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Profile of obstetric cardiac patients delivered with an anaesthetic intervention at an academic hospital

Lunganga Toms Lushiku

A research report submitted to the faculty of Health Sciences, University of the Witwatersrand, Johannesburg, in partial fulfilment of the requirements for the degree of Master of Medicine in the branch of Anaesthesiology

Johannesburg, 2018

DECLARATION

I, Lunganga Toms Lushiku, declare that this research report is my own unaided work. It is being submitted for the degree of Master of Medicine in the branch of Anaesthesiology at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other university.

_____

On this day of 2018

ABSTRACT

Background

Pregnant women with cardiac disease present some of the greatest challenges to the anaesthesiologist. Data from South Africa as to the incidence, the type of anaesthetic technique used as well as maternal cardiac and obstetric outcomes of these patients is scanty. Therefore, the aim of this study is to describe the profile of obstetric cardiac patients who delivered with an anaesthetic intervention at Chris Hani Baragwanath Academic Hospital.

Methods

A retrospective audit using consecutive convenience sampling was done by reviewing the labour ward admission books, the cardiac obstetric anaesthetic assessment forms, the intraoperative anaesthetic forms and the labour epidural forms from January 2014 to December 2015.

Results

Two hundred and three (0.49%) patients were identified with underlying cardiac disease and 83 met the criteria for inclusion. Acquired cardiac disease was most prevalent (65%) and rheumatic valvular cardiac disease being the most dominant (41%) lesion. Pulmonary hypertension was present in 19% of patients. Eighteen percent of patients were included in mWHO class 4 where pregnancy is not advised. Neuraxial anaesthesia was used in 57% of deliveries. Intraoperative complications were present in 8 (10%) patients. Two (2%) patients had cardiac complications. There was no maternal death recorded in the first 24 hours post-delivery.

Conclusions

This audit demonstrated that acquired cardiac diseases were more prevalent than congenital and rheumatic valvular disease is still the most common cause of acquired cardiac disease in pregnancy. Neuraxial anaesthesia was the most used anaesthetic technique for delivery in these patients.

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Abbreviations

ACA	American Cardiology Association
AHA	American Heart Association
ASD	Atrio-septal defect
AVSD	Atrio-ventricular septal defect
CARPREG	Cardiac Disease in Pregnancy
CMACE	Centre for Maternal and Child Enquiries
CHBAH	Chris Hani Baragwanath Academic Hospital
ESC	European Society of Cardiology
GA	General anaesthesia
mWHO	Modified World Health Organization
NYHA	New York Heart Association
PAP	Pulmonary Arterial Pressure
PDA	Patent Ductus Arteriosus
TOF	Tetralogy of Fallot
UK	United Kingdom
USA	United States of America
Wits	University of the Witwatersrand
ZAHARA	Zwangerschap bij vrouwen met een Aangeboren HARtAfwijking

SECTION 1: Literature review

1.1 Background

In 1880, James Mackenzie a young Scottish physician witnessed the death of a young pregnant woman with mitral stenosis complicated with pulmonary oedema during labour. This experience motivated Mackenzie to strengthen his knowledge on the pathophysiology of heart disease in pregnancy. He then became the first specialist in clinical haemodynamically based cardiology. In 1921, he published a document titled “Heart Disease and Pregnancy” which was the first ever book addressing cardiac disease in pregnancy (1).

This chapter will provide an overview of maternal mortality and morbidity related to cardiac disease, followed by pregnancy-related physiological changes and their implications on cardiac diseases, furthermore the classification, clinical presentation as well as the management options with an emphasis on anaesthesia, and lastly the different scoring systems used for predicting the severity of cardiac disease in pregnancy will be discussed.

1.2 Maternal mortality and morbidity related to cardiac disease

The World Health Organization (WHO) defines a maternal death as “ the death of a woman while pregnant or within 42 days of termination of the pregnancy, irrespective of the duration and the site of the pregnancy, from any cause related to or aggravated by the pregnancy or its management but not from accidental or incidental causes” (2).

Maternal deaths can be divided into three groups depending on the cause. Firstly, direct obstetric deaths which are caused by the obstetric complications of pregnancy.

Secondly, indirect obstetric deaths as a result of a previously existing disease or a disease that arises during pregnancy, not induced by the direct causes. Lastly, maternal death caused by unanticipated complications of management such as anaesthesia, surgery and medication (2).

The causes of direct obstetric deaths include diseases such as hypertension, obstetric haemorrhage, ectopic pregnancy, miscarriage, pregnancy-related sepsis and embolism. Cardiac disease in pregnancy is one of the leading causes of indirect obstetric deaths. A study conducted in the United States of America in 2015 by Kuriya et al (3) has shown that the most common attributable causes of maternal mortality are sepsis (21.1%), cardiac disease (18.4%), haemorrhage (15.9%), venous thromboembolism (15.9%) and hypertensive disorders (10%) (3). In contrast, the 2014 Sixth Report on Confidential Enquiries into Maternal Deaths in South Africa had revealed the five main causes of maternal deaths to be non-pregnancy related infections (34.7%), obstetric haemorrhage (15.8%), complications of hypertension in pregnancy (14.8%), medical and surgical disorders (11.4%), and pregnancy related sepsis (9.5%). Cardiac disease in pregnancy represent approximately 34.3% of all maternal mortality caused by medical and surgical disorders (4). In 2008 Haththotuva et al (5) reported a maternal mortality rate of 29% due to indirect obstetric causes following a retrospective study on 145 maternal deaths in Sri Lanka.

Cardiac disease in pregnancy increases maternal morbidity. Robertson et al (6) in 2012 reported a rate of cardiac complications of 2% following a retrospective study on 599 Canadian patients with cardiac disease. However, in 2015 Warrick et al (7) showed a higher rate of cardiac complications (11%) in a retrospective study on 110 American pregnant women with congenital cardiac disease. In 2015, Fu and Lin (8) reported a similar rate of cardiac complications (11%) to Warrick et al (7) following a retrospective study on 1086 Chinese pregnant women with cardiac disease.

1.3 Pregnancy-related physiological changes and their implications in cardiac disease

Physiological changes occur to enable the pregnant woman to meet the increased metabolic demands of pregnancy (9). Although these adaptive changes are well tolerated by healthy pregnant women, those with cardiac disease may not cope and decompensate as a result of their disease (10).

The physiological changes include: cardiovascular, haematological, respiratory, neurological, gastrointestinal, endocrine and renal (11, 12). Only cardiovascular and haematological changes will be discussed in detail.

1.3.1 Cardiovascular changes

Major cardiovascular changes occur during the antepartum period, labour, and delivery (13). During the antepartum period, the plasma volume starts increasing at six weeks gestation and reaches 50% above the pre-pregnancy levels in the second trimester (13, 14). At the end of the first trimester, the cardiac output increases by 30 - 50% due to an increase in stroke volume and heart rate. Maternal cardiac output fluctuates in the supine position due to compression of the inferior vena cava by the gravid uterus (13). The caval compression starts as early as 24 - 28 weeks gestation and may cause a significant drop in preload (15).

During labour, the cardiac output increases from 60 to 80% above the pre-labour levels as a result of auto-transfusion and sympathetic activation by pain and anxiety (13). Immediately following the delivery of the foetus, the relief of caval compression from the gravid uterus coupled with the emptying of the uterus results in fluid shift from the extravascular to the intravascular bed causing a subsequent increase in cardiac output

by approximately 60% (11). The increase in cardiac output during the different phases of pregnancy may cause a relative volume overload state. This may result in cardiac failure in patients with a limited myocardial function from ischaemia or valvular disease (16, 17).

