Yogev et al, 2009[10] in the USA, which gave a prevalence of obesity among pregnant women to be between 18.5% and 38.3%. It is however slightly higher than the general prevalence of obesity in Accra found by Biritwum et al, 2005[11], which was 16%. This can be explained by the higher income earnings of the study population and the tendency for sedentary lifestyles leading to obesity.

Prevalence of Hypertensive disease in pregnancy

The overall prevalence of Hypertensive disease in pregnancy was 11.79%. The overall prevalence of preeclampsia was 5.12%. This corresponds to the worldwide prevalence of 10% for hypertensive disease in pregnancy and 2-8% for pre-eclampsia[2]. The prevalence of preeclampsia also corresponds to a study done in Benin City, Nigeria, which was 5.6%, however the overall prevalence of Hypertensive disease in pregnancy was higher than that found in Benin City of 7.2%[12].

Delivery outcomes

A total of 16 of the 23 women who developed hypertensive disease had caesarean section representing 69.57%. This is comparable to what was found by Hall et al, 2000[13] where 80% of them had caesarean section. This is because the core treatment in literature for hypertensive disease in pregnancy is delivery[14] and sometimes has to be done preterm, with an unfavourable cervix so when induction of labour fails caesarean

section has to be done. Also a total of 6 obese women had caesarean section, which represents 26.09% of the 23 women who developed hypertensive disease in pregnancy. This is comparable to a meta-analysis by Poobalan et al (2008), which showed that 29.02% of obese women had caesarean section[15]. This high percentage is because obesity is an independent risk factor for a caresarean section[15].

A total of 13 of the babies delivered were sent to the neonatal Intensive Care Unit, with the number of babies of respondents with hypertensive disease in pregnancy that went to NICU being 6 representing 46.15% of respondent deliveries that were sent to NICU. This is slightly higher than what was found by Hall et al, 2000[13] where 40.7% of the babies born to early onset pre-eclamptics had been sent to NICU. This can be explained by the fact that our study included the whole spectrum of hypertensive disease in pregnancy. Also 2 of the women in the obese group had their babies sent to NICU representing 15.38%. This was comparable to what was found by Yogev et al (2005), in obese non-diabetic pregnant women who had 12.3% of their babies being sent to NICU[16].

BMI categories and hypertensive disease in pregnancy

The results show that BMI before 20 weeks is a strong independent risk factor for the development of hypertensive disease in pregnancy. It also shows a strong association between increasing BMI at enrolment of the study, which was before 20 weeks and the risk of developing hypertensive disease in pregnancy. This corresponds to what was found by Bodnar et al, 2005[17]. The age group of 27 to 35 years was protective with an unadjusted OR of 0.2057(0.0644-0.6568). However age group 36 years or greater had an OR of 2.5210(0.8108-7.8389), showing a 2.5 times increased risk of developing hypertensive disease in pregnancy compared to age group 16 to 26 years. This therefore shows that the best time to have children is in this age group, to reduce the risk of hypertensive disease in pregnancy which is corroborated by published literature which shows that the extremes of age have an increased risk of developing hypertensive disease in pregnancy[18].

The OR for hypertensive disease in a previous pregnancy was 5.6597(1.6729-19.1474), which shows a high risk 5 times of developing hypertension in pregnancy. This is corroborated by published studies by Duckitt, 2005[18] who got an OR 7.19 (5.85-8.83) for developing pre-eclampsia, in a woman with a previous history of pre-eclampsia. This information is therefore very useful so that such patients can be labelled as high risk and be seen more frequently and be given more attention in the second half of pregnancy. The length of stay was also positively associated with a p value of <0.0001 with a negative association as shown in Table 2. This therefore shows that the shorter the time couples stay together before pregnancy, the higher the risk of developing hypertensive disease in pregnancy. This also agrees with what Klonoff-Cohen et al, 1989[19] found with logistic regression results suggest increasing risk of preeclampsia with decreasing amounts of sperm and seminal fluid exposure by a factor of 1.34 per quartile.

The BMI at enrolment in the study was positively associated with the risk of developing hypertensive disease in pregnancy. It shows that increasing BMI even within the normal BMI group leads to an increased risk of developing hypertensive disease in pregnancy. The OR from enrolment BMI was 1.08 (1.0068-1.1758), showing an 8% increase in risk for each unit of BMI increase which agrees with published literature[17]. Bodnar et al, 2005[17] found a sharp rise in risk across most of the BMI distribution indicates that the risk of preeclampsia increases even within traditional BMI categories. For instance in the study by Bodnar et al, women with a BMI of 28 are 40% more likely to develop preeclampsia as women with a BMI of 25 (adjusted OR: 1.4; 95% confidence interval, 1.1-1.6), even though both are considered overweight by conventional cut off points.

The OR for BMI group 30 or greater (obese) was 1.9415 (CI 0.7678-4.9095) showing an increase in risk when obese compared to overweight was 0.5764 (CI 0.1180-2.8138) and normal weight which was 0.1084 (CI 0.0545-0.2157). The high OR for BMI group 30 or greater (obese) being 1.9415, gives almost double the risk for developing hypertensive disease in pregnancy.

One author found a substantially increased risk of hypertensive disease in pregnancy with high BMI 26 to 34.9 and greater than 35[20]. Women can therefore be advised to lose weight prior to getting pregnant to reduce the risk of developing hypertensive disease in pregnancy. There was an increased proportion of respondents developing hypertensive disease in pregnancy for the abnormal BMI group (14%), compared to 9% in the normal BMI group which agrees with published literature[21].

The mechanisms underlying the BMI–preeclampsia relation have yet to be identified. Reduced placental perfusion, secondary to abnormal implantation and subsequent reduced placental vascularization, is the defining feature of preeclampsia[22]. However, it has been noted that not all women with reduced placental perfusion, develop preeclampsia. This paradox has led to the theory that preeclampsia is a two stage disorder with maternal-foetal interactions necessary to link the two stages[23].

Reduced placental perfusion is thought of as the first stage, while the second stage, the maternal syndrome, develops in a subgroup of women with certain genetic, environmental and behavioural characteristics as a response to factors produced by the poorly perfused placenta[23]. In a suitable maternal environment, oxidative stress and subsequent endothelial activation and injury result, initiating the coagulation cascade and ensuing multisystem sequelae[24]. Abnormal BMI (Overweight and obesity)

can be postulated as one such predisposing maternal characteristic[17].

However on the causal pathway between abnormal BMI and Hypertensive disease in pregnancy, factors like parity, the number of years of stay with the partner, hypertensive disease in previous pregnancy were found to be independent risk factors for the development of hypertensive disease in pregnancy from our study and so had to be controlled for. This is corroborated by published literature[25,14,19]. These factors therefore provide the appropriate maternal environment[24] for the development of hypertensive disease in pregnancy. The observed association between abnormal BMI in the first half of pregnancy and hypertensive disease in pregnancy may be confounded by the presence of chronic hypertension[26], diabetes mellitus[27], each of which are known risk factors for preeclampsia. These were therefore part of the exclusion criteria.

Conclusion

The study found an increased risk of developing Hypertensive disease in pregnancy with increase in BMI within each BMI category. There is also an increased risk (almost double) of developing hypertensive disease in pregnancy in obese pregnant women.

Limitations

The contribution of the baby's weight as pregnancy advanced to the maternal BMI could not be reasonably accounted for. For example, if the BMI was 26 and after delivery it dropped to 24 she was now of normal BMI.

Another limitation was that a history of hypertension in a previous pregnancy was self-reported. This was therefore subject to recall bias. However the strength of association was strong, which agreed with published data.

The other limitation was the generalizability of the findings as the sample was taken from patients only attending the 37 Military Hospital for antenatal care. This is a tertiary hospital and so overweight and obese pregnant women were likely to be referred to the hospital from primary care providers. The results however agreed with published literature so were quite representative.

Recommendations

Medical practitioners attending to obese pregnant women should monitor their blood pressures carefully, especially in the second trimester because they are at an increased risk of developing hypertensive disease in pregnancy. There should be adequate health education on overweight and obese women embarking on pregnancy to try to reduce their weight. Future studies should also confirm hypertensive disease in a previous pregnancy from medical records and not from recall of patients.

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EFFECT OF PLASMODIUM BERGHEI PARASITAEMIA ON LABORATORY INDUCED GASTRIC ULCER IN MICE

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Abstract

Background: Malaria is an important infection in Africa affecting all age groups although its severity depends on the relative immunity of the individual. Malaria has been found to have effects on the gastric mucosa, which include congestion with capillary stasis, necrosis, ulceration and haemorrhage. This study aimed at the effect of malaria parasitaemia on laboratory induced gastric ulcer in mice.

Methods: Thirty-six mice divided into 6 groups thus: Group 1. no malaria parasite and ulcer (control); Group 2. Parasite without ulcer; Group 3. Parasite and ulcer; Group 4. Ulcer without parasite; Group 5. Parasite, ulcer and chloroquine treatment; and Grop 6. Parasite, ulcer and Artemether treatment. These were used for the study. The mice were parasitized with 20% innoculum of *Plasmodium berghei* and ulcer induced with 70% alcohol and pylorus ligation. Parameters such as degree of parasitization, ulcer diameter, gastric acidity and packed cell volume (PCV) were measured in the various groups and comparison made where necessary. The experimental part of the study took 18 days.

Results: The severity of ulceration in the group with ulcer and parasite (11 ± 1.72 mm); and group with ulcer but no parasite (3.62 ± 1.6mm) was compared and was significant (p = 0.002). The groups with parasite showed gradual reduction in the packed cell volume (PCV) as the parasite load increased while the group without parasite showed increase in PCV over the time of study. The ulcer diameters in the groups treated with chloroquine (4.83 ± 2.48mm) and Artemether (5.00 ± 0.89) was not statistically significant (p = 0.889).

The restoration of PCV was better for the treated group than the untreated group. The pH of the gastric content in the untreated group was lower than the treated groups. The parasite clearance by chloroquine and artemether was significant (p = 0.04) compared to the untreated groups.

Conclusion: Malaria parasitaemia has a significant influence on gastric ulceration, PCV and to some extent gastric secretion. Chloroquine and artemether are sensitive drugs to *Plasmodium berghei.*

Keywords: malaria, parasitaemia, gastric ulcer, chloroquine, artemether.

Introduction

The Greek physician Hippocrates, who lived in the 5th century BC, was the first to describe the characteristic symptoms of a malaria infection as intermittent often relapsing fever accompanied by drenching sweats and followed by shaking chills. Centuries later, the medical almanac of 1888 referred to malaria as one of the great scourges of humanity, wreaking havoc in human civilizations throughout history and claiming more lives than any other infectious disease[1,2].

Malaria is still a major health problem, causing an estimated 300 million cases of illness and killing 1-2 million people mostly infants every year. About 2.2 billion people (41% of the world's population) are now in danger of contracting malaria. It has a high mortality and morbidity especially in children, the non-immune and pregnant women[3,4].

Peptic ulcer is found in about 10% of the population and main causes include *Helicobacter pylori* and non-steroidal anti-inflammatory drugs[5]. Malaria has also been found to have both direct and indirect effects on the gastric mucosa in humans presenting with gastrointestinal symptoms especially in children termed "choleric malaria"[6].

In view of the increasing peptic ulcer disease in our population and the pandemicity of malaria infection, the present study aims at studying the effect of malaria parasitaemia on gastric mucosa, gastric acidity and gastric ulcer; and the effects of treatment on these parameters.

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Conflict of Interest : none declared

Methodology

Thirty six mice of 6 groups (average weight 20-25 grams) from the animal house of the College of Medicine, University of Ibadan were used for the study. The mice fed on normal chow meal *ad libitum*.

Each group was kept in a separate cage with food and water and under optimal conditions of temperature 22-25^{0}C and relative humidity of 40-70% with 12 hour day time/night time cycle.

The animals were parasitized with *Plasmodium berghei* collected from the laboratory of Dr. O.G Ademowo of the Institute of Medical Research and Training (IMRAT), College of Medicine, University College Hospital, Ibadan.

The mice were divided into 6 groups:

Group 1 – No malaria parasite, no ulcer (control)
Group 2 – Malaria parasite no ulcer
Group 3 – Malaria parasite and ulcer
Group 4 – No malaria parasite, but ulcer
Group 5– Malaria parasite, ulcer and chloroquine treatment
Group 6 – Malaria parasite, ulcer and Artemether treatment

The mice were parasitized with 20% innoculum of Plasmodium berghei using the intraperitoneal route, ulcer induced with 70% alcohol and pylorus ligation (Bolarinwa et al)[5] and pH measured using a standard pH meter and blood taken for blood film examination from the tail of the mice. The degree of parasitaemia was checked at day 3, day 5 and day 7 along with the PCV. The percentage parasitaemia was estimated from thin blood film. The blood films were made by staining with Leishman stain using standard protocols. The slides were examined on x100 (oil immersion) microscope for percentage parasitaemia.

For the untreated group, ulcer was induced on day 7 with 70% alcohol and pylorus ligation after 24 hours fast[7]. The gastric acidity (pH) and ulcer indices were assessed after 4 hours of pylorus ligation.

For the treated group, the drugs were administered orally using the microintubator. Chloroquine at a dose of 10mg/kg for 2 days; and 5mg/kg for the 3rd day was commenced on day 8. The gastric acidity (pH) and ulcer indices were assessed on day 11 (24 hours after completion of therapy). Also, artemether at a dose of 3.2mg/kg first day; and 1.6mg/kg for the next 4 days was commenced on day 8.The gastric acidity (pH) and ulcer indices were assessed on day 13 (24 hours after completion of therapy). Both were used following standard dose regimen of 3 and 5 days for chloroquine and artemether respectively. The bench-work was concluded after 18 days.

All the mice were fasted for 24 hours before the gastric acidity (pH) and ulcer indices were estimated. The pH of gastric content was measured with an automatic pH meter by insertion into the stomach and the gastric acidity estimated using pH = -log (H^+).

The stomach was harvested and ulcer diameter measured using a tape measure. Gastric samples were kept in formalin for histology. These specimens were examined and the ulcers were scored by measuring the diameter of the ulcers and other morphologic changes were noted. The tissues were put into cassettes and were subsequently transferred to the tissue processor overnight. The processed tissues were embedded in paraffin wax and then cut into 5 microns sections by microtome machine. The sections were mounted on the slides and stained with haematoxylin and eosin and covered by cover-slips; and the slides were reported under the microscope. Physical observations were made over the time of study. Following treatment, the activity of the animal and their feeding rate were better. The data were analysed using SPSS version 16. Continuous variables were compared using the Student t test, while discontinuous variables were compared using the $\chi 2$ test. The level of significance was set at $p \leq 0.05$. Findings were presented in tables and figures.

Results

Six groups of 6 mice each were studied totaling 36 mice. The weights ranged from 20 – 25gm with mean weight 21.5gm.

Parasite Changes With Packed Cell Volume

The animals were inoculated with 20% Plasmodium berghei. There was an initial fall in the percentage parasitaemia and subsequent gradual increase over time. With intervention (drugs) there was a decline in the parasitaemia as seen in table 1.

The packed cell volume in the control group increased gradually over the time of study. The groups with parasite showed a decline in PCV with increasing parasitaemia.

pH and Gastric Acidity

Reduction in pH and increase gastric acidity were seen in parasitized mice. An improvement in these parameters occurred with treatment especially the artemether group 6. (Table 2)

Ulcer Study

Within the 4 hours of ulcer induction with pylorus ligation and 0.1ml of 70% ethanol, the parasitized mice showed significant gastric mucosa ulceration. Also, the animals without ulcers but parasites showed congestion of the gastric mucosa. ($P < 0.05$)

Therapy

With treatment, there was a significant reduction in percentage parasitaemia ($p<0.05$). The pH and gastric acidity showed improvement. The gastric ulceration in the treatment groups were less than the untreated groups. The parasite clearance by chloroquine and artemether was significant ($p < 0.05$). But artemether has a slightly higher clearance although not statistically significant.

Table 1: Average PCV changes with increasing parasitaemia over 7 days

	Pcv %				**Parasitaemia %**		
	Day 0	Day 3	Day 5	Day 7	Day 3	Day 5	Day 7
(Control) Group 1	56	57	57	58			
Group 2	57± 1.75	52±4.59	50±2.28	35±1.94	17.8±2.99	30.7±3.01	40±1.79
Group 3	52±6.47	53±8.73	49±5.90	44.6±6.28	15.2±1.47	31.5±3.012	39.7±2.73
Group 5	56.8±7.81	51.8±5.46	40.5±6.19	41.2±16.98	18±2.45	32.8±6.62	39.6±16.25
Group 6	57±6.19	55.8±3.49	51.7±4.80	47.3±7.00	15.3±2.14	27.7±2.07	36.8±3.92

Table 2: Average pH and acidity of gastric content

	pH	**Acidity mol/L**	**ulcer**
Group 1	5.6±0.31	$2.8x10^{-6}$ ±1.78	-
Group 2	5.3±0.33	$5.0x10^{-6}$ ±4.29	-
Group 3	5.5±0.54	$3.2x10^{-6}$ ±12.28	11±1.79mm
Group 4	6.3±0.15	$5.2x10^{-7}$ ±1.75	3.7±1.633mm
Group 5	5.0±2.06	$1.0x10^{-5}$ ±7.44	4.8±2.483mm
Group 6	6.4±2.90	$4x10^{-7}$ ±12.62	5±0.894mm

Table 3: Differences in the gastric acidity and PCV between the antimalarial treated and untreated groups

	pH	**Acidity (mol/L)**	**PCV (%)**	**Ulcer index**	**Parasitaemia %**
Group 3	5.5±0.54	$3.2x10^{-6}$ ±12.28	44.6±6.28	11±1.79mm	39.7±2.73
Group 5	5.0±2.06	$1.0x10^{-5}$±7.44	47.6±16.98	4.8±2.48mm	21.4±9.13
Group 6	6.4±2.90	$4x10^{-7}$ ±12.62	53.2±7.01	5±0.89mm	16.2±2.90

Table 4. Difference in the average degree of parasitaemia, PCV, gastric acidity and ulcer indices in chloroquine (CQ) and artemether (ART) treated mice.

	Group 5 (CQ)	**Group 6 (ART)**
PCV (%) Pretreatment	41.2±16.98	47.3±7.01
Post Treatment	47.6±19.56	59.2±4.57
Parasitaemia Pretreatment	39.6±16.98	36.8±7.01
Post treatment	21.4±19.56	16.2±4.57
pH	5.0±2.05	6.4±0.23
Acidity (mol/L)	$1.0±10^{-5}$ ±7.42	$4x10^{-7}$ ±2.62
Ulcer index (mm)	4.8±2.4	5±0.89

HISTOLOGY REPORT

The biopsies were processed at the Department of Pathology, University College Hospital, lbadan, Nigeria. Haematoxylin and Eosin stains were used.
Sections of unparasitized mice show normal gastric mucosa glands lined by columnar epithelium with other layers appearing normal. There is congestion of the mucosa in the mice with parasite but no ulcer. (Figure 1)

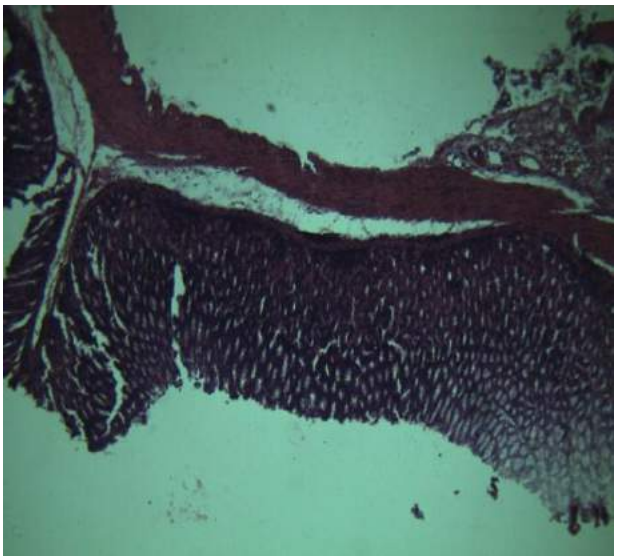

Fig 1. Normal gastric mucosal biopsy with mild congestion (Groups 1 and 2)

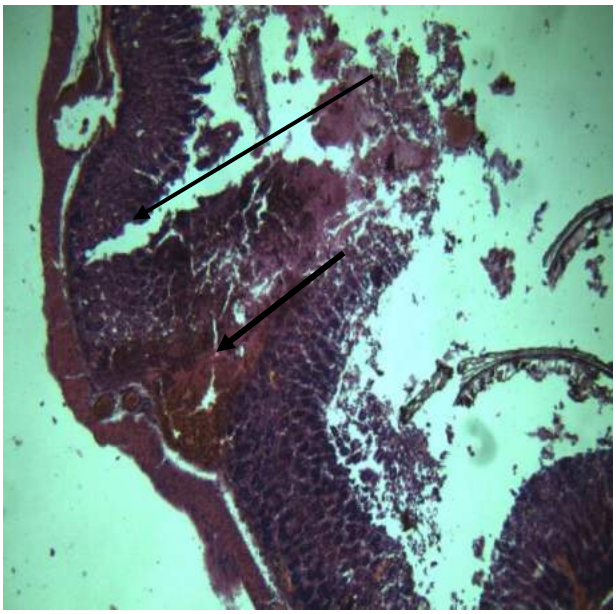

Fig 2. Section of gastric tissue showing severe gastric ulceration, haemorrhage, necrosis and infiltration by acute inflammatory cells consistent with acute severe gastric ulcer (Group 3).