Maternal heart rate increases by 15 - 20% in the third trimester compared to the resting heart rate in non-pregnant women (11, 13). This may result in myocardial oxygen supply and demand imbalance in patients with myocardial dysfunction such as cardiomyopathies and ischaemic heart disease (11).

The systemic vascular resistance decreases in the first trimester as a result of the development of a low-resistance utero-placental circulation and a decrease in vascular response to norepinephrine and angiotensin (11, 18). Hence, the reduction in total peripheral vascular resistance and blood pressure (18). The systolic and the diastolic blood pressure drop by 5 - 10 mmHg and 10 - 15 mmHg respectively. The reduction in systemic vascular resistance may benefit pregnant women with cardiac diseases that are dependent on lower systemic vascular resistance such as cardiomyopathies and regurgitant valvular cardiac lesions (16). The systemic vascular resistance increases rapidly in the 24 - 72 hours following delivery and this can result in a rapid rise in afterload. Consequently, congestive cardiac failure can occur in pregnant women with susceptible systemic ventricle (16).

1.3.2 Haematological changes

During pregnancy there is a considerable rise in pro-coagulant factors such as factors VII, VIII, IX, X, and XII. There is also an increase in fibrinogen, fibrinolysis, protein S and activated protein C. All these pro-thrombotic changes, together with the venous stasis and an impaired venous return worsened by a gravid uterus making pregnancy a hypercoagulable state (19). Pregnant women with congenital cardiac defects and those

with mechanical valves or atrial fibrillation are at a high risk of thrombotic complications such as venous thromboembolism, transient ischaemic attack, stroke and mechanical valve thrombosis. Therefore, these patients may need to be commenced on anticoagulation therapy which may limit the options for anaesthetic management as well as increase the risk for postpartum bleeding (19).

1.4 Classification of cardiac disease in pregnancy

Cardiac disease in pregnancy can be broadly classified into two main groups: acquired and congenital (21). Some of these diseases are rare and will not be discussed. A number of congenital diseases such as aortic stenosis, pulmonary stenosis and aortic coarctation have the same clinical presentation as acquired aortic stenosis, pulmonary stenosis and aortic coarctation. Therefore, they will be discussed only under acquired cardiac disease.

1.4.1 Acquired cardiac diseases

Acquired cardiac disease include a spectrum of diseases such as cardiomyopathies, valvular cardiac disease, aortic dissection and myocardial infarction (20). Some of the cardiac diseases classified as acquired may have a congenital aetiology (21).

Cardiomyopathy

According to the American Heart Association (AHA), cardiomyopathies are defined as a " heterogeneous group of diseases of the myocardium associated with a mechanical and/or electrical dysfunction that usually exhibit an inappropriate ventricular hypertrophy or dilatation and due to a variety of causes that frequently are genetic" (19).

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Cardiomyopathies are divided into primary and secondary cardiomyopathy. Primary cardiomyopathies can have different aetiologies: genetic (hypertrophic cardiomyopathy), mixed (dilated cardiomyopathy) or acquired (peripartum cardiomyopathy). Secondary cardiomyopathies are caused by systemic diseases that affect the heart such as amyloidosis, haemochromatosis, diabetes mellitus, rheumatoid arthritis (19).

Peripartum cardiomyopathy

Peripartum cardiomyopathy is “an idiopathic disease of cardiomyocyte characterised by a sudden onset of systolic left heart failure in the last month of pregnancy or within five months of delivery in the absence of a pre-existing cardiac disease” (22).

The incidence of peripartum cardiomyopathy in the United States of America is 1 in 3000 to 1 in 4000 live births (13, 19). A much higher incidence has been reported in South Africa and in Haiti with 1 in 1000 and 1 in 300 live births respectively (13, 18).

The aetiology of the disease is not well known but viral myocarditis and an abnormal immune response to pregnancy are involved in its pathogenesis (17, 23).

Advanced maternal age, multiparity, black race, multifoetal gestation, family history of cardiomyopathy, and hypertensive disorders during pregnancy are the associated risk factors in its pathogenesis (17, 23). In the United States of America, Ford et al (24) found a mean age of 28 (range 16 - 55) years and 65% of patients were nulliparous after a retrospective study in 2008 on 69 pregnant American women with congenital cardiac disease. Fu and Lin (8) conducted a retrospective study in 2015 on 1086 pregnant Chinese women with cardiac disease and found a mean age of 28 (range 16 -

44) years with 78% of patients being primiparous, 23% multiparous and there no nulliparous.

The proposed pathophysiology includes an oxidative stress secondary to a low serum selenium level, viral infection, stress-activated cytokines, inflammation, and auto-immune reaction. The oxidative stress causes a proteolytic cleavage of prolactin to 16 kilo Daltons prolactin fragment which has a vasotoxic, pro-apoptotic, and pro-inflammatory properties. This fragment is responsible for the endothelial dysfunction and the impairment of cardiomyocyte metabolism (23).

Clinically, pregnant women will present with signs and symptoms of cardiac failure such as dyspnoea at rest or on exertion, fatigue, peripheral oedema, cough, orthopnoea and paroxysmal nocturnal dyspnoea (25).

The National Institute of Health diagnostic criteria for peripartum cardiomyopathy include, clinical and echocardiographic criteria. The clinical criteria comprise a sudden onset of a cardiac failure in the last month of pregnancy or within the five months of delivery, in the absence of a known cause of a cardiac failure and with no prior history of cardiac disease. Depressed left ventricle ejection fraction of less than 45%, fractional shortening of less than 30% and an end diastolic dimension of 2.7 cm/m^2 are the echocardiographic diagnostic criteria (16).

Patients with peripartum cardiomyopathy are at a higher risk of cardiac arrhythmias, progressive cardiac failure and thromboembolic events (16). These patients are best managed by a multidisciplinary team including an obstetrician, a cardiologist, a paediatrician, an anaesthetist, and an intensivist (14).

The anaesthetic management principles are to decrease the preload, decrease the afterload and to avoid tachycardia. GA, combined spinal epidural anaesthesia and epidural anaesthesia have been all used. An epidural anaesthesia causes a reduction in both preload and afterload and it is the preferred anaesthetic technique in patients with peripartum cardiomyopathy (21, 22). However, a single-shot spinal anaesthesia is not advised. (22) The 2011 European Society of Cardiology (ESC) guidelines recommend a combined spinal-epidural anaesthesia for Cesarean section delivery (26). In 2007, Pryn et al (27) reported that an incremental combined spinal-epidural provided an effective anaesthesia in patients with peripartum cardiomyopathy.

Dilated cardiomyopathy

Dilated cardiomyopathy is a primary disease of the myocardium characterised by a left ventricular or a biventricular dilatation and systolic dysfunction while the ventricular wall thickness remains normal (19). The myocardial dysfunction is not caused by a coronary, valvular, congenital or systemic disease (14).

The incidence of dilated cardiomyopathy is approximately 36 per 100 000 live births in the United States of America with African-Americans being the most affected (13, 28). It is the third most common cause of cardiac failure and the most common indication for a cardiac transplantation (19). Dilated cardiomyopathy is rare among women of a childbearing age (28).

The aetiology of dilated cardiomyopathy is not known. It has been linked to A-type lamin gene defects which are responsible for a high rate of cardiac failure and life-threatening arrhythmias (14).

The increased intravascular volume observed in pregnancy combined with ventricular dilatation and the inability of cardiac muscle to contract, will increase the risk of complications such as conduction abnormalities (supraventricular and ventricular dysrhythmias), systemic and pulmonary embolisation and sudden death (14, 19).

Clinically, pregnant patients with dilated cardiomyopathy have the same clinical and echocardiographic features as seen in patients with peripartum cardiomyopathy except that the onset is not restricted to the peripartum period (20).

Patients with a known left ventricular dysfunction (ejection fraction of less than 40%) who are planning a pregnancy, should be advised against this while pregnant women with New York Heart Association functional class 3 or 4 symptoms with moderate to severe left ventricular dysfunction in the first or second trimester should be considered for termination of pregnancy (14).

The anaesthetic management principles include: avoiding excessive anaesthesia-induced myocardial depression, maintaining normovolemia and minimising sympathetic stimulation associated with the labour pains and laryngoscopy (19). Graded epidural anaesthesia will cause minimal changes in preload and afterload which can be beneficial in the setting of reduced ventricular function. Furthermore, general anesthesia (GA) may cause haemodynamic instability secondary to systemic anaesthetic administration as well as during laryngoscopy and endotracheal intubation (14).

Hypertrophic cardiomyopathy

Hypertrophic cardiomyopathy is a genetic disorder with an autosomal dominance inheritance. It is characterised by an asymmetric left ventricle hypertrophy and diastolic dysfunction with preservation of contractile function of the left ventricle. The hypertrophy of the left ventricle causes a dynamic obstruction of the left ventricle outflow tract (14, 22). Hypertrophic cardiomyopathy is more common than dilated cardiomyopathy and has a prevalence of 1 in 500 individuals and affects women of all ages (19).

The signs and symptoms of hypertrophic cardiomyopathy are related to myocardial hypertrophy and ischaemia, dynamic left ventricular outflow tract obstruction, systolic anterior movement of the mitral valve, diastolic dysfunction and dysrhythmias (14). These signs and symptoms include dyspnea, fatigue, angina, palpitation and syncope. An ejection systolic murmur can be heard at the apex on cardiac auscultation (22). The diagnosis is confirmed by echocardiography which shows a hypertrophied left ventricle with a wall thickness of more than 15 mm (13, 14, 22).

In general, pregnancy is well tolerated in most asymptomatic patients with hypertrophic cardiomyopathy. The progression of symptoms will depend on the left ventricular outflow tract gradient. The higher the gradient, the more rapidly the symptoms progress and it has been suggested that pregnant women with a gradient of more than 100 mmHg are at a higher risk of haemodynamic deterioration (14).

The anaesthetic management principles of these patients include blunting of the sympathetic surge induced by labour pain and anxiety, maintaining intravascular volume and venous return, maintaining a low-normal heart rate and sinus rhythm and maintaining myocardial contractility (13, 14). Sympathetic stimulation, Valsalva

maneuver, hypovolemia as well as vasodilation should be avoided as they may worsen the left ventricle outflow tract obstruction (22). The use of beta-blockers should continue during labour and delivery (13).

During labour, neuraxial techniques such as epidural and combined spinal-epidural anaesthesia have been used for analgesia. They attenuate the catecholamine surge secondary to the labour pains which may cause an increase in heart rate and cardiac contractility (13).

Regarding Cesarean section, previously GA was considered as the safest option for pregnant women with hypertrophic cardiomyopathy (22). But the use of neuraxial techniques (epidural and combined-spinal epidural) were included in some case reports (27, 29). In 2015, Ashikmina et al (29) reported the use of a single-shot spinal as well as a combined spinal-epidural anaesthesia for Cesarean section in patients with hypertrophic cardiomyopathy. Due to the lack of retrospective studies comparing the use of GA and neuraxial anaesthesia in pregnant women with hypertrophic cardiomyopathy combined with the possibility of bias in the case reports, it is difficult to extrapolate results from the case reports on all patients with hypertrophic cardiomyopathy. Therefore, GA is recommended for all patients with hypertrophic cardiomyopathy who are either in cardiac failure or have a left ventricular outflow tract gradient of 50 mmHg or greater (22). The 2011 ESC guidelines state that the choice of the type of anaesthesia in patient with hypertrophic cardiomyopathy is determined by the severity of the left ventricular outflow tract obstruction (26). A single-shot spinal anaesthesia is relatively contra-indicated. The hypotension can be treated with phenylephrine. However, ephedrine should be avoided as it may increase the dynamic obstruction (22)

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Valvular cardiac disease

Valvular cardiac disease in women of childbearing age can have a congenital and/or an acquired origin. Bicuspid aortic valve disease is the most common congenital cardiac valve. It is often found in men and is a common cause of aortic stenosis in women of childbearing age (30). It has been shown that the majority of valvular cardiac diseases in developing countries are acquired and 90% are secondary to rheumatic fever (16). In the Canadian study by Jastrow et al (31) in 2011, it was found that 4% of patients had rheumatic cardiac disease after a retrospective on 227 patients with cardiac disease. In China, Fu and Lin (8) in 2015 reported an incidence of rheumatic cardiac disease of 15% following a retrospective study on 1086 pregnant women with cardiac disease. Other causes of acquired valvular cardiac disease in pregnancy include infective endocarditis, systemic disease such as systemic lupus erythematous, valve replacement, myxomatous mitral valve disease and inherited genetic syndromes such as Marfan's syndrome (30).

Regarding valvular cardiac disease, the occurrence of stenotic lesions is different to that of regurgitant lesions. In Spain, Pijuan-Domenech et al (32) in 2015 reported more regurgitant (54%) than stenotic (8%) valvular disease in a prospective study of 179 patients with cardiac disease. In South-Africa, Soma-Pillay et al (33) in 2008 found that 28% of patients had regurgitant cardiac disease compared to 21% with stenotic cardiac disease following a retrospective study of 189 patients at Pretoria Academic Hospital.

Pregnant women with valvular cardiac disease have a higher mortality rates than those with congenital cardiac disease. The risks of developing complications in pregnant women with valvular cardiac disease are determined by the specific valve lesion, the number of valves involved and the degree of a valvular obstruction (16). The most affected valves by order of frequency are mitral, aortic, tricuspid and pulmonic valves (34).

Mitral stenosis

Mitral stenosis is the most common valvular lesion in pregnancy (21) and rheumatic cardiac disease is the most common cause (22). In 2011 Lung (34) demonstrated that more than 90% of pregnant women with cardiac disease admitted in a University Hospital in Senegal presented with rheumatic cardiac disease. Rheumatic mitral stenosis accounted for more than 60% of all cases (34).

The normal mitral valve orifice area is 4 - 6 cm^2. A reduction in the size of the mitral orifice area will impede blood flow across the mitral valve resulting in pressure and volume overload in the left atrium (19). The high left atrial pressure, coupled with an increased blood volume that occurs during pregnancy, will result in pulmonary congestion with subsequent pulmonary oedema. Other maternal complications include atrial arrhythmias (atrial fibrillation, atrial flutter) and thromboembolic events (transient ischaemic attack, stroke) (30).

The incidence of maternal cardiac complications during pregnancy correlates directly to the severity of mitral stenosis. The smaller the valve area is, the higher the rate of maternal cardiac complications (1). Symptoms such as progressive dyspnoea on exertion, fatigue and oedema appear when the size of the mitral valve area is less than 1.5 cm^2 (1, 19).