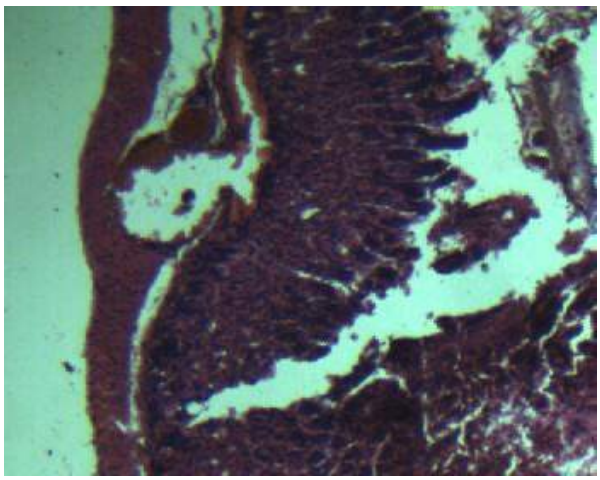

Fig 3: Section shows gastric tissue with ulceration and congestion consistent with gastric ulcer. (Group 4).

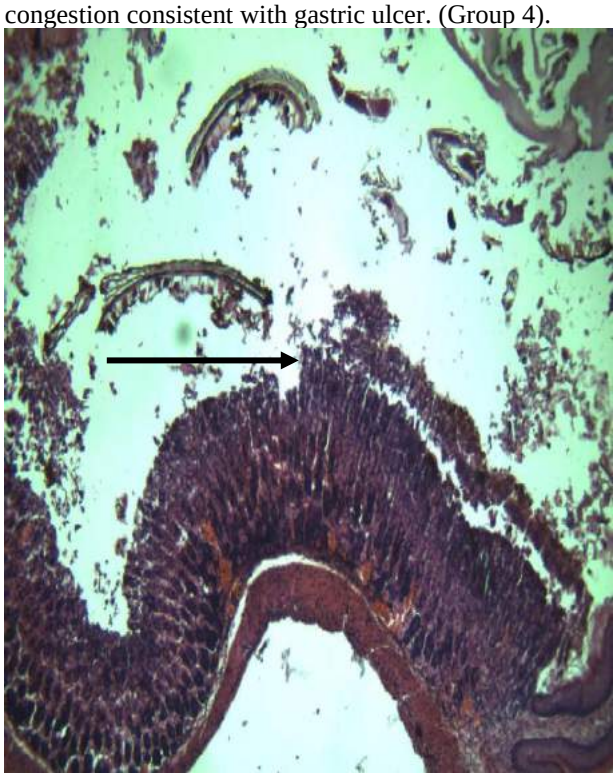

Fig 4: Section of gastric biopsy showing gastric mucosa erosion (Groups 5 and 6)

Section of the group with ulcer and parasite shows ulceration of the gastric mucosa extending beyond the muscularis propria with associated haemorrhage and congestion; and focal area of necrosis and infiltration by acute inflammatory cells consistent with severe gastric ulcer. (Figures 2 and 3).

Sections of the treated groups show erosion of the gastric mucosa with mild infiltration by acute inflammatory cells consistent with gastric erosion. (Figure 4)

Other Observations

The parasitized mice showed reduced activity and anorexia while the un-parasitized ones were more active and were feeding well.

Discussion

The effects of *Plasmodium berghei* parasitaemia on laboratory gastric ulcer in mice was evaluated in 36 mice which were grouped into six.

The decline in PCV with increasing parasitaemia in our study supports the fact that anaemia is a common finding in malaria. This is comparable with the studies in humans by other workers (Francis and Warell 1993 and Menendez 2000)[8,9]. The cause of decline in packed cell volume as a result of malaria is multifactorial, there is lysis of parasitized erythrocytes, immune mediated haemolysis and reduction in the life span of the erythrocytes (Phillips et al 1992, Smith et al 2002)[10,11,12,13]. Kai et al[14] also suggested that anaemia is due to both a great increase in clearance of uninfected cells and a failure of an adequate bone marrow response.

Chloroquine and artemether were sensitive drugs to P berghei parasitaemia as they significantly clear the parasitaemia in the mice studied. Various studies have shown that these drugs are very potent (Nakazawa 2005)[15]. Nakazawa in Japan found that chloroquine is effective in treating P berghei in early and recrudescence phases. Artemether was better in restoring the packed cell volume to nearly pre-morbid state 24 hours after dosage completion than chloroquine. The clearance of parasitaemia by artemether was slightly greater than chloroquine though both showed a considerable clearance to *Plasmodium berghei*. This is comparable with reported observation in Gambia (White el)[16] and that of Myint et al.[17] in 1987 where artemether was reported to have a faster malaria parasite clearance time than quinine.

Parasitaemia was noted to have influence on the gastric mucosa and gastric content.

The parasitized mice showed lower pH and higher gastric acidity compared with the unparasitized counterpart (Jimmy et al., 2014).[18] There was also marked congestion of the gastric mucosa in the parasitized mice.

The ulcers in the parasitized animals were remarkable with moderate to severe congestion of the gastric mucosa.

The congestion noticed in the untreated groups were not present in the treated group and the ulcer diameters were less in the treated group. This showed that with increasing parasitaemia, there is increased likelihood of capillary stasis, haemorrhage and congestion. Despite this, absorption of antimalarial drugs is generally adequate (Francis et al., 1993)[8]. The study by Eweka and Adjene in Benin, Nigeria suggested that antimalarial like artesunate may contribute to the changes found in the stomach in contrast to our finding of decrease gastric mucosa pathology with the use of chloroquine and artemether.[19] Artemether was able to neutralize the acidity of the gastric content better than chloroquine although the mean ulcer diameter for the 2 groups was not remarkable.

The anorexia and reduced activity noticed in the parasitized mice is comparable to the symptoms seen in malaria in humans. After 24 hours of commencement of therapy, the animals feeding and activity improved considerably.

Conclusion

Our study demonstrated that malaria parasitaemia can increase the severity of gastric ulceration and also in the absence of previous history of gastric ulcer; high level of parasitaemia can cause gastric mucosal congestion and erosion. Chloroquine and Artemether showed a remarkable effect on the clearance of parasitaemia and improvement in the packed cell volume. From the study, Artermether show a higher efficacy than chloroquine.

It is recommended that similar studies should be done with other species of Plasmodium on a larger scale and different mode of inducing gastric ulcer should be employed.

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SODIUM HYPOCHLORITE AND ITS USE AS ROOT CANAL IRRIGANT: A SURVEY AMONG GHANAIAN DENTAL PRACTITIONERS

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Abstract

***Background*:** The majority of endodontic treatment in Ghana is provided by general dental practitioners due to the absence of specialists in endodontics. Sodium hypochlorite has been described as one of the commonly used irrigation solutions during endodontic treatment. However, there are no published reports on its use in Ghana.

***Aim*:** The study was to determine the proportion of Ghanaian dental practitioners who have used sodium hypochlorite for irrigation and the concentrations they usually use.

***Materials and methods*:** Self-administered questionnaires were mailed to dental practitioners in private clinics, government hospitals and clinics, teaching hospitals and training institutions across the country between December 2015 and March 2016. The collated data was analyzed using Microsoft Excel 2010 and SPSS 20.0.

Results: The most commonly used root canal irrigant was 2.5% Sodium Hypochlorite (Milton®). This was routinely used by 31 (73.7%) of the respondents as root canal irrigant while normal saline solution was used regularly by only 6(15.8%) respondents. The various concentrations of sodium hypochlorite used were 0.5%, 2.5%,1% and 5.0%; with the following percentage-use respectively, 42.9%, 32.1%,21.4% and 6.1%. Three (10.7%) respondents had reported experiencing some complications with the use of sodium hypochlorite.

Conclusion: Sodium hypochlorite is the most commonly used root canal irrigant by dental practitioners in Ghana. The concentrations usually used ranges between 0.5% and 5.0%.

Keywords : Sodium Hypochlorite, Root canal irrigation, Concentration, Survey, Ghana.

Introduction

Endodontic therapy or root canal treatment is considered an essential treatment procedure in the provision of dental services[1]. This therapy is essential in the control and management of root canal infection in a tooth[2,3]. It involves mechanical instrumentation, irrigation, intra-canal medication with anti-microbial agents and obturation[4].

Root canal infections can be caused by microorganisms as a result of dental caries, fractures of the tooth secondary to trauma[5], periodontal diseases[6] and some operative dental procedures[7].

Sodium hypochlorite (NaOCL) is the most commonly and widely used root canal irrigant in endodontic therapy and it is often used as a baseline to assess other endodontic irrigants[8-10].

It is widely accepted because of its anti-microbial[11] and tissue-dissolving properties and its relatively low cost[12,13]. It dissolves proteins, has a low viscosity, and has a reasonable shelf life[14,15].

NaOCL is a broad spectrum antimicrobial agent. It has the ability to oxidize and hydrolyze cell proteins. It is effective against root canal bacteria such as *Actinomyces naeslundi* (found in untreated necrotic root canals), *Enterococcus faecalis and Candida albicans* (found in endodontic failure cases)[16].

However, sodium hypochlorite has some disadvantages, principally due to its toxicity such as causing tissue damage and pain; when it accidentally comes into contact with surrounding tissues or goes beyond the root apex[17]. It is strongly alkaline, hypertonic and has a very unpleasant taste[14]. Sodium hypochlorite is extremely corrosive to metals. Use of rubber dam and careful irrigation techniques are vital in endodontics to help obviate some of these disadvantages by confining the hypochlorite to the pulp chamber and root canal[14].

The choice of concentration of NaOCl has been a matter of debate. The range extending from 0.5% to 5.25% has been recommended for use in endodontics[14,18]. Few studies have investigated the attitude of general dental practitioners toward various aspects of endodontic treatment in developing countries[19-21]. However, the authors are unaware of any studies that have evaluated sodium hypochlorite use among dental practitioners in Ghana.

The aim of the study was to determine the proportion of Ghanaian dental practitioners who use sodium hypochlorite for irrigation and the concentrations they usually use.

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Conflict of Interest : none declared

Materials and Methods

The study was conducted using self-administered questionnaire with both open and close ended questions. It involved licensed dental practitioners who practice in

private clinics, government hospitals and clinics, teaching hospitals and training institutions. The questionnaire was sent through mass mailing to seventy-two (72) dental practitioners who were recognized members of the Ghana Dental Association. The questionnaire was accompanied by an explanatory email after pretesting.

Data collected included, demographic data, number of years of practice, specialty, foreign trained experience, the use of root canal irrigants, the concentrations of sodium hypochlorite used.

The collected data were entered and analyzed using Microsoft excel 2010 and SPSS 20.0. Data was summarized by frequencies and percentages. Proportions were compared between various variables using chi-square test. The chosen level of significance was $\alpha < 0.05$.

Results

Out of the seventy-two (72) questionnaires emailed, forty–five (45) were correctly filled and submitted. Twenty-nine males (64.9%) and 16 females (35.6%) participated in the survey. The response rate was 60.5%. About half of the respondents were in the 20-30year age group 21(51.2%).A total of 20(45.5%) of the respondents were dental (medical) officers having practiced for a minimum of three years. All the respondents performed endodontic treatment with 26(57.7%) routinely performing endodontic treatment while 18 (40%) performed it sometimes. The distribution of the respondents and the institution where they practiced is shown in Table 1.

Table 1. Institutions of practice by full-time practitioners.

Institution	Number	Percentage (%)
Ministry of Health / Ghana Health Service	24	53.3
Teaching Hospital	11	24.4
Private practice	6	13.3
Dental School	5	11.1

Majority (77.7%) of practitioners work either with the Ghana Health Service or at a teaching hospital

Twenty four (53.3%) respondents said apart from their regular jobs they also engage in some part-time work at other institutions Table 2.

Table 2. Part time practitioners and their institutions of practice

Institution	Number	Percentage (%)
Ministry of Health/ Ghana Health Service	5	20.9
Private Practice	15	62.5
Teaching Hospital	2	8.3
Dental School	2	8.3

Over 60% of respondents did part-time practice in private dental clinics

Sodium hypochlorite was the irrigation solution of choice for most respondents 33(73.3%); followed by normal saline 7(15.6%) and one respondent used chlorhexidine as irrigation solution routinely. Only 4(8.8%) of the respondents used combination of irrigation solutions. There was no significant difference among the institutions of practice and the concentrations of sodium hypochlorite usage (P=0.35). The reasons attributed to the choice of irrigation solution is shown in Table 3 with local availability being the commonest reason given.

Table 3. Reasons that inform choice of irrigation solution

Reason for choice of irrigant	Number	Percentage (%)
Local Availability	33	73.3
Type of Infection	9	20.0
Primary root canal treatment	2	4.4
Cost	1	2.2

Choosing an irrigation solution was mainly determined by its availability

Out of the 33(73.3%) sodium hypochlorite users, 14(42.4%) used 2.5% followed by 12(36.7%) who used 0.5% and 7(21.2%) used 1.0%. Two respondents representing 6.1% used 5.0% concentration of sodium hypochlorite. Comparison between the institution of practice and the concentration of sodium hypochlorite used for both full and part time is shown in figures 1 and 2 respectively. Only 3(6.7%) respondents had experienced complication with the use of sodium hypochlorite without giving details.

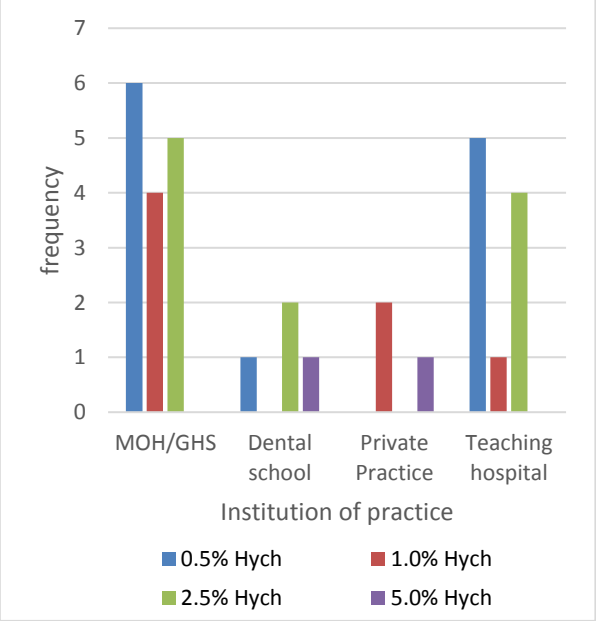

Fig. 1 Full-time institutions of practice and the concentrations of sodium hypochlorite used.

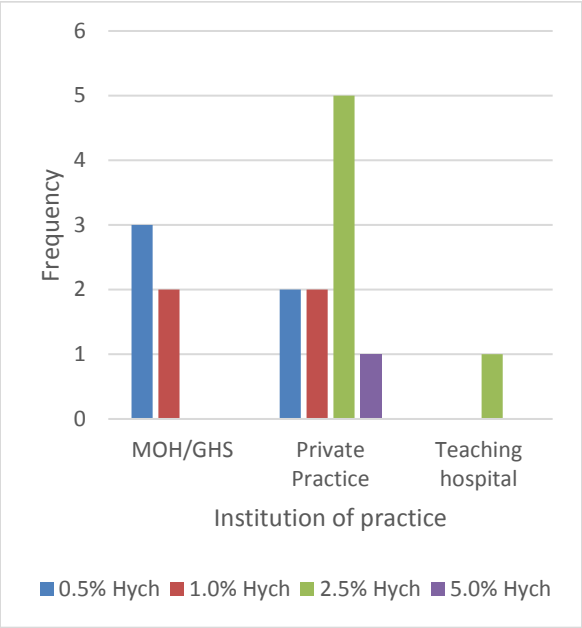

Fig 2. Part-time institutions of practice and the concentrations of sodium hypochlorite used

Discussion

A total of 45 dentists returned their filled questionnaire out of 72, giving a 60.5% response rate. The dental practitioners who responded to the survey had in-depth knowledge and skill to enable them provide accurate and beneficial information about endodontic treatment in Ghana.

All the practitioners who responded to the survey undertook endodontic treatment in their practice. This is expected as even practitioners who generally do not want to perform endodontic treatment would sometimes do so to give their patients pain relief.

The above finding compares with studies in Australia where 98% of general practitioners performed endodontic treatment in their practice[15] but differs with studies in Kenya where only 63% of general practitioners performed root canal treatment, due to unavailability of specialists[20].

In the current survey, most dental practitioners used sodium hypochlorite and normal saline solutions as canal irrigants. Sodium hypochlorite is recommended as the material of choice for irrigating the root canal system because of its effective anti-microbial and its ability to remove smear layer[22]; 31(73.7%) of our respondents shared this opinion.

In Nigeria and Switzerland, most dentists used hydrogen peroxide and sodium hypochlorite solutions[21,23]. In a Sudanese study, over 50% of respondents irrigated root canals with hydrogen peroxide and 14% used normal saline as root canal irrigant[24], while the majority of Flemish respondents (59.2%) used sodium hypochlorite[25].

Among the sodium hypochlorite users, the concentrations commonly used were 0.5%, 2.5% and 1% with the following percentages respectively, 37.5%, 34.4% and 21.9%. Two respondents representing 6.3% used 5.0% concentration of sodium hypochlorite. The other irrigation solutions used were chlorhexidine, normal saline and combination of multiple irrigation solutions.

The choice of more dilute solutions may be related to the reluctance of the dental practitioners to use rubber dam. The reasons that informed the choice of irrigation solution included availability of solution, the type of infection and the cost.

The incidence of complications associated with sodium hypochlorite use is not common but there are reported cases of adverse reactions to sodium hypochlorite use[26,27]. In this study only three (6.7%) of respondent indicated having experienced some complications but none of them indicated the specific complications experienced with Sodium hypochlorite use.

Conclusion

The assumption that sodium hypochlorite is used widely by these practitioners as an endodontic irrigant has been confirmed by this study. The concentrations of sodium hypochlorite used by dental practitioners in Ghana ranges between 0.5% and 5.0% and majority use 2.5%.

Acknowledgements: The dental practitioners who willingly participated in this survey

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AN AUDIT OF THE INFORMED CONSENT PROCESS AT THE SURGICAL DEPARTMENT OF KORLE BU TEACHING HOSPITAL, ACCRA

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Abstract

Background: Surgeons carry out procedures on patients daily, many of which are invasive and may be associated with some risks and complications. The concept of informed consent in surgical practice was introduced after certain legal issues arose. Today patients are entitled to know and be accorded the right to determine what happens to their bodies. This study set out to determine if there had been any improvement in the informed consent process over the years, taking a closer look at the various aspects of the information given.
Method: This was a cross-sectional study carried out at the Department of Surgery, Korle Bu Teaching Hospital. One hundred consecutive post-operative patients were recruited and interviewed on information discussed at various stages during the preoperative period and on the administration of the consent form.
***Results*:** Thirty seven (66.0%) out of 56 elective cases felt they had been given enough information to their understanding to enable them give informed consent. Thirty (68.1%) out of 44 emergencies also felt they had been given enough information. Forty (71.4%) of elective cases were able tell what their diagnosis was but only 23 (41.0%) knew what procedure had been done. Similarly 32 (72.2%) emergency cases were able to tell what their diagnosis was but only 16 (36.3%) knew what procedure had been done.
Conclusion: Informed consent in the Department of Surgery of the Korle Bu Teaching Hospital is unsatisfactory and needs to be improved.

Keywords : Informed consent, consent form, alternatives, complications.

Introduction

Surgeons carry out procedures on patients daily, many of which are invasive and may be associated with some risks and complications. This was not of concern to the physician or patient in ancient medical practice but over the ages this has changed. Current thinking is captured in the decision of Justice Benjamin Cardozo who summarized it as "every human being of adult years in sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits a battery for which he is liable in damages"[1]. This has led to the concept of informed consent in surgical practice. Today patients demand to know and be accorded the right to determine what happens to their bodies.

Informed consent is the process by which the treating health care provider discloses appropriate information to a competent patient so that the patient may make a voluntary choice to accept or refuse treatment[2]. It may also be defined as an instrument of mutual communication between doctor and patient with an expression of authorization/permission/choice by the latter for the doctor to act in a particular way[3]. This process begins from the moment the patient walks into the consulting room to the time the written consent is administered. For consent to be considered valid and truly informed the patient should be aware of the diagnosis, the process through which the diagnosis was arrived at, the procedure to be performed in a descriptive manner and any reasonable alternatives to the proposed intervention[1]. They should also be aware of the relevant risks, benefits, and uncertainties related to each alternative as well as the outcomes.

The patient must be of sound mind and capable of making the decision. Unless a doctor acts within this set of parameters he/she opens him/herself up to litigation. Medical practice in Ghana is no exception. There is now increasing awareness among patients, and the public have openly questioned the quality of the medical care they receive with a number of medicolegal cases in court. An earlier publication in 2005 at the Korle Bu Teaching Hospital (KBTH) revealed that the informed consent process was unsatisfactory[4].This study set out to determine if there had been any improvement, taking a closer look at the various aspects of the information given.

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Methodology

This was a cross-sectional study carried out at the Department of Surgery, Korle Bu Teaching Hospital (KBTH). One hundred consecutive post-operative patients were recruited and interviewed in January 2017. A total of 131 patients had surgery over a two week period. Included were inpatients and outpatients who had emergency or elective surgery and aged over 13

years. Excluded were patients on admission yet to have surgery, those who had undergone general anaesthesia within 24 hours or were sedated, those at the theatre recovery wards and intensive care unit and those who had surgery more than 14 days prior to the interview.

Data collected included patient demographics, information discussed at various stages during the preoperative period and on the administration of the consent form.

Results

One hundred questionnaires were administered to 51 males and 49 females. Ages ranged from 15 to 80 years with a mean age of 43. They were of varied educational and religious backgrounds (Table 1).

Table 1. Demographic data

Characteristic	Number
Age in years	
11 – 20	11
21 – 30	12
31 – 40	26
41 – 50	16
51 – 60	23
61 – 70	9
71 – 80	3
Total	**100**
Gender	
Male	51
Female	49
Total	**100**
Marital status	
Single	29
Married	62
Divorced/separated	9
Total	**100**
Religion	
Christianity	87
Islam	13
Total	**100**
Education	
None	7
Primary	19
Secondary	45
Tertiary	29
Total	**100**

Fifty six per cent had elective procedures done of which 19% (11 of the 56 elective patients) were done as day cases. The rest, 44% had emergency procedures with only 1 done as a day case.

In 16 cases, consent was given by a relative. Out of these, only 7 (44%) felt they were given sufficient information before the form was signed on their behalf. Five (31%) were 18 years or less.

Of the remaining 11 (69%) 8 had emergency surgery and 3 had elective surgery. All 3 patients who had elective surgery were older than 60 years.

Tables 2 and 3 show the various stages at which information on the upcoming treatment was discussed with patients. For both elective and emergency procedures the diagnosis (87.5% and 77.3% respectively), what procedure was to be done (78.57% and 68.2% respectively) and the benefits (60.71% and 63.7% respectively) of the procedure were the most discussed, with more than half in each case being discussed at the OPD or Emergency room. On the other hand the alternatives (17.86% and 9.1%), cost (37.5% and 11.4%), complications (48.34% and 34.1%) and duration of the procedure (48.24% and 9.1%) were the least discussed for both elective and emergency procedures respectively.

Twenty eight per cent of patients did not know their diagnosis, the rest were able to give a diagnosis. 61% of patients did not know what procedure had been done, the rest were able to explain what procedure had been done.

Fifty per cent of patients read the consent form before signing, 50% did not. 43% of patients signed a completely filled form, 8% signed a blank form and 49% could not recall whether the form was filled or not.

Sixty per cent of patients were satisfied that everything had been explained to their understanding.

Figures 1 and 2 show when the consent forms were signed. Day cases formed the majority (65%; 11 patients out 17 patients) of those who signed consent on the morning of surgery.

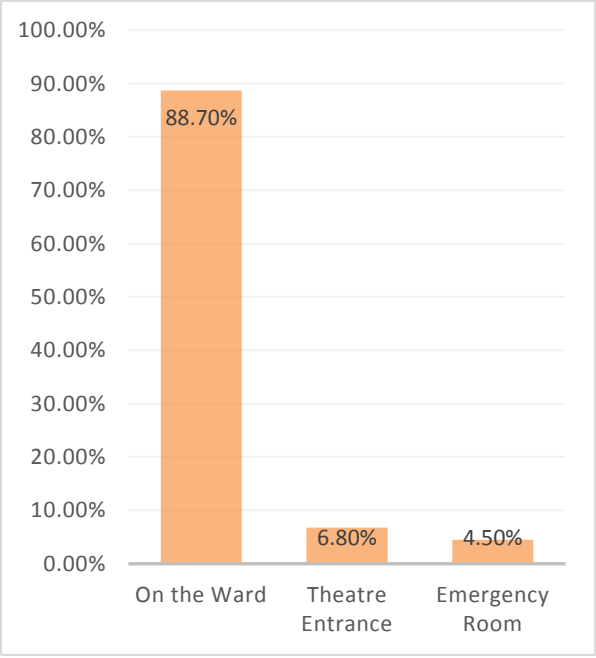

Fig 1. When consent forms were signed in emergency cases

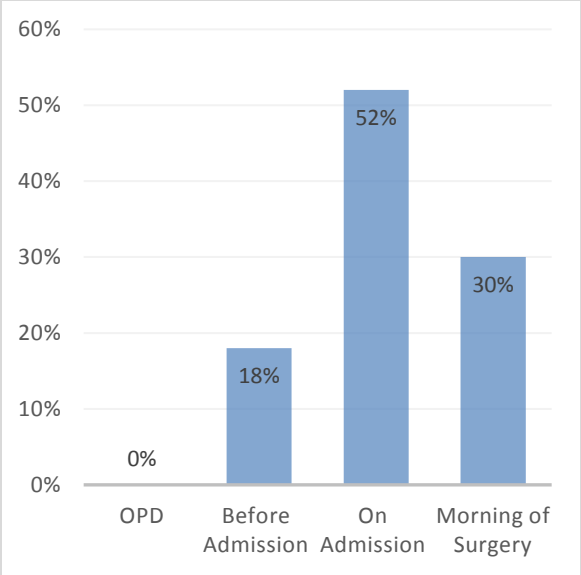

Fig 2. When consent forms were signed in elective cases

Sixty eight patients said the form was administered by a doctor but 45 of them (66%) were not sure by which category of doctor. Ten patients said it was administered by a nurse and 22 were not sure which category of staff administered the form.

Thirty seven (66.0%) out of 56 elective cases felt they had been given enough information to their understanding to enable them give informed consent. Thirty (68.1%) out of 44 emergencies also felt they had been given enough information.

Forty (71.4%) of elective cases were able tell what their diagnosis was but only 23 (41.0%) knew what procedure had been done. Similarly 32 (72.2%) emergency cases were able to tell what their diagnosis was but only 16 (36.3%) knew what procedure had been done.

Discussion

This study looked at patients' recollection of aspects of the information that was given them in obtaining an informed consent. Comparing this with 2005 data from the same institution,[4] there is no significant difference in the number of patients who knew their diagnosis (76% in 2005 and 72% in 2017) and a decrease in those who knew what procedure was done (64% in 2005 and 39% in 2017) but an appreciable increase in information given on possible complications (13% in 2005 and 58% in 2017). The recent increase in information being given on postoperative complications may be a reflection of the era of medical litigation which has recently crept into our society. This should have also reflected in better information given in all the other aspects of informed consent, but was not found to be so. Similarly the educational backgrounds of our patients (Table 1) did not reflect in their responses; those with higher education were not necessarily better informed.

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Typically the Ghanaian patient is not enquiring enough. This attitude is also found in other cultures. In an Indian population 63.6% were not interested in knowing what would be done at surgery provided they got better, though most of them did want to know the complications, cost, duration of the procedure and the chances of a successful surgery.[5]

Unlike developed countries there are no national guidelines on informed consent and the population characteristics are different. Generally literacy levels are low and doctors are overwhelmed with work. In Nigeria where each hospital has its own consent form Ezeome et al carried out a review of forms from all the major teaching hospitals to assess their content and textual readability using the Flesch readability assessment tool. Twenty eight essential components were considered and it was found that most of the forms had scanty information and none of the forms made provision for documentation of patient's permission for blood transfusion, tissue disposal, risks of not undergoing the prescribed treatment, and the risk of anaesthesia. In addition, the forms were found to be too technical for patients to understand.[6] The situation in Ghana may not be much different. The poor readability, variability and inadequacy of contents forms is certainly not limited to less developed countries but also found across the U.S.[7]

In December 2009 the Ministry of Health (MoH)/ Ghana Health Service set up a working group to review the national informed consent forms used in public institutions. This culminated in a national consensus meeting in 2012 to approve three forms: the General Consent Form 1, a Consent Form 2 for minors and one for patients who lacked capacity to give consent.[8] Though the new consent forms have not been adopted nationwide, KBTH adopted its own improved consent form in 2010. The new consent form may be partly responsible for the above improvement. Implementation of comprehensive consent forms by the Ministry of Health is overdue. A valid form should have a portion for an independent third party witness. A section should also be included for the anaesthetist to obtain consent for anaesthesia as they would be in the best position to discuss anaesthetic complications. Perhaps a separate form may be designed particularly for high risk cases.[3,9] Informed consent must also be extended to non-surgical procedures including other invasive procedures such as endoscopy, radiologic examinations like CT scan and high risk medical treatments like chemotherapy and blood transfusion.[7] This is not the current practice at Korle Bu Teaching Hospital.

Not surprisingly, this study reveals that patients undergoing elective surgery were better informed in all aspects of informed consent compared to those undergoing emergency procedures (Tables 2 and 3). Similar findings in Edinburgh have also been attributed to the differing nature of the disease, the urgency of which would make the patients feel less in control and

Table 2. When and what information about the consent was given for elective cases

Information	OPD	Before admission	On admission	Morning of surgery	Not discussed	Total
Diagnosis	37(66.07%)	5(8.93%)	7(12.50%)	0(0%)	7(12.50%)	56 (100%)
Natural prognosis	19(33.93%)	5(8.93%)	5(8.93%)	0(0%)	27(48.21%)	56 (100%)
Procedure to be done	24(44.44%)	5(8.93%)	12(21.43%)	3(5.36%)	12(21.43%)	56 (100%)
Benefits	19(33.93%)	6(10.71%)	8(14.29%)	1(1.79%)	22(39.29%)	56 (100%)
Duration of procedure	19(33.93%)	3(5.36%)	5(8.93%)	0(0%)	29(51.76%)	56 (100%)
Cost	5(8.93%)	10(17.86%	6(10.71%)	0(0%)	35(62.5%)	56 (100%)
Alternatives	5(8.93%)	1(1.79%)	4 (7.14%)	0 (0%)	46(82.14%)	56 (100%)
Complications	7(12.50%)	6 (10.71%)	11(19.64%)	3(5.36)	29(51.76%)	56 (100%)

Table 3. When and what information about the consent was given for emergency cases

Information	Emergency Room	On the ward	Theatre Entrance	Not discussed	Total
Diagnosis	23 (52.2%)	8 (18.1%)	3 (6.8%)	10 (22.7%)	44 (100%)
Natural prognosis	14 (31.8%)	10 (22.7%)	0	20 (45.4%)	44 (100%)
Procedure to be done	18 (40.9%)	11 (25.0%)	1 (2.3%)	14 (31.8%)	44 (100%)
Benefits of procedure	18 (40.9%)	9 (20.45%)	1 (2.2%)	16 (36.3%)	44 (100%)
Duration of procedure	1 (2.2%)	1 (2.2%)	2 (4.5%)	40 (90.9%)	44 (100%)
Cost	2 (4.5%)	3 (6.8%)	0	39 (88.6%)	44 (100%)
Alternatives	2 (4.5%)	2 (4.5%)	0	40 (90.9%)	44 (100%)
Complications	5 (11.3%)	10 (22.7%)	0	29 (65.9%)	44 (100%)

more likely to give consent with minimal information and little discussion.[10] Pain and side effects of some analgesics also influence the quality of the informed consent process and patients are less likely to pay attention to details or read the forms.[10] It is usually the case that an emergency procedure would be done and consented by various levels of surgical trainees who may be less competent in handling the consent and engaging the patient in discussion of viable alternatives and complications. However, an elective procedure may be discussed with more senior surgeons and there would be ample time and several discussions for the patient to explore and understand treatment options before making an informed consent. This study found that 69% of those whose consent form was signed by a relative had emergency surgery and may have been deemed to be in pain and unwell to be bothered with a signature in addition to some being uneducated and illiterate.

The situation is not much different in Nigeria. It was reported in Calabar that 70.3% of patients had the surgical procedure explained pre-operatively but 27.5% of them did not understand it. Here also the majority (51.6%) were not satisfied with the information they had received. This has been attributed to the use of medical terminologies and junior level surgeons and in some cases nurses who may not understand the intricacies of the procedure being left to do the explanation.[11] This study found that during the consent process patients did not know the identity of the staff obtaining consent. Though 68 patients said the form was administered by a doctor, 45 of them were not sure by which category of doctor. Ten patients said it was administered by a nurse and 22 were not sure which category of staff administered the form.

It is of concern that in this audit, 28% of patients claimed they did not know their diagnosis and 61% did not know what procedure they had. It is not adequate that only 48.3% and 34.1% of elective and emergency patients remembered a discussion on possible complications. Overall only 67% of patients were satisfied that everything was explained to their understanding. The process of obtaining an informed consent in KBTH has to be improved upon.

Conclusion and recommendations

Informed consent in the Department of Surgery of the Korle Bu Teaching Hospital has seen some improvement over the past 10 years but is still unsatisfactory and needs further improvement. We recommend that 'Informed Consent' which is part of the first year curriculum of the surgical trainee be emphasised. New and improved consent forms should be adopted nationwide. It is also necessary that informed consent be extended to other procedures including endoscopic procedures, blood transfusion, chemotherapy and others.

Limitation

Patients may have forgotten some information given them as these interviews were conducted in the postoperative period.

Competing interests

The authors declare that we do not have any competing interests.

Acknowledgement

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MIXED-METHODS ASSESSMENT OF A PILOT DECENTRALIZED SURGICAL TRAINING PROGRAM FOR HOUSE OFFICERS IN GHANA

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Abstract

Introduction : There is a critical surgical workforce gap in low- and middle-income countries, particularly at first-level referral (i.e. district) hospitals. To address this gap we piloted a decentralized surgical training program for house officers at a district hospital in Ghana.

***Methods* :** Six house officers took part in the pilot program. Trainees participated in : i) didactic, video-based, and practical modules ; ii) intensive surgical immersion at a district hospital with consultant surgeon oversight ; and iii) a 12-month supervised rotation as a surgical care provider at a district hospital. Case mix and volume, complications, and perioperative mortality rate during the program were tracked. Anonymous feedback from the trainees was analysed with a content analysis framework.

***Results* :** In the 12-month pilot training program, 6 trainees were actively involved in carrying out 606 procedures either independently, under supervision or as assistant (mean : 101 procedures/trainee). The most frequent pre-operative diagnoses were hernia and complications of labour (432, 71.3%), followed by acute abdomen requiring laparotomy (85, 14.0%), soft tissue mass (21, 3.5%), hemopneumothorax or plearal effusion (19, 3.1%), hydrocele (16, 2.6%), abscess (12, 2.0%) and other (47, 7.8%). Twenty-three (3.8%) patients experienced complications, with the most common being surgical site infections (superficial : 8, 1.3% ; deep : 3, 0.5%). The perioperative mortality rate was 1.2%. Feedback from trainees was generally positive, but revealed several unmet challenges.

Conclusion : Through the decentralized surgical training program Ghanaian trainees gained useful experience with essential surgical care at a first-level hospital and provided timely surgical care to patients.

Keywords : Medical officers, House officers, Decentralization, Surgical Training

Introduction

Conditions that can be treated by surgery comprise more than 16% of the global disease burden[1]. However, according to current estimates, 5 billion people do not have access to essential surgical care, resulting in significant rates of premature death and disability from preventable causes[2]. Although, nearly 90% of the 87 million disability-adjusted life-years incurred by conditions that require surgical care could be averted by providing timely, safe and effective surgery in low- and middle-income countries (LMICs)[3], LMICs are least equipped to provide surgical care due to lack of physical and human resources[4]. These resources are particularly deficient in district hospitals, which are integral to the provision of timely care in most LMIC health systems[3].

Many national and international efforts have been implemented with the aim of increasing the numbers of trained surgical care providers in LMICs. While programs such as those establishing task-sharing and exchange visitation[5,6] have been successful in a variety of contexts, the importance of teaching local medical students and junior doctors the knowledge and skills required to provide essential surgical care cannot be overlooked[7]. Furthermore, such training should be designed and carried out in a way that exposes trainees to the realities they will likely face as district hospital care providers which are different from those faced at tertiary centres, where the majority of surgical rotations or training are provided. Providers entering the surgical workforce who are already comfortable in district hospital settings might be more likely to work in them after training thereby improving the overall skilled workforce available to provide access to timely surgical care for those most in need currently[7-9].

Ghana is a heavily indebted LMIC in West Africa, with a population of 26 million people and an annual per capita income of USD1,760[11]. Although predominantly urbanized with several densely-populated cities (e.g., Accra, Kumasi, Tamale), 47% of Ghana's population live in rural areas[12]. Thus, the numerous district hospitals around the country are well positioned to provide the majority of timely essential surgical care if they were staffed by skilled providers[4].

District hospitals in Ghana are usually staffed by a medical officer and nurse anaesthetist and have between 50 and 100 beds. Some rural districts do not have a district hospital and rely on other health facilities such as a neighbouring district. Some of the more densely populated districts however, have several district

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Conflict of Interest : none declared

hospitals in each of their sub-districts. Some medical officers provide surgical care, although such care is often limited to obstetric emergencies[13,14]. In general, however, all of the district hospitals throughout Ghana are under-resourced to provide essential surgical care[4, 15]. Ghana's total four medical schools graduate around 500 doctors annually. The newly graduated doctors go on to complete 2-year training as house officers in tertiary and/or select large hospitals, where they learn practical aspects of general medical, paediatric, obstetric, gynaecologic and surgical care. Upon completion, the trainee doctors are posted to hospitals around the country for another 2-year training as a medical officer. Postings at a district hospital typically involve only one doctor, who is then solely responsible for the entire facility's essential surgical care. Unfortunately, the current training system in Ghana does not adequately prepare medical officers for the realities they will face while autonomously providing essential surgical care in these low-resource settings[14].

To address this gap in surgical education and follow-up on our previous study of this subject[10], we developed and implemented a decentralized surgical training pilot program for senior house officers. The program consisted of preparatory modules, 2 weeks of intensive surgical training in a district hospital, and 1 month of district hospital work experience. Herein, we describe the clinical exposure of our trainees at a district hospital and evaluate the related rates of complications and perioperative mortality experienced by the treated patients (as proxy measures of safety). These descriptive data provide insights into ways by which this and other decentralized training strategies could be improved and designed for maximal effectiveness.

Methods

Development of the decentralized surgical training program

The concept of the decentralized surgical training program was proposed for house officers by the Ghana Health Service (GHS; the branch of the Ministry of Health charged with organizing and supervising government hospitals, with the exception of teaching hospitals, which are directly under the Ministry of Health). The GHS approached the Department of Surgery at the University for Development Studies (UDS) in Tamale, Ghana to design the training program. The training program had three objectives: i) to educate senior house officers on the knowledge and skills required to provide safe essential surgical care; ii) to promote a career of surgical service at district hospitals; and iii) to reduce the backlog of conditions that require surgery in the community.

After the program was designed, the GHS and UDS sought accreditation from the Ghana Medical and Dental Council for a district hospital in which the training program would be implemented as a pilot. Accreditation was dependent on the hospital's demonstrated ability to select appropriate trainees (i.e. senior house officers who have completed rotations in obstetrics and gynaecology) and to provide adequate supervision of the trainees. The latter was defined as immediate supervision by an experienced principal medical officer who performs surgery (i.e. a medical doctor who performs surgery) and proximate supervision by a surgical consultant if needed (i.e. constant availability for immediate communications and capable of arriving at the hospital within 2 hours if needed). The principal medical officer at Yendi Municipal Hospital (Yendi, Ghana) was found to fit the needs as he actively provided basic surgical care for a population 300,000, operated independently, and declared a desire to work in teaching and mentoring capacities at the district hospital.

The program was designed to be intensive and hands-on, and to allow significant face-to-face time with the surgical consultant; the latter being only available at large teaching hospitals in Ghana otherwise. To accomplish these objectives, all trainees participated in the following three phases of the program prior to receiving their postings: i) training via didactic, video and practical modules; ii) intensive surgical immersion at a district hospital with a consultant; and iii) a supervised rotation as a surgical care provider at a district hospital.