The diagnosis is confirmed on echocardiography by measuring the mitral valve area and the transvalvular pressure gradient (19). Patients with a mitral valve area of less than 1.1 cm^2 and/or with a significant pulmonary hypertension who are not pregnant should be advised to avoid pregnancy and those who are already pregnant should have a prophylactic percutaneous mitral balloon valvotomy or an open commissurotomy (1).

The anaesthetic management principles are to maintain a sinus rhythm, maintain a low-normal heart rate, prevent the supine hypotension syndrome, maintain an adequate systemic vascular resistance, prevent and treat events that can cause a reduction in cardiac output such as tachycardia, drug-induced systemic vasodilatation or factors that may increase the pulmonary vascular resistance such as hypoxemia, hypercarbia, acidosis, pain and lung hyperinflation (1, 19, 22). Invasive haemodynamic monitoring is often required in the peripartum management of these patients due to the fact that they are at a high risk of cardiac complications (22).

An epidural for labour analgesia is acceptable and helps in controlling the tachycardia caused by the labour pains and anxiety (1). The delivery by Cesarean section can be achieved with neuraxial techniques (graded epidural or combined spinal-epidural anaesthesia) or GA. The anaesthesia-induced hypotension should be managed with phenylephrine (22).

Mitral regurgitation

Mitral regurgitation is commonly caused by mitral valve prolapse, rheumatic cardiac disease, infective endocarditis or functional mitral valve regurgitation secondary to the dilatation of the left ventricle (30).

The failure of complete closure of the mitral valve during ventricular systole causes a reduction in left ventricular stroke volume with a fraction flowing back into the left atrium during each cardiac contraction. This results in left atrial volume overload and pulmonary congestion (19).

Mitral regurgitation is generally well tolerated during pregnancy due to the bigger fraction of the left ventricle forward stroke volume compared to the regurgitant fraction secondary to the pregnancy-induced systemic vasodilatation (1).

The anaesthetic management goals of mitral regurgitation are to maintain a sinus rhythm, maintain a high-normal heart rate, prevent an increase in systemic vascular resistance to allow the forward flow, maintain the preload and minimise the regurgitant fraction as well as drug-induced myocardial depression (1, 21, 22). An epidural for analgesia and anaesthesia will cause a drop in a systemic vascular resistance favoring a left ventricular forward stroke volume (19, 21). An epidural should be commenced during early labour (22). Both neuraxial and GA have been safely used for Cesarean section delivery in patients with mitral regurgitation (22).

Aortic stenosis

A bicuspid congenital aortic valves is the most common cause of aortic stenosis. Rheumatic cardiac disease has also been implicated particularly if many valves are involved (21). Aortic stenosis can also be associated with the dilatation of the ascending aorta, a coarctation of the aorta or both (30).

The normal aortic valve area varies between 2.5 - 3.5 cm^2. A reduction in aortic valve area will cause a left ventricular outflow obstruction requiring a high left ventricular pressure to maintain the cardiac output. This will cause a left ventricle hypertrophy and subsequent left ventricle dysfunction (1, 19).

Pregnant women with mild disease (valve area of more than 1.5 cm^2, peak gradient of less than 50mmHg) are usually asymptomatic and tolerate the pregnancy well, whereas those with severe disease (valve area of less than 1cm^2, peak gradient of more than 75mmHg or an ejection fraction of less than 55%) are at higher risk of cardiac

complications and may need a catheter balloon dilatation or surgical valve replacement before pregnancy (22, 30).

The anaesthetic management goals of aortic stenosis are to maintain normal a sinus rhythm and a low-normal heart rate, maintain adequate systemic vascular resistance and preload as well avoiding myocardial depression (19, 21, 22). Neuraxial anaesthesia should be used cautiously while avoiding hypotension (21). GA may be the safer option especially in patients with severe aortic stenosis (19, 22).

Aortic regurgitation

Aortic regurgitation is most commonly caused by bicuspid aortic valves, infective endocarditis, rheumatic fever and the use of appetite suppressant drugs (1, 19). Other rare causes of aortic regurgitation during pregnancy include the dilatation of the aortic root secondary to Marfan syndrome and the dissection of the ascending aorta (22).

A failure of complete closure of aortic leaflet results in a decrease in cardiac output due to the regurgitation of a part of the left ventricle stroke volume from the aorta back into the left ventricle. As a result, there is a left ventricle volume and pressure overload with subsequent left ventricle dysfunction (19).

An aortic regurgitation is usually well tolerated during pregnancy (21). However, chronic aortic regurgitation may result in the left ventricle dysfunction with subsequent pulmonary oedema and arrhythmias during pregnancy (30).

The anaesthetic management goals of aortic regurgitation are to maintain normal sinus rhythm, maintain a high-normal heart rate, avoid increased systemic vascular

resistance, maintain adequate preload and avoid myocardial depression (19, 21, 22). Both neuraxial and GA techniques can be used in patients with aortic regurgitation (22).

Pulmonary and tricuspid stenosis

Pulmonary stenosis and tricuspid stenosis are usually congenital and are well tolerated during pregnancy (16, 35).

Pulmonary regurgitation

Pulmonary regurgitation is commonly found in women with a congenital pulmonary stenosis who have been previously treated with a valvotomy or those with a previously repaired tetralogy of Fallot (30).

Acute myocardial infarction

Pregnancy increases the risk of acute myocardial infarction by three to four times compared to non-pregnant women of a childbearing age (35, 36). The reported incidence of myocardial infarction during pregnancy varies between 1 to 10 per 100 000 deliveries (20, 35). Factors such as advanced maternal age, maternal obesity, type 2 diabetes mellitus, smoking and hypertension play a role in increasing the incidence during pregnancy (35). The majority of myocardial infarction occurs in the antepartum or postpartum period (21, 35).

The most common causes of acute myocardial infarction during pregnancy include atherosclerosis, coronary artery dissection, coronary thrombus, aneurysm and spasm (21, 35, 36). The diagnosis is made on the basis of symptoms, raised cardiac enzymes

particularly troponin I, and electrocardiographic changes (21, 35). Maternal complications include cardiac failure, arrhythmias and cardiac arrest (35).

The anaesthetic management goals of myocardial infarction include optimisation of myocardial oxygen supply and a reduction of myocardial oxygen demand (19). Epidural proves to reduce the afterload and to minimise pain and tachycardia, and is recommended for this group of patients (22).

Prosthetic cardiac valves

Two types of prosthetic cardiac valves are available: mechanical and bio prosthetic valves (37).

Mechanical cardiac valves

Pregnancy is associated with hypercoagubility which increases the risk of thromboembolic events (38). Therefore, anticoagulation is required in all pregnant women with mechanical valves to decrease the incidence of valve thrombosis and thromboembolic complications (1, 30). Factors that increase thromboembolic risks include, history of prior thromboembolic events, atrial fibrillation, prosthesis in mitral position and multiple prosthetic valves (1).

The ACC/AHA guidelines suggest that warfarin, unfractionated heparin or lower molecular weight heparin be used in pregnant women with mechanical valves (30). Low-dose aspirin combined with an anticoagulant is recommended in women with prosthetic valves at higher risk of thromboembolic complications (1). Maternal thromboembolic complications are lower with the use of warfarin than unfractionated heparin (1).

Bio-prosthetic valves

Bio-prosthetic valves are less thrombogenic than the mechanical valves and anticoagulation is not required (30). However, these valves deteriorate over time especially in women of a childbearing age (1, 30).

1.4.2 Congenital cardiac disease

Congenital cardiac disease includes any structural defect of the heart and/or major thoracic blood vessel present at birth (39).

The prevalence of congenital cardiac disease is high among pregnant women from developed countries compared to those in the developing countries. Data from a prospective study done by Siu et al (23) in 2001 on 562 consecutive pregnancies from Canadian women with cardiac disease had found that congenital cardiac disease was present in 445 (74%) pregnancies and acquired cardiac was present in 127 (22%) pregnancies. In 2009 Curtis et al (40) conducted a retrospective study on 155 British women with cardiac disease and found that 77% had congenital cardiac disease. In 2015, Arora et al (41) found that 16% of patients had congenital cardiac disease and 84% had acquired in a prospective study on 174 Indian pregnant women with cardiac disease.

Congenital cardiac disease in pregnancy can be functionally classified into those causing left-to-right shunts (acyanotic congenital cardiac disease) and those resulting in right-to-left shunts (cyanotic congenital cardiac disease) (42). Studies from both developed and developing countries have noted that shunt-types congenital cardiac diseases were more predominant. Warrick et al (7) in 2015 conducted a retrospective cohort study of American parturient with congenital cardiac disease who delivered at the

University of Colorado Hospital and found that 40% of patients had shunt-type cardiac lesion. In 2016, Fu and Lin (43) conducted a retrospective study with the aim to predict the accuracy of three clinical assessment systems for cardiac complications among 730 Chinese pregnant women with congenital cardiac disease and found that 76% of patients had shunt-type cardiac lesions.

It is important when assessing these patients to know the anatomy of the lesion, the presence and the direction of a shunt, previous surgical intervention (incomplete or full repair), and the impact that changes caused by the pregnancy have on that particular congenital cardiac disease (20, 22).

Acyanotic congenital cardiac disease

This group includes cardiac diseases that produce some degree of left to right intra or extra cardiac shunt such as atrial septal defects (ASD), ventricular septal defects (VSD), atrio-ventricular septal defects (AVSD) and patent ductus arteriosus (PDA) (42).

In general, pregnancy is well tolerated in patients with left to right shunt in the absence of pulmonary hypertension (22). Intra or extra cardiac shunting of blood through these defects can result in a pulmonary circulation overload and subsequent pulmonary hypertension (21). The direction of the shunt can change from left-to-right to right-to-left as the pulmonary vascular resistance increases as seen in Eisenmenger syndrome (21, 22).

Atrial septal defect

ASD is one of the most common congenital cardiac defects seen in women of a childbearing age and usually results in a left to right shunt (21). Often the defect is repaired during childhood.

Patients with a repaired ASD tolerate pregnancy very well in the absence of pulmonary hypertension (22). However, patients with an unrepaired ASD are at increased risk of pulmonary hypertension due to an increase in pulmonary blood flow (22, 44). Consequently, there is an increased risk of atrial arrhythmias as well as the risk of paradoxical embolism during pregnancy. Therefore, air-bubbles should be avoided in all intravenous fluids (44).

Ventricular septal defect

VSD is a defect communicating the left to the right ventricle. Depending on the size of the defect, the VSD can be small and restrictive (less than 0.5 cm diameter), allowing minimal flow of blood across the defect. Patients with this type of VSD carry a lower risk for paradoxical embolism and Eisenmenger syndrome if not repaired (16, 21). Larger and unrestricted VSD (diameter more than 1 cm) can result in pulmonary hypertension and Eisenmenger syndrome (16, 21).

In general, pregnancy is well tolerated in patients with small defects and in those with uncomplicated repaired VSDs (16, 21, 22, 44). Pregnancy is not recommended in women with unrepaired VSDs complicated with Eisenmenger syndrome due to the high maternal cardiac morbidity and mortality (16, 22).

Patent ductus arteriosus

The majority of PDAs are repaired during childhood. Pregnant patients with unrepaired PDA are very rare (21).

Pregnancy is well tolerated in women with a repaired or a small PDA. However, larger defects may result in pulmonary hypertension and Eisenmenger syndrome. In this case, pregnancy is not recommended (16, 21, 22).

Anaesthetic management of patients with acyanotic cardiac disease

The anaesthetic management principles for vaginal delivery or Cesarean section of patients with uncomplicated acyanotic cardiac disease include the avoidance of intravenous infusions containing air bubbles. The use loss-of-resistance to saline technique is therefore recommended instead of air when identifying the epidural space (22).

The haemodynamic goals are to maintain or decrease the afterload while avoiding a sharp drop in pulmonary vascular resistance which may result in pulmonary circulation overload with subsequent pulmonary hypertension. Graded epidural anaesthesia will prevent a rapid decrease in systemic vascular resistance and can be used for labour analgesia as well as for Cesarean section delivery. Both general and neuraxial anaesthesia have been used for Cesarean section (22). Adequate measures are needed during GA to blunt the sympathetic surge to endotracheal intubation and surgical stimulation which can result in an increase in systemic vascular resistance (42).

Cyanotic congenital cardiac disease

Cyanotic congenital cardiac diseases are associated with significant maternal and foetal complications. There is an increased rate of adverse maternal cardiac events, maternal mortality, premature delivery, intrauterine growth retardation and foetal mortality (16). The cyanosis worsens during pregnancy due to a decrease in peripheral vascular resistance resulting in an increase in the fraction of blood shunted from the right to the left side of the heart (35). Polycythemia induced by hypoxemia coupled with the hypercoagulability associated with pregnancy increases the risk of thromboembolic complications (35).

Tetralogy of Fallot

TOF is a congenital cardiac abnormality which consists of a non-restrictive VSD, an overriding aorta, a right ventricular outflow tract obstruction and a right ventricular hypertrophy (16, 21, 44).

The majority of children born with a TOF have had corrective or palliative surgery before childbearing age (22). Post-repair residual defects are common and include pulmonary valve insufficiency and a ventricular septal defect which can result in right ventricular hypertrophy and dysfunction (16, 21, 22).

Women with a complete TOF repair without residual defects usually tolerate pregnancy well compared to those with an unrepaired or a partially repaired TOF (16). Therefore, a pre-anaesthetic evaluation is paramount and should rule out any pulmonary hypertension, right ventricular dysfunction and arrhythmias (22).

The anaesthetic management of patients with complete and successfully repaired TOF is not very different to patients without TOF. The anaesthetic goals for patients with

unrepaired TOF as well as those with residual defects aim in preventing a decrease in afterload to avoid worsening of the right-to-left shunt. Maintenance of an adequate preload to the right ventricle to relieve the dynamic right ventricle outflow tract obstruction is crucial. The heart chronotropy and inotropy should be reduced to minimise the right ventricle outflow tract muscular infundibular spasm. Graded epidural is advisable for labour analgesia to attenuate pain-induced catecholamines release and can also be used for a Cesarean section (22).

Coarctation of the aorta

Coarctation of the aorta is a congenital aortopathy which consists of a narrowing of the proximal descending aorta (16). Often located distal to the left subclavian artery and may result in proximal hypertension and distal hypoperfusion (16, 21). Other congenital abnormalities such as bicuspid aortic valve, intracranial aneurysm, subaortic membranes, ventricular septal defect, arch hypoplasia and aberrant subclavian arteries are often associated with aortic coarctation (16, 21, 22).