Trainee selection and program

The program was introduced to the entire senior class of house officers in Ghana at a conference, with the background, goals and logistics of program presented in detail and discussed. Eight house officers then voluntarily applied to the pilot training program, and six of the applicants were selected for participation. Three trainees were assigned to one of the two rounds of the 6-month training program.

Each group of three trainees took part in the three-module phase of the program over a 2-week period to ensure that a basic level of surgical knowledge and skill was acquired for immediate application when they presented to the district hospital. First, the trainees were given a series of lectures on the diagnosis, management and potential complications of conditions they will frequently encounter at district hospitals (e.g. inguinal hernias, intestinal obstructions, severe soft tissue infections, soft tissue tumours, breast masses and acute abdomen). Second, the trainees were shown a Basic Surgical Skills Training video produced by the Royal College of Surgeons of England (including skills training on wound debridement, suturing and knotting techniques, laparotomy, soft tissue mass excision, intestinal anastomosis); after each module of the video, the key principles were discussed and the trainees were given the opportunity to practise each skill under supervision. Next, the trainees underwent training for basic life support techniques. Finally, the trainees participated in a 1-week hands-on practical that used discarded animal tissues to demonstrate and practice incisional, suturing and intestinal surgical techniques.

For the next 2 weeks, the trainees were immersed in surgical training with a general surgery consultant at the selected district hospital. In preparation for this intensive study, the resident principal medical officer at the hospital booked elective general surgical cases ahead of time. This served two purposes: i) to improve the timely access to care for patients in the district hospital's catchment area; and ii) to allow teaching opportunities for the immediately supervised trainees.

For the next 12 months, the trainees worked under direct supervision of the resident principal medical officer at the district hospital to care for patients with conditions requiring surgical intervention. The medical officer was constantly available for immediate supervision. The consultant surgeon remained available by telephone and would present if needed. In addition, the consultant would spend 1-2 days per week with the trainee at the district hospital discussing cases encountered during the week and operating together on elective cases and attending to emergency cases if they presented. However, the trainee was positioned and operated as if he or she was the senior surgeon.

Daily communication between the trainees, the medical officer and the consultant surgeon was facilitated by the WhatsApp instant messaging application (WhatsApp Inc., CA, USA). The WhatsApp cross-platform facilitated the instantaneous sharing of text, voice, images and video. Thus, the supervision of the consultant was effectively extended to the district hospital for a significant proportion of the clinical decision-making.

Data collection and analysis

To evaluate the decentralized training program, we performed two analyses: i) descriptive analysis of surgeries performed by the trainees during the program (e.g., case mix and volume, perioperative mortality and complications); and ii) content analysis of anonymous feedback from house officers who participated in the program.

Information on diagnoses made and procedures performed by the trainees were extracted from the surgical logbook at the district hospital and organized to describe the case mix and volume during the training program. To assess program-related patient safety, information on all deaths and all complications that occurred during the training program from date of surgery to hospital discharge were also extracted.

A questionnaire was created to identify the successes and challenges of the training program from each of the trainees' perspective. In the pilot stage, the questionnaire was first administered to surgical residents in order to make improvements based upon their feedback prior to its use with the house officer trainees. The finalized questionnaire was distributed to the trainees via an online survey platform (SurveyMonkey, CA, USA) in a single batch in order to avoid being able to single out the responses of a particular trainee; the surveys were completed privately. The introductory page of the questionnaire stated clearly that all responses would be anonymous and that the findings would in no way affect performance evaluation. Responses to open-ended questions were examined using a content analysis framework[16]; first, responses were grouped into categories based on codes that represented response clusters, then categories were further refined into useful themes and described.

Ethics

The training program and its evaluation received ethical approval from the GHS (#TTH/TN/32), Ghana Medical and Dental Council and Yendi Municipal Hospital administration.

Results

In the total 12 months of the pilot training program, the 6 trainees were involved in 606 procedures (mean: 101 procedures/trainee; Table 1. Each trainee took an active role in procedures either under supervision, independently or as an assistant.

Cases and procedures

The median age of patients who underwent operation during the training program was 32 years (range: 1 – 97 years; interquartile range: 24 – 49 years). The most frequent pre-operative diagnoses were hernia and complications of labour (432, 71.3%), followed by acute abdomen requiring laparotomy (85, 14.0%), soft tissue mass (21, 3.5%), hemopneumothorax or pleural effusion (19, 3.1%), hydrocele (16, 2.6%), abscess (12, 2.0%) and other (47, 7.8%).

Complications and perioperative mortality rate

Twenty-three (3.8%) patients experienced complications, with the most common being surgical site infections (superficial: 8, 1.3%, deep: 3, 0.5%; Table 2). The perioperative mortality rate (i.e. death from start of anaesthesia to hospital discharge) was 1.2%. (Table 3). Review of the overall deaths showed that three may have been prevented by better surgical technique; these included: failure of a perforated peptic ulcer repair in a patient with severe malnutrition; failure of intestinal anastomoses in a patient who suffered an abdominal gunshot wound; and death of a 4-year-old male after emergency strangulated umbilical herniorraphy. Two of the total deaths were potentially

Table 1: Level of participation of trainess in procedures performed at a district hospital in rural Ghana

Procedure performed	n	(%)	Level of trainee participation
Inguinal hernia repair	221	(36.5)	Independent
Cesarean section	211	(34.8)	Independent
Bowel resection and anastomosis	27	(4.5)	Supervised/independent
Repair of intestinal typhoid perforation	22	(3.7)	Supervised/independent
Excision of lipoma	21	(2.0)	Independent
Wound debridement	19	(3.6)	Independent
Tube thoracostomy	19	(3.1)	Independent
Salpingectomy for ruptured tubal pregnancy	18	(3.0)	Independent
Amputation	13	(2.1)	Supervised/independent
Hysterectomy	10	(1.7)	Supervised/independent
Hydrocelectomy	8	(1.3)	Independent
Appendectomy	7	(1.2)	Independent
Others	10	(1.7)	Assisted/supervised/independent
Total	606		

Table 2. Complications among patients cared for by trainees at a district hospital in rural Ghana

Complication	*n*	(%)
None	576	(95.0)
Superficial SSI	8	(1.3)
Deep SSI	3	(0.5)
Organ injury	2	(0.3)
Enteroatmospheric fistula	2	(0.3)
Anaesthesia complication	2	(0.3)
Medication reaction	2	(0.3)
Hematoma	1	(0.2)
Missing information	3	(0.5)
Total	599	

Table 3. Deaths among patients cared for by trainees at a district hospital in rural Ghana

Age	Sex	Diagnosis	Procedure	Details	Preventable
4	Male	Umbilical hernia	Umbilical herniorraphy		Yes
22	Male	Gunshot to the abdomen	Laparotomy, bowel resection and anastomosis		Potentially
60	Male	Typhoid perforation	Primary repair of perforation	Anaphylaxis	Yes
84	Male	Peptic ulcer perforation	Graham patch		Potentially
44	Male	Parapneumonic effusions	Tube thoracostomy		Potentially
82	Male	Peptic ulcer perforation	Graham patch	Airway mismanagement	Yes
23	Female	Placental abruption	Caesarean section	Uncontrolled haemorrhage	Potentially

preventable with better anaesthesia management, being cases of anaphylaxis during the procedure and airway mismanagement. The preventability of the final two deaths was not ascribable, due to insufficient information, being cases for which no autopsy was performed and the cause of death was unknown.

Feedback from trainees

As shown in Table 4, the trainees were appreciative of the hands-on skills training, progressive autonomy, use of WhatsApp for real-time decision support, and exposure to broad clinical care (e.g., essential obstetric and urologic surgery, interpretation of radiographs and laboratory results). In addition, trainees praised being introduced to the importance of communicating with patients, other clinical staff and non-clinical staff, as well as the integral role that all staff play in good clinical care. Perhaps most importantly, trainees reported being eager to return to a district hospital setting and provide surgical care after completing their house job.

Conversely, trainees wanted to be exposed to greater breadth of essential surgical care (e.g., essential orthopaedic care) and to have a longer district hospital training experience. Trainees wanted to be remunerated for costs incurred during the rural training (e.g., telephone, internet and transportation). Other feedback included improving the general hospital orientation, increasing the number of trainees or mid-level providers to reduce working hours and allow for studying, and use of morning meetings and regular morbidity and mortality reports for quality improvement purposes.

Table 4. Feedback from trainees at a district hospital in rural Ghana

	Pros	**Cons**
Anticipated	Hands-on training, progressing from models to animal tissues to patients	Lack of training in sub-specialty surgical care (e.g., ENT, ophthalmology, orthopaedics, urology)
	Targeted skill and procedure training specific for care at a first-level hospital	Skills and clinical training periods were too short
	Progressive autonomy for decision-making and operating	Lack of remuneration for costs of phone/internet and transport (given the rural location)
	Use of WhatsApp platform to facilitate continuous decision support from a surgical consultant	
	Exposure to obstetric emergency surgery in addition to general surgery	
	Improving interpretation of radiology and laboratory results in the context of surgical management	
	One-on-one mentorship and surgical supervision, greatly improving decision-making capabilities and technical skill	
	Eager to provide district hospital care after completing training	
Unanticipated	Learned importance of pre-operative patient counselling	Inadequate general orientation by the hospital administration
	Recognition of value of good communication between patients and staff, and between staff	Significant time demand for non-operative care compared to operative care
	Better appreciation of integral role that all clinical and non-clinical staff play in achieving good clinical care	Insufficient use of morning meeting and morbidity and mortality reports for quality improvement purposes
		Inability to read and study given clinical workload

Discussion

This study aimed to describe a pilot decentralized surgical training program for house officers at a district hospital in rural Ghana. The findings suggest that the trainees received adequate training in general, obstetric and urologic essential surgical care in the district hospital setting, as evidenced by the trainees abilities to operate with acceptably low complications and mortalities (i.e. safely). Benefits beyond skill obtainment were that the trainees were more eager to return to the district hospital setting after completing their house job, and the patients treated in the district hospital received timely care, as opposed to otherwise having to navigate the healthcare and referral system to a regional or tertiary facility. These findings suggest that this and similar programs might be developed and/or expanded elsewhere in Ghana, as well as other LMICs, as a potential method for improving access to safe and timely surgical care at the district hospital level.

Such a program is not novel in medical sciences training in LMICs. In Kenya, the University of Nairobi has piloted a decentralized training program for fourth-year medical students[16], whereby 29 students were posted to district and referral hospitals around the country. Analysis of the focus group discussions afterward revealed that the Kenyan students felt much more engaged in patient care, had gained important clinical skills, and had learned to navigate certain sociocultural challenges that they had not been exposed to during their medical education. Importantly, as in our program, the students' responses suggested that they wished to return to non-tertiary hospitals after their post-graduate training. Additionally, the consultants with whom they were paired reported that they had new-found motivation to teach and mentor students and acknowledged that the academic interaction positively impacted patient care.

Other successful examples of decentralized education for medical students exist[17]. However, the formal training of house officers at district hospitals has not been reported in Ghana. Given that recently graduated medical officers are typically the most senior clinicians at district hospitals in Ghana, teaching essential surgical care to this cadre is a promising approach for improving access to essential surgery nationwide. Thus, the model described herein might be useful for other teaching institutions that hope to grow the surgical workforce of district hospitals in their area.

When considering decentralized training programs with graduated autonomy and only mid-level provider supervision, patient safety concerns are obvious. Although we did not collect the incidence of complications and perioperative mortality data from prior to the training program, we observed relatively low rates of the safety indictors during the program and which are consistent with reports from elsewhere in Africa[18-23]. The complication and mortality rates from the present study may have been underestimated due to our inability to follow-up for 30 days postoperatively, as a result of insufficient logistics and infrastructure to support such an endeavour.

Pre-program surgical orientation, a 2-week period of surgical immersion with immediate supervision, and 3 months of proximate supervision by an experienced medical officer and a consultant if needed should not be considered extensive surgical training experience. However, it may represent the bare minimum amount of training and supervision necessary to provide safe surgical care for the conditions often encountered in a district hospital. We would recommend erring on the side of providing too much training, rather than too little, when developing such a program in order to avoid creating a dangerous situation for patients and discouraging house officers from pursuing a career in surgical care.

Given the critical shortage of surgical care providers in LMICs, an important consideration in developing and evaluating a decentralized training program is retention of surgical care providers after they complete their training and national service experience (i.e. placement as a medical officer for 2 years in a non-tertiary hospital). Implementation of task-sharing of surgical care with non-surgeon phisicians and non-doctors to meet the surgical demand at district hospitals has yielded good retention of these providers at target facilities[22]. However, there has not been a report that describes the impact of decentralized training programs on retention of non-surgeons (i.e. medical officers) with surgical capabilities in Ghana. This will be an important outcome during assessment of this and similar programs in the future. In addition to such programs, healthcare systems must ensure concessions are made to incentivize and adequately remunerate surgical care providers who travel to and/or practice in district hospitals, particularly those who choose to provide district hospital care immediately after completion of training.

There are several limitations worth consideration while interpreting the findings from our pilot program. First, this was an evaluation of a small pilot program and the few complications observed and favourable feedback from the six total trainees might not mirror the situation if the program were expanded. As this and similar programs expand, patient safety must be the primary concern and be closely monitored with structured feedback to the trainees. Second, the pre-program surgical orientation lacked surgical simulation equipment and exercises. These tools have been demonstrated to improve the performance, learning curve and safety of trainees in the operating theatre and when working in teams during emergencies[24]. The patient outcomes in our program might have been better if simulation equipment and exercises were incorporated into the training; such resources should be considered when planning future decentralized training programs. Third, the six trainees who volunteered for the program after it was made available represent a small cohort for systematic analysis. Given their interest in a pilot study,

they might not represent the overall house officers population; thus, these results might be biased toward those achieved by interested participants. However, these trainees might also be the individuals that, with steady recruitment, might be the most likely to continue to work in district hospitals after their training. Lastly, we did not assess the impact of the training program on the staff of the district hospital or the costs of care. These issues will require closer examination as we continue to develop and expand the program.

Despite these limitations, these findings allow reasonable conclusions to be made about the potential value of decentralized surgical training programs towards improving both the surgical care training of house officers in the district hospital setting and timely access to safe essential surgical care for patients who might have otherwise not been able to receive surgical care at all. This successful pilot study of a decentralized surgical training program at a rural district hospital in Ghana shows that trainees gained useful experience with essential surgical care at a district hospital, patients were able to receive needed surgical care, and patient safety did not seem to be compromised.

Conclusion

Decentralized surgical training programs have the potential to dramatically improve the surgical workforce at district hospitals in Ghana.

Recommendations

1. Decentralized surgical training program must be developed and expanded cautiously and evaluated systematically and continuously to ensure patient safety is not jeopardized.
2. Going forward, this and similar training programs might benefit from several initiatives: i) institutions might appropriate funds for surgical and team simulation equipment and exercises prior to placing trainees in the district hospitals; ii) comparative assessments might include direct examination of surgical knowledge and skills before and after the program; and iii) long term follow-up should be planned to determine if the program improved recruitment of surgical care providers to district hospitals.
3. Comprehensive feedback from trainees specific to the training program should be elicited and incorporated into the program as it develops.
4. Long-term impact of such programs on the surgical workforce at district hospitals and on population-level access to surgical care should bemonitored, evaluated and reported on in the international literature.

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RISK FACTORS, ASCRIBED CAUSES AND EFFECTS OF OBSTETRIC FISTULA AMONG WOMEN IN NORTHERN GHANA: A CASE CONTROL STUDIES

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Abstract

Background: Obstetric fistula is a demoralizing maternal morbidity. In Ghana, majority of the fistula occur in the northern sector. This study sought to identify the risk factors, ascribed causes and effect of obstetric fistula.

***Methods*:** A matched case control study was conducted from April to June 2013. The fistula patients were taken from the Fistula Centre in Tamale whiles the controls were from the Tamale Teaching hospital. Eligible cases were confirmed fistula patients admitted for fistula repair while controls were women who have delivered but without obstetric fistula. Cases and controls were matched on year, region and district of index delivery.

***Results*:** the following factors were associated with obstetric fistula; age below 20 years, total labour duration more than 24 hours, height 150 cm and below, still birth, operative delivery, residence in a rural area and lack of formal education. Divorce rate among cases over the period was 55.3% while that among the controls was 2.3%. About 20% of cases were likely to be currently using alcoholic beverages compared to 6% in controls (OR=5.3, 95% CI= 1.4 – 19.7). 40% of cases currently have no living child compared to 2% of controls. Majority of fistula patients blame lack of health facilities and an act of God as a cause of fistula.

***Conclusions*:** Majority of women who suffer obstetric fistula are young, poor, of short stature, illiterate and resident in remote areas. There is widespread lack of understanding of the causes of Obstetric fistula among women.

Keywords : Obstetric fistula, Risk factors, Ascribed causes, Vesico-vaginal fistula

Background

Obstetric fistula (OF) is a demoralizing and demeaning maternal morbidity.[1-7] It is associated with continuous leakage of urine or faeces or both into the vagina. The resultant effect of the leakage is a continuous and persistent offensive odour leading to social stigmatization and shunning of affected women.[8-11] It is a completely avoidable and eradicable.[12] However, it still remains a problem in Africa, majority of which are confined to the "fistula belt". [7,13]

In Ghana it is described as the most dreaded maternal condition [2,3] with poor support system available for patients with Obstetric fistula.[14] Some factors ascribed to obstetric fistula include lack of basic education, poverty and early marriage.[15]

Other factors include increased duration of labour for more than 24 hours at home before going to the hospital[14,16] and some biological or medical factors such as; young age, short stature, large fetus, malnutrition, mal-presentation and maternal medical diseases.

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Some studies show that, fistula patients have little or no knowledge about obstetric fistula. In such studies, women cite causes like curse, spiritual attack and punishment as the cause of obstetric fistula.[19] In a study conducted by Banger in Tanzania and Uganda, they found women testimony to be consistent with physical, socio-economic and cultural constraints, as well as health system failures, that led to fistula formation.[20]

Obstetric fistula greatly impact the life its victims. It is associated with stillbirth [21] and reduced quality of life.[22] Some studies have cited psychological problems such as depression[23] and suicidal ideation.[24,25] Some victims are shunned by their friends and family and are left to fend for themselves. Complicating the social problems is the sexual problems and frequent divorce that follow the fistula. The aim of the study is to determine the risk factors and ascribed causes of obstetric fistula among women in northern Ghana. Adequate information about the risk factors in our environment is key to strategies that would help reduce the incidence of Obstetric fistula in Ghana.

Methods

Study design

This was a matched case control study. In the study, patients from the Tamale fistula centre served as cases whiles controls were mothers without obstetric fistula who have delivered during the same time period as the cases. Controls and cases were matched on the region and district of index delivery. Cases and controls must

be seeking care in the Tamale metropolis at the time of the study. Controls were hospital controls from antenatal clinic in Tamale teaching hospital where as cases were from the Tamale fistula centre.

Study area

Data collection was from April to June 2013 in the Northern region of Ghana. The Tamale fistula centre is the only fistula centre providing free services to women with fistula from the three northern regions and the northern aspect of the Volta region of Ghana.

Study Population

The source population for this research was women seeking care in the Tamale metropolis. The study population in this study included all women who have delivered and are seeking care at the fistula centre in Tamale and matched controls seeking care in the Tamale Teaching hospital.

Eligibility and matching criteria

Eligibility criteria for the cases in the study were: the woman must be diagnosed as having obstetric fistula after a standard examination by a specialist/ consultant obstetrician gynaecologist. A fistula patient is eligible as a case if the fistula resulted from the index childbirth. Fistula patients that have gone through previous fistula repair were excluded from the research. The eligibility criteria for the controls were women who have delivered safely and without obstetric fistula. Cases and controls were matched on the following parameters; Cases and controls must deliver in the same year or within a year's interval. This was done to control for infrastructural and socioeconomic development over time that may confound the relationship. Also, cases and controls were matched on the region and district of last delivery in Ghana. The region and district of delivery was a matching criteria because: people from the same geographical area are usually likely to have the same taboos, socio-cultural practices and health seeking behaviour. Also, matching on region and district of delivery may control for socio-economic factors in the environment that are likely to confound the relationships.