Pregnant women with an unrepaired coarctation of the aorta can present with severe upper body hypertension, the treatment of which can result in foetal loss due to uterine hypoperfusion. They are also at a high risk of aortic dilatation, aneurysm and rupture (16, 44).

Graded epidural and combined-spinal epidural anaesthesia have been safely used in patients with aortic coarctation for labour analgesia as well as for Cesarean section. Due to the potential of sudden cardiovascular changes, a single-shot spinal anaesthesia may not be a good anaesthetic choice in patients with aortic coarctation. GA can also be used, provided that the sympathetic surge caused by an endotracheal intubation and the surgical stimulation can be adequately minimised (22).

Pulmonary hypertension and Eisenmenger syndrome

Pulmonary hypertension is present when the mean pulmonary arterial pressure is equal to or more than 25 mmHg at rest (22, 28). Pulmonary hypertension can be classified into five groups: pulmonary arterial hypertension which can be idiopathic, heritable, drug-induced, pulmonary hypertension due to connective tissue diseases or congenital cardiac diseases, pulmonary hypertension due to left cardiac disease, lung disease, thromboembolic disease and lastly pulmonary hypertension of unknown origin (19, 22, 28).

Congenital cardiac diseases with a left-to-right shunt results in volume overload of pulmonary circulation which will cause an increase in the pulmonary vascular resistance and pulmonary hypertension. These structural changes in pulmonary vasculature will result in a progressive rise in pulmonary vascular resistance causing a reversal of shunt from left-to-right to right-to-left. This phenomenon is called Eisenmenger syndrome (16, 22, 28).

The incidence of pulmonary hypertension in pregnant women with cardiac disease is not well known (45). A prospective multicenter study conducted in 2001 in Canada by Siu et al (23) described an incidence of 4% of 562 pregnant women with cardiac disease. A retrospective study conducted by Liu et al (46) in 2013 on 529 Chinese pregnant women with congenital cardiac disease found that 14 (3%)patients had pulmonary hypertension.

Regardless of the aetiology, pulmonary hypertension in pregnant women carries a higher mortality rate, estimated to be around 17% to 33% (22,28). Therefore, women diagnosed with pulmonary hypertension should be counselled against pregnancy and those who are already pregnant termination of pregnancy should be proposed.

Pregnant women who desire to continue with the pregnancy should be managed by a multidisciplinary team in an appropriate centre (22, 28).

Diuretics are used to correct the volume overload and right ventricle failure can be treated with dobutamine infusion (28). The specific treatment for pulmonary hypertension includes inhaled nitric oxide, prostacyclins and phosphodiesterase type-5 inhibitors. Endothelin receptor inhibitors have proved to be teratogenic in animals and are therefore, contraindicated in pregnant women with pulmonary hypertension (22, 28).

The anaesthetic principles in the management of patients with pulmonary hypertension include the maintenance of sinus rhythm, maintenance of preload, maintenance of adequate systemic vascular resistance, prevent an increased pulmonary vascular resistance (avoid pain, hypoxaemia, hypercarbia and acidosis), avoidance of aortocaval compression and myocardial depression (22).

Graded epidural needs to be inserted early during labour to prevent catecholamines surge from pain. The balance between the systemic and pulmonary vascular resistance should be maintained to avoid the reversal of the shunt. Any drop in systemic vascular resistance (hypotension) needs to be treated aggressively with phenylephrine. Graded epidural or combined spinal-epidural can also be used for Cesarean section and are the preferred anaesthetic techniques as they avoid myocardial depression associated with the induction of anaesthesia and the negative effects on pulmonary vasculature of positive pressure ventilation associated with GA. A single-shot spinal anaesthesia is contra-indicated (22).

When GA is used for Cesarean section, the patient should be invasively monitored before the induction of anaesthesia. The induction of anaesthesia should be titrated slowly to minimise drop in systemic vascular resistance. Ketamine and etomidate are

the preferred induction agents. However, propofol and thiopentone can also be used with caution. Nitrous oxide should be avoided as it increases the pulmonary vascular resistance (22). Due to the high maternal mortality rate, postoperative or post-delivery care should be provided in a high dependence care unit (22).

Transposition of great arteries

Transposition of great arteries is a congenital condition in which the aorta and the pulmonary artery originate from the right ventricle and the left ventricle respectively (16, 22, 44). There are two types of transposition of the great arteries: complete transposition also called d-transposition which manifests as a cyanotic congenital cardiac disease; and the congenital corrected transposition (L-transposition) which is rare (16, 44). The common characteristic of the two types is that the aorta emerges from the right ventricle and the right ventricle pumps blood into the systemic circulation (44).

The d-transposition of the great arteries is usually repaired by an arterial switch operation (Mustard or Rastelli procedure) in early infancy (16, 22, 28, 44). Pregnant women who are post d-transposition repair are at an increased risk of atrial arrhythmias, systemic right ventricle dysfunction, systemic tricuspid valve regurgitation, atrial obstruction or leaks, pulmonary hypertension, and preterm labour (16, 22). Pregnancy is well tolerated in women with L-transposition (22).

Neuraxial anaesthesia and GA have both been used in patients with a repaired d-transposition and a congenitally corrected transposition of great arteries (22).

1.5 Severity scoring system

A number of risk stratification systems have been used to assist clinicians to deal effectively with risk stratification of pregnant women with cardiac disease (16, 17, 44, 47). Most of the models available for the risk assessment of pregnant with cardiac disease are based on multiple case series and limited prospective studies (17). The most commonly used risk scores in pregnant patients with cardiac disease are the New York Heart Association (NYHA) functional classification of cardiac failure, modified World Health Organization (mWHO) classification system, Zwangerschap bij Aangeboren Hartafwijking (ZAHARA) score and Cardiac Diseases in Pregnancy (CARPREG) score (14, 16, 17, 21, 44, 47). Although not specific to pregnant women with cardiac disease, the New York Heart Association (NYHA) functional status is the most commonly used in various studies to risk classify and predict cardiac complications in pregnant cardiac patients (23, 31, 48, 49). The NYHA classification was not used in this study due to the fact that patients' NYHA classes were not consistently recorded in their files. Instead, the modified WHO scoring system was used in this study as patients can be classified retrospectively based on their cardiac disease. Only the mWHO risk classification system will be discussed briefly as this is used in this study.

1.5.1 Modified WHO risk classification system

This scoring system allows the triage of specific cardiac lesions into general risk categories and it is based on cardiac pathology and co-morbidity (17, 47). The main disadvantage of this system is the overlap of lesions depending on their severity (17).

Pregnant women with cardiac disease are classified into five groups as shown in the table below.

Table 1: Modified WHO risk classification

mWHO class	Risk	Lesion
1	Risk not relatively higher than the general population	• Uncomplicated small VSD • Mild pulmonary stenosis • Small PDA or mitral valve prolapse with mild mitral regurgitation • Successfully repaired simple lesions (secundum ASD, VSD, PDA and anomalous pulmonary venous connection)
2	Small increase risk of maternal mortality or moderate increase in morbidity	• Unrepaired ASD or VSD • Repaired TOF
2 - 3	Depending on the individual	• Mild systemic ventricular impairment (ejection fraction less than 55%) • Native or tissue valvular cardiac disease not considered in mWHO class 1 or 4 • Marfan syndrome without aortic dilatation (aortic size less than 40 mm) • Aorta less than 45 mm in association with bicuspid aortic valve disease • Repaired coarctation of the aorta
3	significantly increased risk of maternal morbidity and mortality compared with the general population	• Mechanical valve replacement • Systemic right ventricle • Fontan circulation • Unrepaired cyanotic cardiac disease • Other complex congenital cardiac disease • Aortic dilatation 40 - 45 mm in Marfan syndrome • Aortic dilatation 45 - 50 mm in bicuspid aortic valve disease
4	Extremely high risk of maternal morbidity and mortality Patients should be counseled against pregnancy	• Pulmonary arterial hypertension from any cause • Severe systemic ventricular dysfunction from any cause (ejection fraction less than 30%, New York Heart Association class 3 - 4 symptoms) • Severe mitral stenosis • Severe symptomatic aortic stenosis • Marfan syndrome with dilated aorta more than 45 mm • Bicuspid aortic valve disease with dilated aorta more than 50 mm • Native severe coarctation of the aorta.

(Adapted with permission from Dr Jonathan N. Ginns et al.) (17).

Studies from both developed and developing countries have suggested that the mWHO risk classification system gives better prediction of cardiac complications in pregnant women with cardiac disease. In 2015 Pijuan-Domenech et al (32) concluded that the mWHO risk classification provided better prediction of maternal cardiac complications than CARPREG after a prospective study on 179 Spanish pregnant women with cardiac disease. Cauldwell et al (50) in 2017, found that the majority of maternal adverse events were observed in patients who belonged to mWHO class 3 and 4 following a retrospective study conducted in 2017 on 76 cardiac pregnant women in the United Kingdom. A retrospective study conducted by Fu and Lin (43) in 2016 on 730 Chinese pregnant women with congenital cardiac disease 38% of patients classified as mWHO 3 and 15% of patients classified as mWHO 4 had cardiac complications. In South Africa, Sliwa et al (51) found a 100% maternal mortality rate in patients who belonged to mWHO class 3 and 4 following a prospective study on 152 South African women with cardiac disease in 2014.

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SECTION 2: Journal guidelines to authors

This section highlights the guidelines that the author has followed with regards to the length and formatting of the research article. The guidelines followed in creating the draft article were those of the Southern African Journal of Anaesthesia and Analgesia, which is the intended journal of publication.

Southern African Journal of Anaesthesia and Analgesia guidelines to authors

Article sections and length

The following contributions are accepted (word counts exclude abstracts, tables and references)

Original research (2800 – 3200 words/ 4-5 pages)

FULL AUTHOR GUIDELINES

Title page

All articles must have a title page with the following information and in this particular order: title of the article; surname, initials, qualifications and affiliation of each author; the name, postal address, e-mail address and telephonic contact details of the corresponding author and at least 5 keywords.

Abstract

All articles should include an abstract. The structured abstract for an Original Research article should be between 200 and 230 words and should consist of four paragraphs labeled: Background, Methods, Results, and Conclusions. It should briefly describe the problem or issue being addressed in the study, how the study was performed, the major results, and what the authors conclude from these results. The abstracts for other types of articles should be no longer than 230 words and need not follow the structured abstract format.

Keywords

All articles should include keywords. Up to five words or short phrases should be used. Use terms from the Medical Subject Headings (MeSH) of Index Medicus when available and appropriate. Key words are used to index the article and may be published with the abstract.

Acknowledgements

In a separate section, acknowledge any financial support received or possible conflict of interest. This section may also be used to acknowledge substantial contributions to the research or preparation of the manuscript made by persons other than the authors.

References

Cite references in numerical order in the text, in superscript format (Format> Font> Click

superscript). Please do not use brackets or do not use the footnote function of MS Word.

In the References section, references must be typed double-spaced and numbered consecutively in the order in which they are cited, not alphabetically.

The style for references should follow the format set forth in the Uniform Requirements for Manuscripts Submitted to Biomedical Journals (http://www.icmje.org) prepared by the International Committee of Medical Journal Editors.

Abbreviations for journal titles should follow Index Medicus format. Authors are responsible for the accuracy of all references. Personal communications and unpublished data should not be referenced. If essential, such material should be incorporated in the appropriate place in the text.

List all authors when there are six or fewer; when there are seven or more, list the first three, then "; et al."; When citing URLs to web documents, place in the reference list, and use the following format: Authors of document (if available). Title of document (if available).URL (Accessed [date]).

The following are sample references:

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More sample references can be found at:
http://www.nlm.nih.gov/bsd/uniform_requirements.html"

Tables

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For footnotes use the following symbols, in sequence: *, †, ‡, §, ||, **, ††, ‡‡

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10. All numbers below ten, without percentages or units, must be written in

words.

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SECTION 3: Draft article

This section presents the draft article in the format according to the authors' guidelines. The format of the draft article is presented according to the Southern African Journal of Anaesthesia and Analgesia, which is the intended journal of publication.

Profile of obstetric cardiac patients delivered with an anaesthetic intervention at an academic hospital

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Keywords: Survey, obstetric cardiac patients, anaesthetic intervention

ABSTRACT

Background

Pregnant women with cardiac disease present some of the greatest challenges to the anaesthesiologist. Data from South Africa as to the incidence, the type of anaesthetic technique used as well as maternal cardiac and obstetric outcomes of these patients is scanty. Therefore, the aim of this study is to describe the profile of obstetric cardiac patients who delivered with an anaesthetic intervention at Chris Hani Baragwanath Academic Hospital.

Methods

A retrospective audit using consecutive convenience sampling was done by reviewing the labour ward admission books, the cardiac obstetric anaesthetic assessment forms, the intraoperative anaesthetic forms and the labour epidural forms from January 2014 to December 2015.

Results

Two hundred and three (0.49%) patients were identified with underlying cardiac disease and 83 met the criteria for inclusion. Acquired cardiac disease was most prevalent (65%) and rheumatic valvular cardiac disease being the most dominant (41%) lesion. Pulmonary hypertension was present in 19% of patients. Eighteen percent of patients were included in mWHO class 4 where pregnancy is not advised. Neuraxial anaesthesia was used in 57% of deliveries. Intraoperative complications were present in 8 (10%) patients. Two (2%) patients had cardiac complications. There was no maternal death recorded in the first 24 hours post-delivery.

Conclusions

This audit demonstrated that acquired cardiac diseases were more prevalent than congenital and rheumatic valvular disease is still the most common cause of acquired cardiac diseases in pregnancy. Neuraxial anaesthesia was the most used anaesthetic technique for delivery in these patients.

Introduction

The progress made in medical and surgical management of patients with congenital cardiac disease has resulted in more women with cardiac disease surviving to the childbearing age. [1-3] This has resulted in a rise in pregnant patients with cardiac disease requiring anaesthetic services.