Sampling method

All fistula patients admitted into the Tamale fistula centre during the period of the study were admitted into the study. A one case to two controls was the target. The controls were however selected following these research protocols so as to minimize bias. The investigator matched cases and controls. In the instance where more than two controls match the case, a ballot without replacement was carried out to identify the controls that would be admitted into the study as a matched-pair for that particular case. Data Analysis The data generated in the research were entered into Epidata 3.1 and exported into STATA/MP 11.0 (copyright 2004-2009) for analysis. The primary outcome in the study was the development of obstetric fistula. The background characteristics of the respondents were obtained by cross tabulation. Logistic regression was used to analyse the impact of certain factors on obstetric fistula patient. Multiple response analysis was carried out to identify the commonest ascribed causes of obstetric fistula between both groups of controls and cases. Also, logistic regression was used to analyse the risk factors for development of obstetric fistula. First, the association between each of the potential risk factor and the development of obstetric fistula was examined ignoring other variables. This analysis was important because it gave a fair idea as to which of the variables are strong predictors of obstetric fistula. Second to construct a model with risk factors that is independently associated with obstetric fistula, each of the independent variable was a candidate provided that the p-value was 0.05 or less. To investigate whether the relationship between obstetric fistula and a continuous covariate was non-linear, likelihood ratio test was used to compare the fit of the models when the continuous covariate was included as continuous or a categorical variable. Epimap 8 was used to display a case cluster of the distribution of obstetric fistula by district of index delivery.

Ethical considerations

Ethical review and approval was obtained from the Ethical Review Committee of the Ghana Health Service, Research and Development Division, Accra. Approval was also obtained from the Fistula Centre in Tamale and the Tamale Teaching hospital. Consenting to the study participants aged 18 years and above was given after fully explaining the aims, objectives and requirements of the study to the patients. Accent by participants less than 18 years and consent from caretakers were obtained for study participants less than 18 years. Written informed Consent was voluntary and each study participant had the right to withdraw at any stage of the study process. Uttermost privacy and confidentiality were maintained. No compensation or payments were made to any study participants. Data files were password protected. Hard copy and electronic data were stored in locked file cabinets.

Results

Background characteristics

Fifty-one cases and 100 controls took part in the study as found in table 1. Of this, 98.04% are of the vesicovagina fistula type associated with leakage of urine per vaginam.

1.96% of cases have both vesico-vagina and rectovagina fistula type and therefore associated with leakage of both urine and faeces. The median age of fistula patients seeking care in the Tamale metropolis is 30 years (interquartile range=8 years). Fistula patients were more likely to have obtained the fistula at an age less than 20 years, MOR = 5.5 (p-value < 0.0001).

Table 1: Participant characteristics

Participants characteristics	**Controls**		**Cases**		
	N	**(%)**	**N**	**(%)**	**X^2 (P-value)***
Number of participants	100		51		
Employment status prior to index child					
Unemployed	35	35	41	80.4	30.1 (<0.001)
Self-employed	36	36	9	17.7	
Employed	29	29	1	2.0	
Current Employment status					
Unemployed	46	46	34	66.4	13.8 (<0.005)
Self-employed	28	28	16	31.4	
Employed	26	26	1	2.0	
Marital status at index child					
Married	87	87	47	92.1	33.0 (<0.001)
Cohabiting	13	13	1	2.0	
Single, never married	-	-	3	5.9	
Widow					
Divorced					
Current marital status					
Married	86	86	20	39.2	58.7 (<0.001)
Cohabiting	11	11	-	-	
Single, never married	-	-	3	5.9	
Widow	1	1	2	3.9	
Divorced	2	2	26	51.0	
Current self-ranked economic status					
Average rich - very rich	62	62	16	31.4	12.7 (<0.001)
Extremely poor - poor	38	38	35	68.6	
Index delivery outcome					
Live baby	85	85	8	15.7	68.6 (<0.001)
Still birth	15	15	43	84.3	
Number of children alive					
None	2	2	21	41.2	40.2 (<0.001)
1-2	49	49	16	31.2	
3 or more	49	49	14	27.5	
Current Alcohol use					
No	94	94	41	80.4	6.6 (<0.05)
Yes	6	6	10	19.6	
Area of residence					
Urban	52	52	9	17.7	16.6 (<0.001)
Rural	48	48	42	82.4	
Religion					
Christian	44	(44.0)	33	(64.7)	6.2 (<0.05)
Islam	50	(50.0)	17	(33.3)	
Traditional	6	(6.0)	1	(2.0)	
Age at index delivery in years					
20 and above	96	(96.0)	44	(46.3)	19.8 (<0.001)
19 and below	4	(4.0)	7	(13.7)	

X^2 (P-value) *: Chi-square (P-value)

Residency Factors related to OF

Majority of women with fistula seeking care in the Tamale Metropolis had the fistula occurring in the Northern Region (82.4%). This was followed with the northern part of Volta Region (9.8%), the Upper East Region (5.9%) and Ashanti Region (1.96%). Figure 1 is a case cluster map displaying the geographic distribution of districts within which the fistula cases occurred.

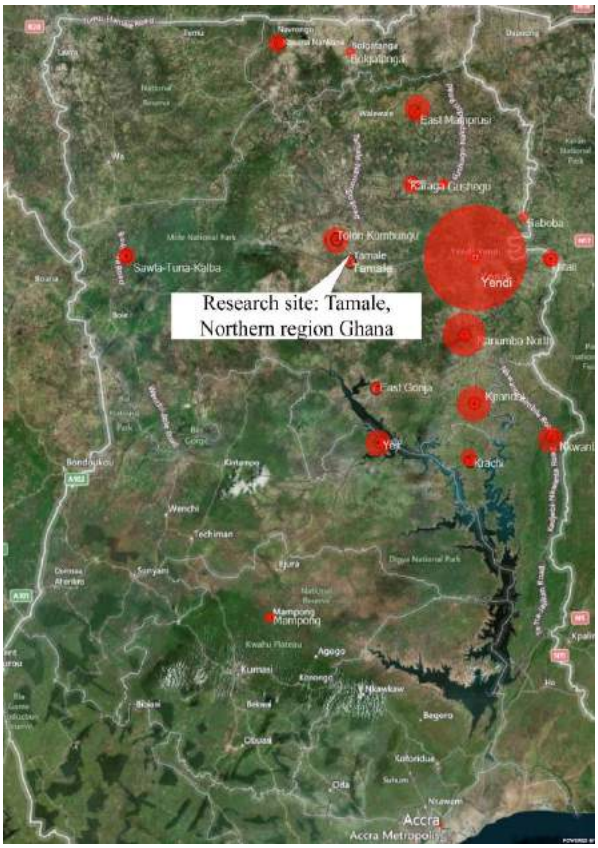

Fig1 : Case cluster of the distribution of obstetric fistula cases by district of index delivery

Fistula patients were more likely to be resident in rural part of their districts (OR=5.5, 95%CI=2.2 - 13.5) as shown in table 2.

Also, fistula patients were more likely to be staying further away from the nearest hospital with capabilities for caesarean section compared to women without fistula (mean difference of 12.8 miles, p-value < 0.0001) and hence more likely to pay higher public transport fare to access care compared to controls (mean difference = 0.5 Dollars, p-value < 0.0005). Also, fistula patients lived in places where the available means of transport to the nearest hospital in time of emergency is most likely to be by motorcycle/tricycle/bicycle or walking (OR= 4.8, 95%CI =1.9 – 12.3). Fistula patients were more likely to have delivered in a hospital (home /TBA delivery appear to be protective OR =0.24, 95% CI=0.08 – 0.64) as shown in table 3.

Table 2: Crude odds ratio of Socio-demographic risk-factors at index child birth

Risk factors	OR (95% CI) $^{+}$	P-Value
Age at index delivery in years		
20 and above		
19 and below	13 (3.0 – 57.7)	<0.005
Area of residence		
Urban		
Rural	5.5 (2.2 – 13.5)	<0.001
Employment status		
Employed		
Non-employed	13.2 (4.0 – 43.8)	<0.001
Educational status		
Formal education		
No formal education	13.1 (4.2 – 45.9)	<0.001
Health insurance status		
Insured		
Not insured	5.3 (2.4 – 11.8)	<0.001
Legal Marital status		
Married		
Not Married	2.6 (1.1 – 5.8)	<0.05
Distance in Miles to Hospital		
Up to 10		
Above 10	11.5 (4.0 – 33.1)	<0.001
Access to means of transport to hospital		
Car/ Ambulance		
Bicycle/walking	4.8 (1.9 – 12.3)	<0.005
Self-Ranked Economic Status		
Rich		
Poor	4.1 (1.8 – 9.3)	<0.005

OR (95% CI)$^{+}$: Crude odds ratio (95% Confidence interval)

Personal Factors related to OF

The median age of fistula patients seeking care in the Tamale metropolis is 30 years (interquartile range=8 years). Fistula patients were more likely to have obtained the fistula at an age less than 20 years, MOR = 5.5 (p-value < 0.0001) as shown in table 2. They carried the fistula for a median 4 years at the time of presenting for treatment (interquartile range= 6years) ranging from 3 months to 19 years. Fistula patients have greater odds of being primiparous (OR=2.5, 95% CI=1.1 - 5.8) as shown in table 2. Fistula patients were relatively shorter and were more likely to be of height less than 150cm (OR=11.8, 95% CI=4.1 – 33.9). They were more likely to be unemployed (OR = 13.2, 95% CI = 3.0 – 43.8) and of no formal education (OR =13.9, 95% CI =4.2 – 45.9) as shown in table 2. Also, fistula patients have higher odds of being without national health insurance (OR = 5.3, 95% CI =2.7 – 11.8), currently single or cohabiting (OR=2.3, 95% CI =1.2 – 5.8) however less likely to be Muslims (OR= 0.5, 95% CI = 0.2 – 1.0) even though the Muslim religion is the dominant religion within the area of study.

Table 3 – Crude odds ratio of Obstetric risk factors at index child birth

Obstetric risk factors	OR (95% CI) *	P-value
Parity		
Multiparous		
Primiparous	2.5 (1.1 - 5.8)	<0.05
Height in cm		
Above 150		
150 and below	11.8 (4.1 – 33.9)	<0.001
Place of delivery		
Hospital	4.2 (1.6 – 11.4)	<0.01
Home/ TBA		
Diagnosed of disease/complications in pregnancy		
Not diagnosed		
Diagnosed	0.08 (0.01 – 0.7)	<0.05
Total duration of labour in hours		
Up to 24		
More than 24	8.3 (3.7 – 18.8)	<0.001
Delivery Mode		
Spontaneous vagina delivery		
Operational delivery	9.2 (3.8 – 22.1)	<0.001
Delivery outcome		
Baby born alive		
Still birth	32.9 (7.9 – 136.7)	<0.001
Baby weight		
Baby weighs less than 4kg		
Baby weighs 4kg and above	3.2 (1.4 – 6.9)	<0.005
Family Planning status		
Never used family planning	4.0 (1.3 – 12.0)	<0.05
Used family planning		

OR (95% CI) *: odds ratio (95% confidence interval)

Fistula patients were more likely to have attended ante-natal clinic (OR= 0.9, 95% CI= 0.3 – 2.4), were less likely to be diagnosed of any medical disease/ complication of pregnancy during all trimesters of the pregnancy (diagnoses of medical condition in pregnancy is protective, OR=0.08, 95%CI=0.01 – 0.65) and were less likely to have used herbal concoctions with suspected uterotonic activity (kaligotim) during the pregnancy or labour period (OR=0.5, 95% CI=0.3 – 1.3). Fistula patients were more likely to have delivered by operative delivery (caesarean section, instrumental delivery) when compared to controls (OR=9.2, 95% CI=3.8 – 22.1) as shown in table 3. In most cases, the outcome of the index delivery is stillbirth (OR=32.9, 95% CI=7.9 – 136.7). Finally, fistula patients were less likely to have used a modern family planning method and more likely to rate themselves poor or extremely poor in a self-ranked economic status rating (OR=4.1, 95% CI =1.8 – 9.3).

Labour duration Factors related to OF

Fistula patients were more likely to have laboured longer hours compared to controls. Mean difference between total duration of labour in hours is 27.6 hours (95% CI 20.6-34.6 hours). They were also more likely to have spent more hours at home before getting to the hospital (mean difference=9.2 hours, 95% CI=4.5-13.9 hours). Time interval from delivery to onset of fistula ranges from one day to sixty days. The median however is 2 days (interquartile range=8 days). On the average, fistula cases had higher matched odds of being in labour for more than 24hours (MOR 5.4 CI=1.6 -18.1) as shown in table 4.

Ascribed causes of Obstetric Fistula among women

Table 5 displays ascribed causes of Obstetric fistula. Most of fistula patients blame lack of health facilities as the main cause of obstetric fistula (52.9%). Health workers related errors was ranked 3rd by both fistula and control women. Among the controls that have some ideas about obstetric fistula, 66.7% think God or the gods are responsible for the fistula. Overall test of significance shows that, there exist significant difference between the perception of fistula patients and controls with regard to the causes of cases (Pearson chi square 35, p-value < 0.05).

Effect of Obstetric fistula

Patients seeking care for obstetric fistula have carried the condition for a median 4 years before seeking care in the fistula centre (interquartile range= 6years). Duration of fistula ranged from 3 months to 19 years. They were more likely to be unemployed (OR = 13.2, 95% CI = 3.0 – 43.8). Also, they are more likely to have no formal education (OR =13.9, 95% CI =4.2 – 45.9). Also fistula patients have higher odds of being currently single or cohabiting (OR=2.3, 95% CI =1.2 – 5.8). In most cases, the outcome of the index delivery was a stillbirth (OR=32.9, 95% CI=7.9 – 136.7).

Table 4: Adjusted[#] Matched Odds ratio of independent risk factors

Characteristics at index delivery	Adjusted MOR*	95% CI	P-value
Area of residence			
Urban			
Rural	13.3	2.6 – 67.3	<0.005
Employment status			
Employed			
Non-employed	15.7	2.6 – 93.3	<0.005
Educational status			
Formal education			
No formal education	16.7	2.8 – 101.0	<0.005
Health insurance status			
Insured			
Not insured	6.6	2.1 – 21.2	<0.005
Distance in Miles to Hospital			
Up to 10			
Above 10	10.6	2.8 – 41.0	<0.005
Access to means of transport to hospital			
Car/ Ambulance			
Bicycle/walking	8.7	2.2 – 35.4	<0.005
Self-Ranked Economic Status			
Rich			
Poor	3.3	1.1 – 10.2	<0.05
Place of delivery			
Hospital			
Home/ TBA	6.2	1.4 – 27.3	<0.05
Diagnosed of disease/complications in pregnancy			
Not diagnosed			
Diagnosed	12.7	1.3 – 121.9	<0.05
Total duration of labour in hours			
Up to 24			
More than 24	5.7	2.0 – 16.0	<0.005
Delivery Mode			
Spontaneous vagina delivery			
Operational delivery	6.2	1.9 – 20.0	<0.005
Delivery outcome			
Baby born alive			
Still birth	24.1	4.6 – 127.0	<0.001
Baby weight			
Baby weighs less than 4kg			
Baby weighs 4kg and above	3.3	1.0 – 10.7	<0.05
Artificial contraception use status			
Ever used			
Never used	6.9	1.3 – 35.6	<0.05

Adjusted[#]: Adjusting for age at index child birth and height; MOR*: Matched Odds Ratio; reporting for only significant values

Table 5: Multiple response analysis of what women perceive as cause of obstetric fistula

		Controls	Cases	All participants
Rank	Perceived cause	N (%)	N (%)	N (%)
1	God/ gods	22 (66.7)	26 (51.0)	48 (57.1)
2	Lack of health facilities	18 (54.6)	27 (52.9)	45 (53.6)
3	Health worker related errors	18 (54.6)	22 (43.1)	40 (47.6)
4	Poverty	11 (33.3)	12 (23.5)	23 (27.4)
5	Big Baby	10 (30.3)	11 (21.6)	21 (25.0)
6	Spiritual problem	9 (27.3)	7 (13.7)	16 (19.1)
7	Work of enemies	8 (24.2)	7 (13.7)	15 (17,9)
8	Curses/ punishment	6 (18.2)	4 (7.8)	10 (11.9)
9	Kaligotim* intake	5 (15.2)	2 (3.9)	7 (8.3)

Finally, fistula patients were more likely to rate themselves poor or extremely poor in a self-ranked economic status rating (OR=4.1, 95% CI =1.8 – 9.3).

Among women who were married prior to the index child, there was higher incidence of divorce among cases compared to that of controls.

Divorce rate among cases over the period was 55.3% while that among the controls was 2.3%. Chi square test showed a significant difference in the marital status among study groups (Chi square 32.2, p-value < 0.001). Among fistula patients who were cohabiting prior to index child, all were currently separated. Alcohol consumption had increased among cases compared to that of controls such that fistula women were more likely to be currently taking alcoholic drinks compared to controls. 19.6% of cases were likely to be currently using alcoholic beverages compared to 6% in controls (OR=5.3, 95% CI= 1.4 – 19.7). Still birth rate of index delivery was about 85% among cases while about 15% among controls. About 41.2% of cases currently have no living child whereas only 2% of controls have no living child. Health shopping was common among fistula patient. About 37.3% of women with fistula tried alternative treatment for their condition before going to the hospital. Of this number, 65% visited spiritual churches and prayer camps, 30% visited the herbalist and tried various concoctions and 5% visited the traditionalist for rituals.

Discussion

This study found out that, most of women who suffer obstetric fistula are young and illiterate. Young age, particularly age less than 20 years was significantly associated with obstetric fistula in this study. Other studies report a bi-modal age distribution of obstetric fistula with peaks at teenage and an age within the third decade of life[3]. This bi-modal pattern was not immediately obvious in this study, rather what could be described as a tri-modal distribution with peaks at ages 19, 25 and 29 years.

Fistula patients were relatively shorter and were more likely to be 150Cm or less .(OR=11.77, 95% CI=4.08 – 33.94). A study among women in Ethiopia found the mean height of fistula patients to be 149 cm (SD=8Cm)[16]. In this study however, the mean height of fistula patients was 152.4 Cm (SD= 5.2Cm).

One unique characteristic of obstetric fistula in this study contrary to other works outside Ghana is the strong association of Obstetric fistula with skilled attendant at delivery. Key factors in published work done outside Ghana seem to be conclusive on the fact that, OF patients were more likely to have delivered at home with unskilled attendant at birth. This was not the case in the Northern sector of Ghana where OF patient were more likely to have delivered in a hospital (home /TBA delivery appear to be protective OR =0.24, 95% CI=0.08 – 0.64). Also OF patients were more likely to have delivered the index child through caesarean section. The national report on the burden of fistula in Ghana published in 2015 by the Ghana Health Service and UNFPA also found also found out that over half of deliveries among Fistula patients resulted in Caesarean section[27]. The plausible explanations to this observation may be because of the following factors: In the Northern sector of Ghana, there is usually a long journey to the nearest hospitals and considerable amount of challenges in obtaining means of transport to the nearest hospital at certain times of the day. Hence, most pregnant women would normally deliver at home/ TBA with the difficult obstructed labour cases transferred to the hospital. As a result, the women with difficult obstructed labour were more likely to have been transported to the hospitals and delivered in the hospitals. This gave the initial impression that delivery at home or TBA's place is protective compared to hospital delivery. However adjusting for mode of delivery (spontaneous vaginal versus operative), the place of delivery (home versus hospital place of delivery) became insignificant. Mode of delivery remains significant after adjusting for all other variables depicting higher odds of Obstetric fistula among women delivered by caesarean section compared to those delivered by spontaneous vaginal delivery[26]. It could be argued that most of the cases presenting for caesarean section might have stayed too long with obstructed labour prior to presentation at the referral centre where the operative delivery took place and hence, the fistula might occur even with or without caesarean section. Also, in such prolonged obstructed labour scenarios, it is possible that hypoxic tissues become delicate and are more prone to injuries. The skills of doctors performing these caesarean sections were however not ascertained in this study and as such intra-operative injuries cannot be rule out. Further studies in this area can make this clear.

Total labour duration for more than 24 hours was significantly associated with development of Obstetric fistula in this study. This agrees with other works that attributed labour more than 24 hours with significantly increased incidence of obstetric fistula[18]. The national report on the burden of fistula in Ghana published in 2015 by the Ghana Health Service and UNFPA however noted that 50% of fistula patient had total duration of labour less than 12 hours with only 36% having duration of labour more than 24 hours[27]. A systematic review reported average duration of labour at home to range from 2.5 to 4 days[19]. In this study however, duration of labour at home ranges from 1 hour to 72 hours. Fistula patients laboured on the average, nine hours more before delivery compared to controls. Some factors are known to directly contribute to increase total duration of labour. The three delays: delay in decision making, delay in getting to the hospital, delay in the hospital all play a part in the increased total duration of labour. Health seeking behaviour is a known factor that influences the decision-making process that result in delays at home before getting to the hospital. Rural residency, distance from the nearest hospital with capabilities for caesarean section, high transport fare more than 1 Dollar from home to the nearest hospital with capabilities for caesarean section as well as lack of ambulance or car in

case of emergency were found in this study to be significantly associated with increased duration of total labour in hours. Also lack of formal education, low socio-economic status was also associated with increase duration of labour at home. Fistula patients were more likely to be resident in rural part of their districts (OR=5.47, 95%CI=2.22 - 13.46). Residency in rural areas where there is lack of good access roads and health facilities contribute to the delays in getting to the hospital. This factor is not peculiar to this study group. Research done elsewhere has demonstrated that fistula patients were more likely to be resident in remote areas prior to the development of Fistula[13-17].

Another factor associated with obstetric fistula is the high rate of illiteracy [20-25]. High illiteracy has been associated with obstetric fistula and is believed to correlate well with low social role as well as low socio-economic power, which complexly influence delay at seeking care. In this study, OF patients had higher odds of no formal education (OR =13.9, 95% CI =4.21 – 45.88). A study conducted by Tebeu et al in 2009 found out that 50% of women reported that they had received no antenatal care. We found contrary to the above, findings suggesting that, antenatal clinic attendance is protective against obstetric fistula. OF patients in this study were more likely to have attended antenatal clinic compared to controls (OR= 0.88, 95%CI= 0.33 – 2.35). "*Kaligotim*" a local herbal concoction frequently consumed by pregnant women to self induce labour and also speed up labour was not found to be associated with increased risk of developing OF. Its usage was rather associated with shorter duration of total duration of labour. This supports its suspected uterotonic activity.

Median age of fistula patient was 30 years, meaning most of the fistula occurs in women in their prime, working age. This has consequence on the productivity of this women and their contribution to their nation. This study also found out that, the median duration of onset of fistula to seeking of treatment is 4 years (interquartile range= 6years) ranging from 3 months to 19 years. This may compare with other findings by Leye et al. (2012) in a study of women suffering from obstetric fistula in southeastern Senegal concluded that the average time between the occurrence of Obstetric fistula and the first consultation was 50.7 months.[28] Comparing the divorce rate among study participants over the same period of time, one could conclude that fistula has a strain on the marriages of its victims as this study noted a divorce rate of 55.3% among cases compared to 2.3% among controls over the same time period.

With regard to ascribed causes of Obstetric fistula, there was paucity of knowledge of women about obstetric fistula. 60% of controls have no knowledge about the causes of obstetric fistula. This suggests that about 60% of women who develop fistula have no idea what the causes are. It is suggestible that these unfortunate victims of fistula are caught unawares by a "strange phenomenon". Among those who claim to have knowledge about the causes, most of the answers were not accurate. Even among fistula women, the leading ascribed cause of Obstetric fistula was God/ gods. Even though some studies have reported adequate knowledge of women about the causes of obstetric fistula,[15,20] this study agrees with studies citing lack of adequate knowledge of women on causes of Obstetric fistula.[19]

There were some limitations inherent in some of the variables on which data was collected. Measures were taken to reduce their effects. First, distance from the nearest hospital was based on estimates and could not be precise. However, a proxy to distance considered in this study was the transport fare from participant's residence to the nearest hospital with capabilities for caesarean section. Even though distance and the transport fare described above correlated well with each other, the transport fare when used in the analysis resulted in insignificant p-values. Secondly, the National Health Insurance (NHI) status with regards to pregnant women was of no significance because of Ghana's free maternal health policy, which means all pregnant women without health insurance can access care for free. Hence data on the NHI status were not considered in the final analysis.

Conclusions

Obstetric fistula development in northern Ghana is influenced by the following; age below 20 years, total labour duration more than 24 hours and height 150 cm and below. Other factors include: stillbirth, operative delivery, residence in a rural area and lack of formal education. OF affects the quality of life of its victims. The knowledge of women on the causes of obstetric fistula was inadequate.

Competing interest

The authors declare that they have no competing interests

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A SURVEY OF DENTAL SURGEONS IN GHANA ON THEIR UTILIZATION OF SUPPLEMENTAL LOCAL ANAESTHETIC METHODS DURING ROOT CANAL THERAPY

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Abstract

***Background*:** Teeth with irreversibly inflamed pulps can be preserved with endodontic or root canal treatment (RCT). The primary methods used to manage pain during RCT are local infiltration injections and nerve blocks. When infiltrations are used, it is reasonable that the acidic nature of inflamed tissues, can reduce the availability of the active form of the local anaesthetic agent. In the case of nerve blocks, the acidity of the inflamed tissue is unlikely to play a significant role in the failure to achieve anaesthesia. Supplemental anaesthesia methods including periodontal ligament injection (intraligamentary), intraosseous injection, and intra-pulpal injection have been suggested as adjuncts to obtaining complete anaesthesia of the symptomatic irreversibly inflamed dental pulp.

***Aim*:** This study was to ascertain the types of supplemental anaesthesia techniques, and their levels of utilization during lower molar RCT in Ghana.

***Materials and methods*:** An online survey was done by e-mailing questionnaires to practicing dental surgeons registered on the Ghana Dental Association(GDA), google's group platform. Data obtained was analyzed using SPSS version 21.

***Results*:** Eighty-five percent (34) of respondents indicated that they employ supplemental injections during RCT. Pulpal and intraligamentary techniques were the most commonly used, with 70.6% and 47.1% of dentists reporting utilization respectively.

Conclusion: There is the need for update courses in the utilization of intraosseous supplemental local anaesthesia. Other supplemental injection techniques like the inferior alveolar nerve block (IANB) plus nitrous oxide inhalation have to be introduced to dentists carrying out RCT, so they can add such techniques to their pain management portfolio.

Keywords : RCT pain control, supplemental anaesthesia in Ghana, supplemental anaesthesia survey.

Introduction

In RCT the pulp cavity is accessed through the crown, and the dental pulp completely removed so the root system of the tooth can be chemo-mechanically cleaned and shaped for subsequent placement of a three-dimensional root filling. The chemo-mechanical cleaning and shaping is done with files and chemical irrigants. RCT is the definitive treatment when the dental pulp is irreversibly inflamed (as in symptomatic irreversible pulpitis), or necrotic (as in non-vital teeth) resulting from trauma to the tooth. Symptomatic teeth (diagnosed with irreversible pulpitis) resulting from for example, deep dental caries, cracked tooth syndrome; are examples of teeth that usually require RCT in other to be saved. RCT may however be carried out as an elective procedure in healthy teeth with severe wear (having vital and non-inflamed pulps) as part of the restorative treatment plan.

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Pain management during RCT, is generally more challenging in symptomatic teeth, as compared with healthy teeth or teeth with necrotic pulps.

Predictable and consistent pain control throughout root canal therapy (RCT) is essential not only for the comfort of the patient, but also for the dental practitioner since it contributes to the success of the RCT appointment(s).[1] Conventional local anaesthetic techniques involve nerve blocks or infiltration with local anaesthetic agents. The site of local anaesthetic action is the voltage-gated sodium channel.[2] It is especially challenging to anaesthetize mandibular posterior teeth with a history of pain and a diagnosis of irreversible pulpitis. Several explanations have been offered for this observation in these teeth, commonly referred to as 'hot' teeth.[1,3,4] These explanations include the following;

i. The failure of penetration by the anaesthetic agent into the nerve bundle to reach the sensory nerves that innervate the pulp, particularly during inferior alveolar nerve blocks (IANB)[1],
ii. Failure to reach the core of the nerve bundle to block the nerves that supply the anterior lower teeth leading to high failure rates in achieving anaesthesia for these teeth following the IANB (central core theory)[1],
iii. Sensitization of peripheral pain receptors leading to disproportionate and even spontaneous firing in

response to stimuli ie, allodynia and hyperalgesia respectively[1],

iv. Acidic nature of inflamed tissues leading to a decrease in the ionized form of anaesthetic solution inside the nerve.[1]

Rosenberg[5] also suggests that, apprehensive patients may be a cause of local anaesthetic failure. Odontalgia often leads to increased anxiety in patients, resulting in a lowered pain threshold. A cascade of negative events may then follow in such patients, with initial anxiety leading to a reduced pain threshold, followed by a complication with the anaesthesia and thus increased apprehension.[5]

During inflammation, there is a change in the type of sodium channel expressed in the nerves.[6] Sodium channel expression shifts from tetrodotoxin-sensitive (TTXs) to tetrodotoxin-resistant (TTXr), leading to hyperalgesia of C nerve fibers.[6] These TTXr sodium channels are relatively resistant to local anaesthetics compared with TTXs channels.[6] Scholz et al[6] found that bupivacaine (long acting local anaesthetic) may be the anaesthetic of choice when there is hyperalgesia, because it is found to be more potent than lidocaine (Intermediate acting local anaesthetic) in blocking TTXr channels.

Following IANB, patients may report numbness of the lower lip suggesting achievement of anaesthesia. Objective tests with provoking stimuli based on the presenting complaint returns a response of no pain, but when endodontic access is commenced, the patient may complain of acute pain. This sequence of events frequently encountered in teeth diagnosed with symptomatic irreversible pulpitis, can be addressed with the use of supplemental injection techniques. These supplemental injection techniques currently include intra-ligamentary, intraosseous, intra-pulpal injections, and nitrous oxide with IANB.[5]

Rosenberg[5] suggests that, nitrous oxide provides minimal sedation, an analgesic effect and decreases the pain of the initial IANB in the anxious patient. These coupled with the impressive safety record of nitrous oxide allows the dentist to combine it with the usual IANB, as a form of supplemental injection.

Intra-ligamentary injections are done by positioning the needle firmly into the periodontal membrane space and expressing anaesthesia under back pressure. Intra-pulpal injections are made directly into the pulp chamber of the tooth, once some access has been obtained into the pulp chamber (but there is pain when contact is made with the pulp). Intraosseous injection techniques allow the direct deposit of the anaesthesia into the medullary bone after perforating the cortical plate (of the lower jaw) with specially designed needle tips (eg. Stabident and S-Tip).[7] Supplemental injection techniques (ie, intrapulpal, intraligamentary, and intraossous) not involving IANB, should only be employed after a successful IANB, objectively confirmed by lower lip numbness[5].

It has been suggested variously that, when RCT is indicated for symptomatic lower molars diagnosed with irreversible pulpitis, the employment of supplemental injection techniques should be anticipated.[3,5,8] When supplemental injection techniques are anticipated and implemented as part of the process of anaesthetizing such teeth prior to initiating RCT, supplemental injection methods that do not require access to the pulp chamber are usually preferred.

This survey was carried out to ascertain the types of supplemental anaesthesia techniques, and their level of utilization during RCT in Ghana. Secondary investigations included finding out which teeth were most frequently root treated, treatment choices resorted to by respondents when they are unable to achieve pulpal anaesthesia at the initial RCT appointment, the teeth that were difficult to anaesthetize during RCT, the diagnosis of teeth undergoing RCT that were difficult to anaesthetize, and the type (based on the duration of action) of local anaesthetic drugs they regularly use during RCT.

It was also meant to identify knowledge gaps and provide information that will help with designing further training for dentists on the indications for supplemental injection techniques. Finally, the outcome of this survey will help dentists who carry out RCT, to better manage patients in whom there is incomplete anaesthesia.

Materials and Methods

A cross sectional online survey of dental surgeons who undertake RCT in Ghana was carried out between March and July 2016. The weblink to the questionnaire asking about years of practice/rank, what teeth RCT was frequently carried out on, the diagnosis and tooth type that were frequently difficult to completely anaesthetize, what they considered as supplemental injection techniques, what supplemental injection techniques were used by them during RCT, what group of local anaesthetic drugs (based on the duration of action) was regularly used during RCT, and what treatment options were employed when incomplete anaesthesia was encountered as a problem during the initial RCT appointment; was sent to all registered dental surgeons who are members of the Ghana Dental Association (GDA), practice in Ghana and subscribe to the GDA google's group.

Respondents were informed in the email that the survey was a postgraduate research project. To encourage unbiased responses, no identification was requested. The questionnaire was designed so that respondents were reminded to answer questions they had omitted before progressing to the next page. If respondents answered that they do not undertake RCT, their survey was ended.

The weblink to the questionnaire was piloted on restorative dentistry residents of the University of Ghana School of Medicine and Dentistry prior to being emailed to dentists on the GDA google groups platform. All

responses to the questionnaires were electronically recorded.

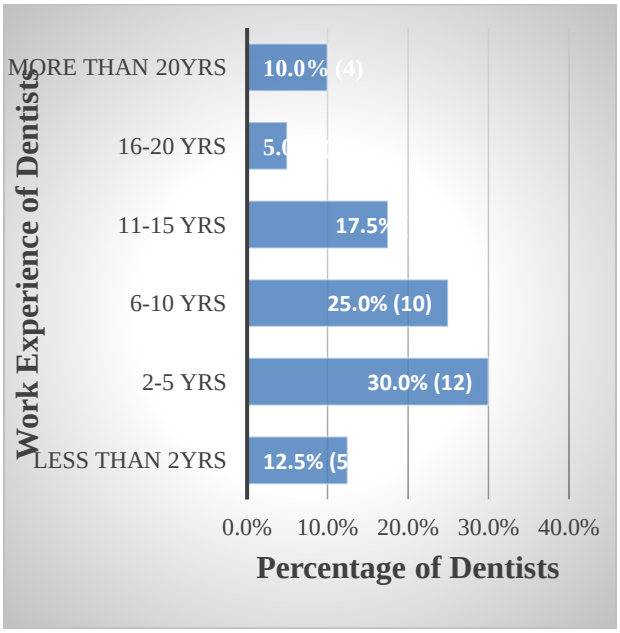
Descriptive statistics, including frequencies of responses and demographics of the respondents was analyzed using SPSS version 21. Data collected was used solely for purposes of research.

Results

Forty dentists completed the questionnaires (Response rate of 62%). Of the 40, (70.0%, 28) were males and (30.0%, 12) were females. Nine (22.5%) of the respondents had received postgraduate training involving endodontics. The distribution of working experience of the dentists is as shown in Figure 1.

77.5% of dentists indicated that they usually carryout RCT on mandibular molars **(Table 1a)**.
Lower molar RCT's were carried out by different ranks. Dentists with the rank of medical officer, carried out the most lower RCT's (Table 1b).

Figure 1. Distribution of working experience of the dentists



When asked for which teeth respondents experienced difficulties achieving anaesthesia during RCT? The responses in Table 2a were obtained.

In general, 57.5% (23) of the dentists reported ever having difficulty with achieving anaesthesia and maintaining anaesthesia during RCT. Specifically, 82.5% (33) of respondents mentioned lower molars in particular, as teeth that are frequently difficult to anaesthetize when RCT is indicated (Table 2a). The ranks of the 82.5% (33) dentists, is as shown in Table 2b. Thirty-one (77.5%) of the respondents reported further that, symptomatic irreversible pulpitis was the established diagnosis, of teeth that presented with difficulties in achieving complete anaesthesia.

Thirty-four dentists in this study (85.0%, p = 0.0000095) alluded to the use of some supplemental anaesthetic technique during lower molar RCT as opposed to 6 (15%) who had not. Figure 2 shows the supplemental methods as indicated by the 34 respondents. Table 3a and Table 3b breaks down the responses according to rank and years of practice of respondents respectively. In Figure 3, the preferred local anaesthetic agents (depending on the duration of action) used by dentists to anaesthetize the pulps prior to RCT is shown.

In situations where dentists were unable to achieve pulpal anaesthesia during the initial RCT appointment, the options shown in Figure 4 below were usually resorted to.

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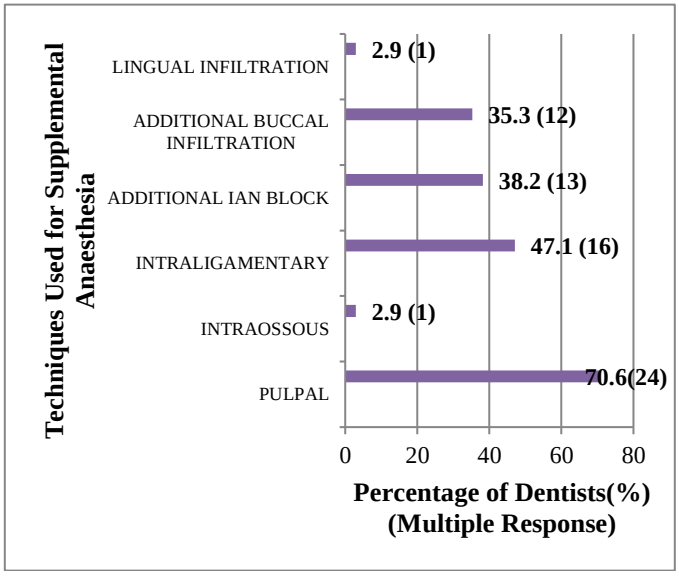

Figure 2. Supplemental anaesthetic Techniques

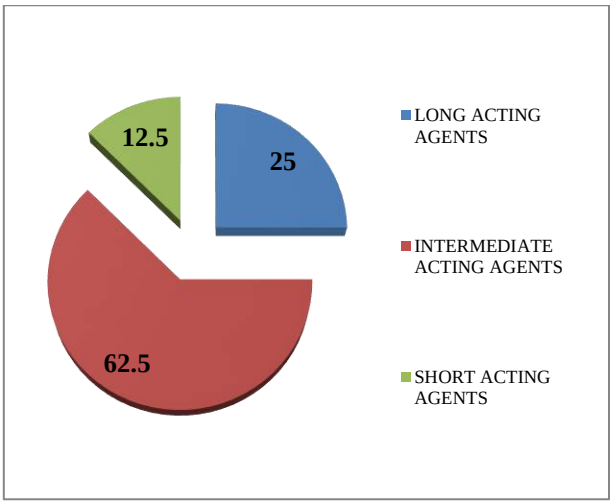

Figure 3. Local anaesthetic Used (%)

Table 1a. Teeth for which RCT is routinely carried out by respondents

Tooth type	Yes (Count/%)	No (Count/%)	Total responses (Count/%)
Upper anterior	21 (52.5)	19 (47.5)	40 (100.0)
Lower anterior	6 (15.0)	34 (85.0)	40 (100.0)
Upper premolar	25 (62.5)	15 (37.0)	40 (100.0)
Lower premolar	12 (30.0)	28 (70.0)	40 (100.0)
Upper molar	20 (50.0)	20 (50.0)	40 (100.0)
Lower molar	31 (77.5)	9 (22.5)	40 (100.0)

Table 1b. Work experience of surveyed dentists that perform lower molar RCT

Work experience	Number of dentists	Percentage (%)
< 2 years	4	12.9
2 - 5 years	9	29.0
6 - 10 years	7	22.6
11 - 15 years	5	16.1
16 - 20 years	2	6.5
> 20 years	4	12.9
Total	31	100.0

Table 2a. Teeth that respondents find difficulty in achieving and maintaining anaesthesia during RCT

Tooth type	Yes (Count/%)	No (Count/%)	Total responses (Count/%)
Upper anterior	2(5.0)	38 (95.0)	40 (100.0)
Lower anterior	2(5.0)	38 (95.0)	40 (100.0)
Upper premolar	4(10.0)	36 (90.0)	40 (100.0)
Lower premolar	4(10.0)	36 (90.0)	40 (100.0)
Upper molar	9(22.5)	31 (77.5)	40 (100.0)
Lower molar	33(82.5)	7 (17.5)	40 (100.0)

Table 2b. The rank/Position of dentists who selected lower molars in Table 2a

Rank/Position	Number of dentists	Percentage (%)
House Officer	3	9.1
Senior House Officer	5	15.2
Medical Officer	14	42.4
Senior Medical Officer	7	21.1
Specialist	4	12.1
Total	33	100.0

Table 3a. Supplementary anaesthesia techniques utilized based on rank

Rank/Position of Respondents	Pulpal	Intraosseous	Intraligamentary	Additional IAN	Additional Buccul Infiltration	Lingual Infiltration
House Officer (2)	1	0	0	0	1	1
Senior House Officer (5)	3	0	2	2	1	0
Medical Officer (13)	9	0	8	9	5	0
Senior Medical Officer (7)	5	1	2	1	1	0
Specialist (7)	6	0	4	1	4	0
Total Respondents/ %Respondents (34, 100%)	24 70.6%)	1(2.9%)	16 (47.1%)	13 (38.2%)	12 (35.3%)	1 (2.9%)

Table 3b. Supplementary anaesthesia techniques utilized based on years of practice of the respondents

Years of Practice (Number of Respondents)	Pulpal	Intraosseous	Intraligamentary	Additional IAN	Additional Buccul Infiltration	Lingual Infiltration
< 2yrs (4)	3	0	1	0	1	1
2 – 5yrs (12)	8	0	7	7	4	0
6 – 10yrs (9)	8	0	3	3	3	0
11 – 15yrs (4)	3	1	1	0	2	0
16 – 20yrs (2)	2	0	2	1	1	0
>20yrs (3)	0	0	2	2	1	0
Total Respondents/ Percentage of Respondents (34, 100%)	24 (70.6%)	1 (2.9%)	16 (47.1%)	13 (38.2%)	12 (35.3%)	1 (2.9%)

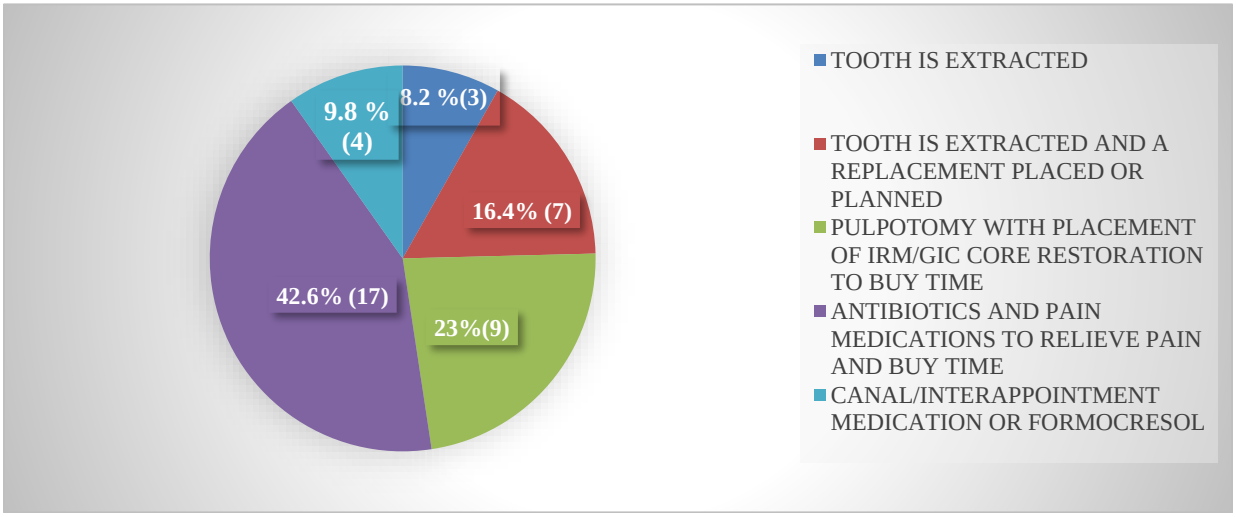

Figure 4. Treatment choices made by dentists when unable to achieve anaesthesia at initial RCT visit

Discussion

Most RCT's were carried out by general dental practitioners, with 9 (22.5%) of surveyed dentists having received postgraduate training involving endodontics.

Lower molar teeth had the greatest frequency of RCT undertaken on them (77.5%, 31). This was followed by upper premolar teeth (62.5%, 25), upper anterior teeth (52.5%, 21), upper molar teeth (50%, 20), and lower anterior teeth (15%, 6). Lower molars were also found in studies by Ismail and Ismail,[9] and Oglah et al[10] to be the teeth most frequently treated[9,10]. Al-Negrish[11] and Umanah et al[12] on the other hand reported that RCT's were more frequently undertaken in maxillary teeth than in mandibular teeth[11,12].

It has been observed that the leading pathology necessitating RCT is caries linked. This may imply that if the rate of uptake of RCT is high, the pattern of teeth treated may follow the reported order of susceptibility of teeth to caries in a population[13,14].

Success rates for pulpal anaesthesia with inferior alveolar nerve blocks (IANBs) have been found to range from 42% to 73% in noninflamed pulps[15,16] and 19% to 55% in teeth diagnosed with irreversible pulpitis[17–19]. All the patients in these studies[15–19] had expressed 100% lip numbness, an indication that their IANBs were successful. The findings in such clinical studies were confirmed by our surveyed dentists, with 77.5% (31) mentioning symptomatic irreversible pulpitis as the definitive diagnosis of teeth that are difficult to anaesthetize.

Considering the influence of tooth type, the reported difficulty in achieving anaesthesia is more in mandibular molars, followed by the mandibular premolars, the maxillary molars and premolars, and the mandibular anterior teeth. The maxillary anterior teeth present the least challenge[20]. In our survey, 82.5% (33) dentists also reported that lower molar teeth undergoing RCT are the most difficult to anaestheticize.

Eighty-five percent (85%, 34) of dentists reported having ever employed a supplemental anaesthetic method during RCT. The apparent utilization of supplemental anaesthetic methods by a significantly large portion of respondents (85%, p=0.00000955), may be explained by the fact that most of the dentists frequently treated lower molar teeth.

The most popular supplemental local anaesthetic injection method in our survey, was the intra pulpal (70.6%, 24), followed by the intraligamentary (47.1%, 16) and the intraosseous (2.9%, 1). The popularity of the intra pulpal method, may be because it is instinctive to resort to it once access has been secured to the pulp chamber. The intra-pulpal injection is however very technique-sensitive and requires the creation of adequate intra-pulpal pressure to ensure success[21]. A study by Birchfield and Rosenberg[22] highlighted the importance of getting the technique right.

Their study concluded that sterile saline or lidocaine 2% with 1:50,000 epinephrine were equally effective in producing pulpal anaesthesia when the intra-pulpal injection technique is used in the correct fashion[22]. To guarantee the generation of adequate intra-pulpal pressure during this injection, practitioners have to use the technique before widening the access cavity. It is possible that poor technique of intra pulpal injection technique may account for the difficulty in achieving anaesthesia during RCT of lower molars, despite the popularity of the intra pulpal injection method among the dentists we surveyed. In a survey done in the United States of America among Endodontic specialists, 94.77% of them used some form of intraosseous anaesthesia. The intraligamentary supplemental method was reported as the most popular (49.78%)[7] in that study. The fact that intraligamentary and intraosseous methods require special equipment may account for their low utilization by the dentists we surveyed.

The combination of IANB with inhalation of nitrous oxide as a form of supplemental anaesthesia during RCT, was not utilized by any of our surveyed dentists. This method requires equipment to deliver the nitrous oxide to the patient, whiles the rubber dam is still in place to protect the airway during RCT. Lack of familiarity with this concept of combining the IANB and nitrous oxide as a supplemental injection technique coupled with the absence of equipment needed to deliver the nitrous oxide gas whiles ensuring that the rubber dam isolation of the treated tooth is in place, may account for its non-utilization during RCT.

Twenty-six (76.4%) of the dentists however wrongly carried out additional IANB (38.2%, 13), additional buccal infiltrations (35.3%, 12), and lingual infiltrations (2.9%, 1) as supplemental injection techniques during RCT on molar teeth.

Our study participants were not asked reasons for their choice of local anaesthetic during RCT. Some clinical studies have however shown bupivacaine anaesthetic agent, to be more effective when used as IANB in teeth with irreversible pulpitis[23–26]. Such findings may explain the choice of bupivacaine anaesthetic agent (a long acting local anaesthetic) by 25% (10) of dentists during RCT.

In the case where time constraints or difficulties in achieving anaesthesia prevent pulp extirpation from been carried out, research has shown that the ideal treatment is pulpotomy followed by the placement of intermediate restorative material (IRM)[27]. The prescription of antibiotics as part of the management in this situation, has been shown not to be beneficial to the patient[28,29]. Seventeen (42.6%) of the survey respondents wrongly included prescription of antibiotics as part of their pain management modality, in situations where there had been failure to achieve anaesthesia at the initial RCT visit.

CONCLUSION

Even though there was wide adoption of supplemental local anaesthesia methods by 85% (34) of dentists, only (2.9%, 1) used the intraosseous supplemental anaesthetic method.

There is the need for update courses in the utilization of intraosseous supplemental local anaesthesia methods. Such update courses can also correct the misapplication

of additional IANB, lingual and buccul infiltrations as supplemental local anaesthesia methods. Supplemental injection techniques like the IANB plus nitrous oxide have to be introduced to dentists carrying out RCT, so they can add such techniques to their pain management portfolio.

The addition of new supplemental injection techniques, correction of practices like the prescription of antibiotics as part of endodontic pain management, and the bridging of knowledge gaps in the use and place of supplemental injection techniques during RCT will lead to greater success of endodontic practice in Ghana.

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CHICKENPOX IN GHANA: IS IT TIME TO CONSIDER UNIVERSAL IMMUNIZATION?

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Summary

Chickenpox is a very common disease worldwide. It is one of the most frequently reported infectious diseases in North America. Although childhood varicella disease is not usually a life-threatening condition, it can cause major financial and social problems to parents and society from lost working time spent looking after sick children. Besides, there is a large number of unrecognized complications including fatalities from invasive infections. The availability of an effective vaccine, has made universal immunization a cost-effective approach to prevention and minimizing the effects of the disease in some settings. The exact burden of the disease in Ghana and for that matter most of Africa is unknown. Thus, in Ghana, a surveillance system and selective immunization is recommended as more information is gathered on the burden of disease and its impact on Ghana and the rest of Africa.

Keywords : Chickenpox, immunization, morbidity, Vaccination

Introduction

Chickenpox or Varicella is a very contagious disease which occurs worldwide[1,2]. It is one of the most frequently reported infectious diseases in North America and it impacts on the practice of Internal Medicine, Family Medicine, Paediatrics and Obstetrics. The minimum estimated number of individuals affected by varicella globally each year is 140 million cases, with severe complications necessitating hospitalization occurring in 4.2 million and an estimated 4,200 deaths[1,2].

In 2008, 77,790, cases of chickenpox representing 0.7% of total outpatient morbidity were reported by the Ghana Health Service[3]. In 2002, 2003 and 2004, it was 35,667 (0.5%) 19,614 (0.3%) and 45,512 (0.6%) respectively, suggesting a gradual rise in the contribution of chicken pox to outpatient morbidity[3]. Unfortunately, more recent facility-based or population-based figures for Ghana are unavailable. However, chickenpox remains a problem in Ghana.

According to a report in 2003, chicken pox was among the top ten leading causes of out-patient attendance at the 37 Military Hospital in Accra[4].

In 2014, it was reported to be endemic in the Agona West municipality of Ghana[5]. A news article also reported an outbreak of chickenpox in a prison population in Ghana, which was difficult to control that same year. Although in most cases, childhood varicella disease is not a life- threatening condition, it can cause major financial and social problems to parents in lost working time spent looking after their sick children, while the children themselves suffer from the disease and lose valuable time away from school[6].

Besides medical costs, infection in some previously healthy children, adolescents and adults can be complicated by serious secondary bacterial infections[1,2,7].

Historically, in the late 19th and 20thcenturies, outbreaks of chicken pox occurred close in time with outbreaks of scarlet fever in the USA[8]. Severe invasive disease became the subject of reports in the late 1980's and the 1990's[7,9,10]. Since the development of a vaccine against the disease in 1974 and commencement of universal varicella immunization in the USA in 1995, varicella disease has assumed global significance[2,11]. Introduction of the vaccine has led to significant reductions in varicella incidence, morbidity, mortality, hospitalisations and ambulatory visits in the population and in vulnerable groups[11,12,13]. Thus, some countries are reviewing the evidence for universal varicella immunization in their own setting[14,15]. This review looks at the evidence for universal varicella immunization in an African country, like Ghana. We searched google, google scholar, PubMed and Scopus for literature on the subject using search terms such as chicken pox, chickenpox, varicella, vaccine, vaccination, immunisation, cost-effectiveness, Accra, Ghana, Africa.

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Conflict of Interest : none declared

Literature Review

Although in the majority of healthy children, chicken pox resolves with no complication, it has been associated with 2-3 hospitalisations per 1000 cases and 1 death per 60,000 cases[16]. The disease is characterised by a mild prodrome, prominent in adults, and a vesicular rash[16]. However, complications such as secondary bacterial infection, aseptic meningitis, encephalitis with cerebellar involvement and pneumonia, (viral or

bacterial), may occur. Rare complications include thrombocytopenia, arthritis, orchitis, uveitis, iritis, hepatitis, glomerular nephritis, pupura fulminans, transverse myelitis, Reyes syndrome and Guillian Barre syndrome[2,16]. Though the risk is low, Congenital Varicella Syndrome characterised by low birth weight, limb hypoplasia, skin scarring, eye and neural defects can occur after infection in the first 20 weeks of pregnancy[2,16]. Maternal varicella zoster virus (VZV) infection with a rash occurring 5 days before delivery and 2 days after delivery may result in severe disease in the neonate and mortality in 30%[16]. These neonates, patients older than 15 years, infants less than 1 year and immune-compromised individuals are most at risk. The virus remains latent after infection and may cause Herpes Zoster (shingles) later in life when immunity falls.

Chicken pox is regarded as the single largest risk factor for the development of invasive group A Streptococcal (GAS) infection in otherwise well children, with published rates of between 6-37% of total cases[7]. In the majority of cases an obvious source of infection, often the skin was found. In their study to describe the incidence and clinical features of invasive group A streptococcal infection in Ontario Canada, and determine the risk of invasive GAS infection following chickenpox, Laupland et al found the incidence to be 1.9 per 100,000 childrenper year, with 15% of children identified to have preceding chicken pox infection, all under the age of ten years[7]. The incidence of invasive group A Streptococcus was 58 times greater in patients with a history of varicella infection in the preceding two-week period compared with those without. Bacteremia without focus was one of the least common presentations[7]. Streptococcal Toxic Shock Syndrome (STSS) as well as invasive Group A Streptococcus (GAS) have been well described[7,17].

Group A streptococcus causes cellulitis, necrotizing fasciitis, septic arthritis, pneumonia, streptococcal toxic shock-like syndrome, meningitis and bacteremia. Case-fatality rates in the Laupland study were 56% for Streptococcal Toxic Shock Syndrome, 10% for Necrotizing Fasciitis, and 4% overall[7]. The presence of chronic underlying illness other than asthma was associated with death (relative risk [RR]: 11; 95% confidence interval [CI]: 2.4-45). In their conclusion Laupland et al suggested that childhood invasive GAS disease occurs at an incidence similar to the adult population and that Chickenpox dramatically increases the risk for acquiring invasive GAS disease[7]. They recommended thatuniversal chickenpox vaccination could potentially prevent up to 15% of all pediatric invasive GAS disease. Data from the Strep-EURO surveillance program estimated the incidence of invasive GAS infection as 3.5 per 100,000/year in England, Wales and Northern Ireland and 3.6 per 100,000/year in Scotland[18]. Within Europe, trend patterns vary markedly, but they suggested an overall increased incidence over the past two decades.

While practicing in the UK, the corresponding author was involved with the management of two children who developed invasive streptococcal infection following VZV infection which has since been published[19]. Both children, whowere from the same daycare facility, presented within 14 days of each other. One survived but required intensive care at a tertiary Paediatric Intensive Care Unit. The other did not survive. Following the incident, a ten-day course of oral penicillin was prescribed to all children attending the child care facility, and all children older than a year with no previous history of VZV were vaccinated. Health alerts were sent to all general practices and accident and emergency departments within the region.

Meningitis is a significant cause of mortality in Ghana and most of Africa. "The African meningitis belt" in sub-Saharan Africa, a region that extends from Ethiopia to Senegal, is particularly vulnerable to meningococcal disease epidemics during the dry harmattan season[20,21]. Other studies have found pneumococcalmeningitis due to streptococcus pneumoniae to be the most important causative agent of bacterialmeningitis in certain areas of the belt[22,23]. The association between Group A streptococcus and Staphylococcus aureus has been consistentlyreported, but one between Streptococcus pneumonia or meningococcus and Chickenpox has not been established[7,9,10]. Howeverisolated cases of pneumococcus and chickenpoxhave been reported[10]. Sincechickenpox causes mucosal damage thatcouldpredispose to invasive pneumococcal or meningococcaldisease, itwouldbeintriguing to examine the epidemiology of chickenpox in the meningitisbelt to determinewhether, likescarletfever, thesediseases are related. Mortality from chickenpox, and its relationship with invasive Group A Streptococcus (GAS) have not been studied extensively in Ghana but it does not mean the relationship as established in the West does not exist. Ghana, like the rest of Africa, has several risk factors for severe chicken pox disease[24]. Theseinclude, the high prevalence of HIV disease, overcrowding in big cities, weak health systems to manage complications and the occurrence of the disease at an older age than it occurs in the West[24]. While varicella associated morbidity and mortality in Africa is currently under review, a review of varicella seroprevalence in Singapore, Malaysia, Philippines, Thailand and India, showed a low seroprevalence in children and greater susceptibility in adolescents and young adults[25]. A seasonal prevalence was reported in India with most cases occurring in the cooler months. Data from Latin America and the Caribbean's on the other hand revealed that, children were most affected with an incidence of 42.9 cases in under 15-year olds per 1000 individuals per year[26]. The general admission rate was 3.5 per 100,000 population. In Turkey, varicella-related hospitalizationwas 5.29-6.89 per 100,000 in all children between 0-15 years with most cases occurring in children under five years, in spring and summer months[27]. Universal varicella

immunization is practiced in Turkey, Taiwan and Japan[13,27,28]. Prior to this, vaccination coverage was found to be higher in some high-income households in Japan[28].

Currently, two live attenuated virus vaccines, Varilrix and Varivax, containing the Japanese varicella virus strain Oka, are in use and both have been found to be safe and highly immunogenic[1,2]. They can be given as a single dose, though a two-dose regimen is recommended to prevent breakthrough disease[1,12,13]. It is available as a monovalent vaccine or in combination with MMR (measles-mumps-rubella vaccine). The side effects are minor, and the common ones are redness, pain and a rash at the injection site[1,11]. Vaccine failure leading to school outbreaks involving immunized children has also been noted[1,13]. Presently in Ghana, the vaccine is being administered at the government's special vaccination centre and a few other private immunization centres mainly to people who need to meet their requirements for travel.

Before vaccine licensure in the United States, about 4 million cases per year resulting in nearly 10,000 hospitalisations and 100 deaths occurred[11,29]. Children bore the brunt of the health burden, accounting for more than 46% of deaths[12]. The risk of severe complications and death was highest among infants, adults, and immuno-compromised individuals[12,30,31,32]. Moreover, complications and deaths were commonly described among previously healthy individuals[33].

Currently, the worldwide epidemiology of varicella has changed dramatically since the introduction of the varicella vaccine in 1995. In the United States and Canada, routine childhood immunization has reduced disease incidence, complications, hospital admissions, and deaths in children and in the general population, indicating strong herd immunity. Several other countries, including Uruguay, Germany, and Australia, have adopted similar immunization programs[13,34]. Other countries like the UK have a selective vaccination policy which means that immunization is only offered to high risk groups such as non- immune health care workers and household contacts of the immuno-suppressed[15].

There are several reasons for the reluctance to introduce universal vaccination of varicella vaccine although a safe and effective vaccine exists. The reasons for this includes, the cost involved, fear of an increase in the incidence of Herpes Zoster due to reduced exposure to the virus and an upward shift in the age of reported cases to older age groups which increases the propensity for severe disease[1,11,13,15]. In addition, it depends on public health priorities and the general perception among both the public and health workers,since they may see chickenpox as a mild disease and value natural immunity, making the argument for routine immunization unconvincing[13,35]. The predicted increase in Herpes Zoster infection has been reported by some countries but has not been observed by others, in any case, it may not show for several years and remains a subject of controversy which requires further study[11,13,15,36]. There has also been a slight increase in the peak incidence age of varicella infection though the incidence rates in adolescents and adults have fallen[12,13,15]. Concerns about cost are tenable as vaccine protection is reported to be optimal only after two doses which makes the cost prohibitive for most low and middle income countries whose vaccination programmes are supported externally by the global fund[1,12,13,15].

The World Health Organisation's position is that although the burden of severe disease due to VZV infectionis generally lower than that of other vaccine-preventable diseases, the public health value of the vaccine in lowering morbidity and mortality due to the disease is well established[1]. Therefore, it recommends that, where varicella infection is an important public health burden, countries should consider introducing the vaccine in the routine childhood programme if they have enough resources to achieve 80% coverage in order to reduce the possibility of an age shift of primary infection[1,2]. However, before countries decide to vaccinate, there should be a surveillance system to determine the burden of disease which should continue after introducing the vaccine[1,2]. They also recommend immunising special groups such as household contacts of immunocompromised persons, susceptible health workers and immunocompromised patients with HIV infection, Acute Lymphoblastic Leukaemia, and certain solid tumors if they meet specified criteria. Post-exposure prophylaxis is only recommended if the vaccine has been introduced[1].

It might appear that the safer option for preventing chicken pox in Ghana, especially in communities where facilities are not available to manage the most serious and potentially fatal invasive complications, would be universal VZV immunizations if this can be afforded. However, there are several factors which militate against this. Cost will be an issue as funding for immunisations is limited. Besides Ghana, is still struggling with a high burden of disease and mortality from pneumonia, diarrhoea and malnutrition so death from chicken pox may not receive the same the kind of prominence and significance as it does in western countries with low child mortality. For this reason, when considering an additional vaccine, it needs to be weighed against the cost benefit of introducing another child health intervention or vaccine which might be more cost effective inreducing morbidity and mortality[37,38]. Furthermore, the detailed background preparatory work to determine the burden of disease and its effects prior to introducing the vaccine as well as a surveillance system to assess the effects are lacking. This makes the argument for universal immunization less convincing. Additionally, public opinion and education needs to be considered due to the perception among the general population and some in the medical community that the disease is a non-life threatening condition so vaccination is unnecessary and co-morbidities may go unrecognized.

So, is it time to consider universal varicella immunization in Ghana? Currently there is insufficient evidence for this to be aggressively promoted. However, the available evidence is more in support of vaccination of high risk individuals, collection of information on the burden of disease and setting up a surveillance system so that this position can be revisited at a future date. Meanwhile, the government can make the vaccine and the immunoglobulin available to those that need it most, especially the immunosuppressed andstrengthen the health system to make this possible[1]. There is, however, a growing middleclass population in Ghana and other middle income African countries, who may be able to afford the vaccine and want it for their children. The private sector may be able to meet this need, as is done in South Africa, nevertheless, it could cause an age-shift due to low coverage[39].

Conclusion and recommendation

Presently, the exact burden of chickenpox in Ghana is unknown. With the availability of a safe and effective vaccine, preventing varicella deaths and GAS disease, especially septicaemia through vaccination should be considered a public health priority. Investigation and mandatory reporting of all varicella-related hospitalisations and deaths will provide more accurate and complete data on the age distribution of the disease, and its health and economic effects. This can be done by making varicella, a reportable disease on its own and linking it to the disease surveillance system currently in place. In addition, health personnel and the public need re-orientation on the disease to increase awareness and reporting of its co-morbidities. Once the aforementioned conditions are realised, then it may become necessary to re-consider the country's readiness foruniversal varicella immunization. In the meantime, it would be prudent for the government and relevant public health agencies to consider selective immunization in the health setting.

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REVIEW ARTICLES

BREAST CANCER IN MEN

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Summary

Breast cancer in males is a relatively rare entity. In the sub-region, several reports indicate a higher incidence rate compared to other regions in the world. For many years, management strategies were derived from evidence based protocols established for managing female breast cancer. There are however, differences in the epidemiology, presentation, molecular profiles and response to therapies including chemotherapy, hormonal and targeted therapies. Outcomes even though mirroring female breast cancer may actually exhibit differences dependent on stage, race, prognostic and economic variables. The lack of large randomized trials on this subject has resulted in ad hoc management practices across the globe. With new information from renewed interest in the subject, screening and diagnostic guidelines are being established for high-risk groups and we expect to see improvements in outcomes for patients with male breast cancer. This article attempts to bring to light a summary of the current interest, recommendations and controversies in the management of male breast cancer.

Keywords : male breast cancer, hormone therapy, chemotherapy, surgery, radiotherapy, survival.

Introduction

Breast cancer in men accounts for approximately 1% of all breast cancers diagnosed in the United States each year[1]. In Ghana, it accounts for about 2.9% of all breast cancers seen, consistent with the slightly higher rates reported in other parts of Sub-Saharan Africa with most patients presenting with advanced disease[2]. To date there are no randomized trials or large databases to validate current treatment strategies. Most of the information on breast cancer in men is derived from retrospective studies spanning several decades, and treatment recommendations are extrapolated from results of trials in female patients. Male breast cancer behaves like postmenopausal women with breast cancer. However, compared to all female breast cancers, it has poorer outcomes attributed to advanced stage at diagnosis and less aggressive management practices[3].

Epidemiology and Risk Factors

Male breast cancer usually occurs in the 7th decade, a decade later than occurs in females, with younger male patients more likely to have inherited genetic mutation[4]. Several risk factors are associated with higher incidence. These include Klinefelter syndrome, a family history of breast cancer, increased estrogen levels as occurs in conditions such as testicular disorders (e.g., cryptorchidism, mumps orchitis, and orchiectomy, use of finasteride and other hormonal ablation therapies used to manage prostate cancer , previous radiation exposure , gynecomastia, thyroid diseases, occupational and environmental exposures such as thermal heat, electromagnetic fields, polycyclic aromatic hydrocarbons, and dietary factors)[5-7]. Male breast cancer seems to have a higher male to female ratio in blacks compared to whites[8]. The Surveillance, Epidemiology, and End Results(SEER) database form the united states records on breast cancer from 1976 - 2005 shows that improvement in overall breast cancer cause specific death rates is less pronounced in males compared with females (28% versus 42% respectively)[9].

A meta-analysis of male breast cancer in 27 African countries suggests more late presentation , younger age (54.7years), higher incidence rates compared to developed countries, with Zambia reporting rates as high as 15%[10].Higher incidence rates in the sub region could be attributed to high estrogen levels following endemic infectious and other chronic liver disease processes [6,11]. Cirrhosis of the liver results in hyperestrogenism in men secondary to increased binding of androgens to increased sex tubulins[12]. This has been reported as a causative association and could be a result of gynecomastia predisposing to cancer.

Genetics

BRCA1 and *BRCA2* autosomal dominant genes are the major breast cancer susceptibility genes associated with a significant proportion of heritable breast cancer cases[13]. Mutation of these DNA repair genes in women confer a 40%–70% lifetime risk of breast cancer. There is a greater representation of BRCA2 tumors (41.7% vs 8.3%, p=0.0008) and under representation of BRCA1

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tumors in men compared to women (5.0% vs 14.4%, p=0.0001)[14]. Male patients with *BRCA2* mutations tend to present at a younger age and associated with a poorer survival[14]. Mutations in other genes may be implicated in the etiology of male breast cancer but are yet to be confirmed. BRCA2 is associated with aggressive prostate cancer and few reports indicate a higher incidence of breast cancer in males with this genetic mutation, and therefore it is recommended they undergo screening for both prostate and breast cancer [15].

Androgen suppression therapy for the management of prostate cancer may be associated with increased breast cancer risk secondary to altered androgen to estrogen ratio or may be related to inherited genetic mutations conferring a higher risk[16] . On the other hand transgender males who received androgen suppression therapy so far have not demonstrated an increased risk of breast cancer[17].

Screening for Male Breast Cancer

Current recommendations for screening are based on guidelines developed for females with BRCA mutations. All males with a family or personal history of breast cancer should undergo screening: monthly self breast examination, semi annual clinical breast examination and yearly mammograms for those found to have gynecomastia on the baseline mammogram[18]. The standard of choice remains mammography which has a sensitivity and specificity value of 92 and 90% respectively and a positive and negative predictive value of 99 and 55% respectively[19]. Mammograms are reliable for distinguishing gynecomastia from malignancy; the two could coexist in the same breast. Sonography by itself has a high false positivity rate but is valuable for evaluating complex masses, whereas Magnetic resonance imaging is currently recommended in males who require further evaluation of a highly suspicious mass[20]**.**

Pathology

Data from the SEER cancer registry show that 93.7% of male breast cancers are ductal carcinomas, 2.6% papillary, 1.8% mucinous, and 1.5% are lobular carcinoma[21]. Ductal carcinoma in situ (DCIS) occurs in about 10% of male breast cancers with the most common growth patterns being papillary and cribriform. Lobular carcinoma in situ is very rare because the male breast lacks terminal lobules[21].

Approximately 80-90% of male breast cancers are estrogen receptor positive, and 65-90% are progesterone receptor positive[4]**.** The *her2-neu* proto-oncogene is less likely to be overexpressed in male breast cancer. A large Italian study by Ottini et al identified 382 MBC with *her2- neu* positivity of 2.1%, and triple negative tumors as 3.7 %. Also, BRCA2 mutation was associated with family history, high grade, hormone receptor negative disease and resulted in poorer outcomes[22].

The hormone positivity rate for male breast cancer is expected to be lower in Africa following similar patterns as female breast cancer , therefore receptor testing is highly recommended to individualize treatment[23].

Clinical Features

The most common presenting symptoms in male breast cancer are painless sub-areolar lump, nipple retraction, and bleeding from the nipple[24-26]. Men with a previous history of breast cancer have a greater risk of developing contralateral breast cancer and a few present with *de novo* metastatic disease[27]. Based on the American College of Radiology of Appropriateness criteria, males younger than 25 years with a breast mass have lower chances of harboring a malignancy and therefore should have initial ultrasonography complemented by mammography if suspicious, whereas males older than 25 years should have bilateral mammography with ultrasonography, and biopsy for a breast mass[28]. Mammographic findings are abnormal in up to 90% of male breast malignancy and often depict eccentric masses with irregular spiculated edges[29].

Significant prognostic factors are tumor size and lymph node involvement. Tumors measuring 2–5 cm have a 40% higher risk of death than men with tumors <2 cm in maximum diameter[4]. Similarly, lymph node involvement is associated with a 50% higher risk of death compared to those without lymph node involvement[6]. Other identified prognostic features associated with better survival are ER+/PR+, Androgen Receptor negative, *her 2 neu negative* and ki67/p53 low group (median: 11.5 years; 95%CI: 6.2–16.8 years) and worst in PR- group (median:4.5 years; 95%CI: 1.6–7.8 years)[30].

Management of Early Disease

Generally follows the same management strategies as in females as no prospective randomized trials have been conducted to establish treatment protocols in men[31]. Trucut biopsies are preferable to ensure enough tissue is obtained for further mandatory immunohistochemistry testing.

Even though several small studies have reported the successful use of sentinel node biopsy in males, randomized studies establishing the sensitivity and specificity of sentinel node biopsy in male breast cancer have not been possible[32]. Breast conservation in males may be a challenge due to difficulties in obtaining negative margins resulting in a high rate of upfront radical mastectomies performed[33]. As pertains in females, a minimum of ten axillary lymph nodes should be dissected to obtain adequate prognostic and therapeutic information[34].

The indications for adjuvant radiation therapy in male breast cancer patients' follows same recommendations as in women, which includes breast conservation, T3/T4 tumors and positive axillary nodes. Following mastectomy, lesions greater than 5 cm with persistently positive surgical margins, lymph node positive disease, lympho-vascular space invasion, peri-

neural invasion should be referred for radiation therapy[35]. Predictors of local regional failure included margin status, tumor size, and the number of involved axillary lymph nodes, lympho-vascular and peri-neural invasion[35].

Adjuvant chemotherapy is recommended in all breast cancer patients who have a substantial risk of recurrence. Whereas the data supporting adjuvant chemotherapy in women are strong, there are few studies with low numbers on the effectiveness of adjuvant chemotherapy in men. A prospective study conducted by the National Cancer Institute (NCI) in USA in which 24 male patients with stage II breast cancer were treated with adjuvant CMF (cyclophosphamide, methotrexate, and fluorouracil) showed a projected 5-year survival rate of more than 80%, significantly higher than a similar cohort of historical controls[36]. Retrospective series have suggested adjuvant chemotherapy lowers the risk for recurrence in male patients[37]. Given the established benefit of chemotherapy in women and the suggestive evidence in men, most clinicians use similar guidelines for adjuvant chemotherapy as in female patients.

Tamoxifen is the recommended choice for positive hormone receptor staining in men[37]. Aromatase inhibitors are considered contraindicated because at least 20% of circulating estrogen in males is independent of aromatase and therefore indicated only in circumstances when tamoxifen is contraindicated or fails to control disease[38].

All patients exhibiting Triple negative and *Her 2* positive disease should receive adjuvant chemotherapy, preferably anthracycline and Taxane based chemotherapy with or without Trastuzumab depending on *Her 2 neu* staining[39].

Management of Locally Advanced Disease

Neoadjuvant chemotherapy should be considered for localized unresectable disease to improve resectability followed by radiotherapy to control local symptoms[40]. For patients with persistently unresectable disease, radiation therapy should be offered. Hormonal therapy has a role in receptors- positive disease most often following chemotherapy. Neoadjuvant hormonal therapy may be an option when there are contraindications to chemotherapy. However more than six months of treatment is required to achieve adequate shrinkage of disease and complete responses are rare with tamoxifen even in females[41].

Maximal tumor reduction with systemic therapies should be achieved prior to surgical intervention and this may require administering several cycles of chemotherapy and switching protocols. Positive surgical margins directly correlate with poor outcome and should be avoided[42].

Management of Recurrent Disease

Poorly managed local recurrence may result in early distant disease. A disease free interval of greater than one year has a better prognosis compared with less than 6 months[43]. All patients should be evaluated for metastatic disease including radiological assessment of the lungs and liver. Bone scans and brain imaging are only indicated when there is high suspicion of disease involvement. Plain X-ray of the involved bone is recommended where bone scintigraphy is unavailable. The latter is preferred because bone scintigraphy completely assesses the skeletal system for evidence of osteoblastic bony involvement.

Second line treatment depends on previous therapies received, response achieved and disease extent. Surgery is an option for resectable lesions and clear surgical margins must be achievable. Patients who did not receive prior radiotherapy should be offered chest wall radiation. Anthracycline chemotherapy is associated with cardiotoxicity and lifetime maximal doses should not be exceeded[44]. The role of hormone and *Her2 neu* therapies are dependent on receptor status obtained for new lesions[45].

Management of Metastatic Male Breast Cancer

The general approach to the treatment of metastatic male breast cancer is similar to that in female breast cancer. Hormonal therapy is often the first approach in men with estrogen and/ or progesterone receptor positive tumors in the absence of a visceral crisis. Tamoxifen has established efficacy in the metastatic setting with an approximate 50% response rate and is currently the preferred first-line approach for receptor positive male breast cancer[36]. Surgical ablative therapies such as orchiectomy, adrenalectomy, hypophysectomy and chemical castration using luteinizing hormone–releasing hormone agonists, with or without antiandrogens are reported to be effective in metastatic male breast cancer following tamoxifen failures[46].

Men with hormone receptor negative, hormone-refractory disease or rapidly progressing visceral metastases should be managed with chemotherapy using the same protocols established for women[47]. The tole of Trastuzumab in managing *Her2-neu* overexpressing metastatic male breast cancer is however currently under debate as response rates are considered suboptimal[39].

Survival Patterns for Male Breast Cancer

Several studies have demonstrated similar survival rates for both sexes with breast cancer after correcting for age, stage, molecular subtyping and other prognostic indicators[48].

Male breast cancer patients are less likely to receive post lumpectomy radiation and adjuvant chemotherapy compared to their female counterparts and these poor management practices could account for poorer outcomes[49]. BRCA2 mutations are associated with significantly lower survival compared to normal males ($p=0.04$)[50]

In a series of 137 male patients, adjuvant chemotherapy was beneficial in node positive disease

(HR =0.78), and significant survival benefit for patients with hormone positive disease treated with hormonal therapy (hazard ratio= 0.45,p=0.02)[51]. Several reports indicate worse prognosis in black compared to white patients with breast cancer specific mortality hazard ratio in black males is at least double compared to white[49]. A small study from Nigeria reports a 5 year overall survival for 57 men following adequate surgery to be less than 25% compared to 47.6 % in a study of survival for female breast cancer patients from Ghana (11,53) . This poor outcome may be attributed to general lack of hormone receptor testing for male breast cancer patients in the sub region. A recent publication from the USA comparing outcomes for black versus white male breast cancer patients revealed a worse outcome in younger black males which became non-significant when corrected for covariates such as income and insurance i.e. access to care[53]. In the latter study, there were no differences observed for males older than 65 years and could be explained by improved access to Medicare facilities above age 65 years.

Conclusion

In spite of the rising incidence, male breast cancer is still considered rare. Many present with advanced disease resulting in poor control in spite of better prognostic features compared to female counterparts. Tumors of the male breast are more likely to express estrogen and progesterone receptors and less likely to overexpress *Her 2 neu* compared to women and therefore receptor staining is pivotal in the management of male breast cancer. A multidisciplinary approach is recommended with decisions based broadly on principles established for female breast cancer. Education of patients, families and health providers will increase awareness of male breast cancer, ensuring early presentation, prompt referral for early diagnosis, treatment and improved survival. Large randomized trials in male breast cancer are encouraged to direct evidence based therapies in Africa as conclusions from small studies may be biased.

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KWASHIORKOR

and

Dr. Cicely Delphine Williams

Cicely Williams

Cicely Williams with severely malnourished child

Children suffering from Kwashiorkor

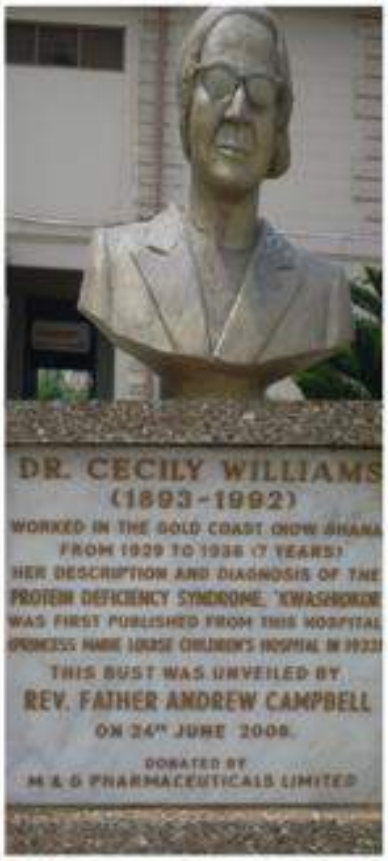
Princess Marie Louis Hospital (PML), where Dr. Williams first described Kwashiorkor

Dr. Cicely Williams was a Jamaican national who worked in the Gold Coast from 1929-1936.

She was the first woman to be appointed in the British Colonial Medical Service to be sent to Gold Coast (now Ghana).

Dr. Williams' most important work in the Gold Coast was her diagnosis of the common and often fatal condition **Kwashiorkor**. She learned that "Kwashiorkor" meant the sickness the older child gets when the next baby is born. This seemed to indicate that, when they were no longer breast-fed, children were not receiving enough to eat. Dr. Cicely Williams discovered that the medical symptom of swollen bellies, diarrhoea, and vomiting was protein-calorie malnutrition. The cure for kwashiorkor was therefore education on children's nutritional needs. She quickly published her diagnosis of kwashiorkor as a protein deficiency disease, which attracted the attention of the medical world.

The first description and diagnoses of the protein deficiency syndrome "Kwashiorkor" was first published from the Princess Marie Louis Children's Hospital.



Due to her efforts in the hospital a sculpture of her was mounted in the hospital in memory of her. (Above)

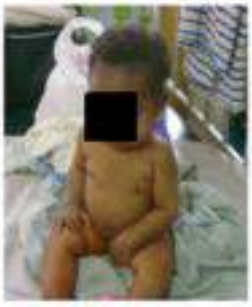
KWASHIORKOR cont'd

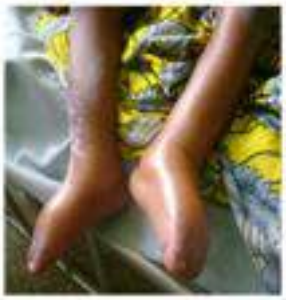
Cure

The cure of Kwashiorkor was therefore education on children's nutritional needs due to Dr. Cicely Williams publication. This led to the establishment of a Nutritional Rehabilitation Center in the hospital.

Below are some pictures of their cases treated and reported to the centre in picture presently.

CHILDREN WITH KWASHIORKOR





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Book
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EVIDENCE-BASED MEDICINE COURSE

DATE: 18th - 20th June 2018

TIME: 9:00am – 5:00 pm each day

VENUE: Ghana College Of Physicians and Surgeons,Accra

REGISTRATION FEE: GHS 300.00 PER PERSON

Rationale

The primary aim of every doctor is to secure the best possible outcome of care to the patient. To achieve this, the clinician needs to find, appraise and apply evidence from existing scientific research to inform their treatment decisions and choices through the practice of Evidence-based Medicine (EBM). Evidence Based Medicine is the conscientious explicit andjudicious use of current best evidence in making decisions about the care of individual patients. The growing application nowadays underscores the need for all health providers to have adequate knowledge in EBM. This course will stimulate interest and passion among Ghanaian doctors and equip them with essential skills that can be utilized to provide evidence driven care to the patient.

Aims

- **To introduce Residents to the value and concept and practice of EBM**
- **To develop skills required to search relevant electronic databases for literature and critically appraise the retrieved articles for validity and relevance**
- **To encourage the application of EBM and the value of systematic review and other forms of evidence synthesis as providing the best possible evidence to inform EBM**

Learning outcomes

By the end of the course, you should be able to:

- **Formulate clear clinical questions from clinical problems**
- **Carry out focused searches using electronic databases to answer clinical questions**
- **Use structured guidelines to apply the relevant principles of critical appraisal to articles relating to treatment, predictions and diagnosis**
- **Apply the evidence obtained from critically appraised articles to practice, recognizing the challenges and practicalities often encountered**

Course Outline

The course will be delivered using problem-based learning approach to introduce Residents to EBM and how their beliefs and experiences can influence decisions and choices they make in the provision of care; how to turn a clinical problem into an answerable question using PICO (P= Patient, I = Intervention, C = Comparison, and O = Outcome) to define the patient in question, the intervention given, the comparison (if any) and the outcomes considered; and a step-by-step guidance on how to practice EBM.

Output

Each participant would be expected to identify a relevant clinical problem, formulate a question using PICO, build a search concept to retrieve relevant articles from relevant databases, screen the search output, select the most relevant article and critically appraise the evidence for validity and usefulness.

Resources Needed

It is advisable for participants to bring a laptop. Resources for further study will be provided.