Pregnant women undergo anatomical and physiological changes necessary for coping with the increased metabolic demands of pregnancy. [4] Whilst these adaptive changes are well tolerated by healthy pregnant women, those with cardiac disease can decompensate resulting in significant morbidity and mortality. [5]

The World Health Organization (WHO) defines a maternal death as "the death of a woman while pregnant or within 42 days of termination of pregnancy, irrespective of the duration and the site of pregnancy, from any cause related to or aggravated by the pregnancy or its management but not from accidental or incidental causes." Maternal mortality can have a direct or indirect cause or both. Direct obstetric deaths are those resulting from obstetric complications of pregnancy while the indirect obstetric deaths are those resulting from previously existing disease such as cardiac disease. [6]

Although the maternal mortality rate is decreasing in the United Kingdom, according to the 2011 report from the Centre for Maternal and Child Enquiries, the deaths that do occur are increasingly related to indirect obstetric causes. The second most common indirect obstetric cause of mortality in this report was cardiac disease. [7] In the United States of America, there were 1 102 maternal deaths among 7 785 583 births between 2003 and 2011 and the overall maternal mortality was estimated to be 1.42 per 10 000 pregnancies. Maternal mortality due to cardiac disease represent 18.4% of all maternal deaths. [8]

In South Africa, the report released by the Confidential Enquiries into Maternal Death in 2014 [9] revealed a fall in the institutional maternal mortality ratio from 176.22 per 100 000 live births between 2008 to 2010 to 154.06 per 100

000 live births between 2011 to 2013. The indirect causes of maternal death represent approximately 44% of the overall maternal mortality, of which 34.3% are related to cardiac disease. [9]

Due to the complexity of their cardiac lesion, coupled with the significant increase in morbidity and mortality, pregnant patients with cardiac disease need to be managed by a multidisciplinary team including the obstetrician, the cardiologist, the anaesthetist and the intensivist. [10, 11] The anaesthetists are in an ideal position to coordinate the multidisciplinary team due to their background in critical care combined with the knowledge of perioperative medicine. [11] Therefore, it is essential for the anaesthetist to know the profile of the pregnant patients with cardiac disease. The data from South Africa on pregnant cardiac patients is limited.

The profile and the anaesthetic management of obstetric patients with cardiac disease presenting at Chris Hani Baragwanath Academic Hospital (CHBAH) was not known. Therefore, a study with the aim to describe the profile of obstetric cardiac patients who had delivered with an anaesthetic intervention at CHBAH was undertaken.

Methodology

Approval to conduct the study was obtained from the Human Research Ethics Committee (Medical) of the University of the Witwatersrand and other relevant authorities. A retrospective, contextual, descriptive research design was used in this study.

The study population was the records of the obstetric cardiac patients who delivered with an anaesthetic intervention at CHBAH. The records, all paper based, included the labour ward admission book, the cardiac obstetric anaesthetic assessment form, the intraoperative anaesthetic form and the labour epidural form.

The sample size was determined by the number of obstetric cardiac patients who delivered with an anaesthetic intervention at CHBAH during the period 1 January 2014 to 31 December 2015. Consecutive, convenience sampling was used.

All data were collected by one author (LTL). The labour ward admission book was used to determine the number of deliveries over the duration of the study. The number and identifying information of obstetric cardiac patients was obtained from the obstetric cardiac clinic records. The number of obstetric patients who required an epidural for vaginal deliveries was determined from the Department of Anaesthesiology epidural record file. The number of obstetric cardiac patients who had Cesarean sections was determined from the intraoperative anaesthetic forms.

The following data were collected: demographics, cardiac pathology, classification according to the modified WHO (mWHO) risk stratification for pregnant women with cardiac disease, echocardiographic parameters, type of anaesthetic management, maternal intraoperative complications, discharge destination from theatre and 24-hour patient outcome.

Patients' data were entered directly onto a Microsoft Excel® spreadsheet by one author (LTL). The data were analysed using descriptive statistics. Categorical data were summarised using frequencies and percentages. Means and standard deviations were utilised for continuous variables as they were normally distributed. All percentages were rounded off to whole numbers and therefore, may not exactly add up to 100%.

Results

A total number of 41 294 deliveries were conducted at CHBAH during the two years of the study; 21 060 deliveries in 2014 and 20 234 deliveries in 2015. Of these patients, 203 (0.49%) were identified with an underlying cardiac disease. Records of 117 (58%) patients were available. Of the 117 patients, 83 (71%) delivered with an anaesthetic technique; either general anaesthesia and/or neuraxial anaesthesia.

The mean (SD) age of the patients was 30 (6) years, with the range of 18 to 44 years. The age and parity are shown in Table I. There was no pregnancy recorded in patients aged less than 18 years.

Table I: Demographics

Demographics	Number	Percentage
Age		
• 18 – 35 years	68	82
• More than 35 years	15	18
Parity		
• Nulliparous	20	24
• Primiparous	27	33
• Multiparous	28	34
• Missing data	8	10

Of the 83 pregnant cardiac patients, 54 (65%) had acquired cardiac disease, and 29 (35%) had congenital cardiac disease. The different types of acquired cardiac disease are summarised in Table II.

Table II: Types of acquired cardiac disease

Type of cardiac disease	Number	Percentage
Rheumatic valvular cardiac disease	22	41
• Mitral valve	14	64
• Aortic valve	2	9
• Pulmonary valve	1	5
• Mitral and aortic valves	5	23
Cardiomyopathies	19	35
• Peripartum	13	68
• Dilated	4	21
• Hypertrophic	2	11
Others	13	24
• Pulmonary hypertension	5	38
• Myxomatous mitral valve	2	15
• Submitral valve aneurysm	1	8
• Abdominal aortic aneurysm with aortic regurgitation	1	8
• Arrhythmias	3	23
• Angina pectoris	1	8

The majority of patients with congenital cardiac disease, 20 (69%), had shunt-type lesions. The types of congenital cardiac disease are shown in Table III. Of the 29 patients diagnosed with a congenital cardiac disease, 27 (93%) had previously corrective surgery.

Table III: Types of congenital cardiac disease

Type of congenital cardiac disease	Number	Percentage
Shunt-type lesions	20	69
• Atrial septal defect	3	15
• Ventricular septal defect	9	45
• Patent ductus arteriosus	5	25
• Atrioventricular septal defect	2	10
• Anomalous pulmonary venous return	1	5
Conotruncal defects	4	14
• Tetralogy of Fallot	3	75
• Transposition of great vessels	1	25
Obstructive lesions	2	7
• Pulmonary stenosis	1	50
• Aortic coarctation	1	50
Miscellaneous	3	10
• Noonan's syndrome with cardiac defects	3	100

There was no consistency at which gestational age the echocardiography was done. Of the 83 patients, the echocardiographic records for 10 (12%) patients were not available. Of the 73 patients with echocardiography reports, 30 (41%) did not have the ejection fractions recorded, and 10 (12%) had the ejection fractions recorded as normal without a numerical value attached. The mean (SD) ejection fraction of the other 33 patients was 61 (0.11) % with the range of 25 – 84%.

Of the 73 patients, 44 (60%) did not have recorded pulmonary arterial pressures (PAP), 10 (14%) were recorded as normal without a numerical value attached and 19 (26%) patients had a numerical value. The mean (SD) PAP was

49 (32) mmHg with a range of 8 – 101 mmHg. Of the 73 patients, 14 (19%) had pulmonary hypertension. Of these 14 patients, 11 (79%) had left cardiac disease (mitral regurgitation, mitral stenosis or mixed mitral valve disease), 1 (7%) previously had pulmonary tuberculosis, 1 (7%) had a previous pulmonary embolus, and 1 (7%) had a repaired atrioventricular canal. The types of valvular lesions observed on echocardiography are shown in Table IV. There was no patient with either mixed aortic, tricuspid or pulmonary valve disease.

Table IV: Type of valvular lesions seen on echocardiography

Type of valvular lesion	Number	Percentage
Regurgitant	44	85
• Mitral valve	22	50
• Aortic valve	8	18
• Tricuspid valve	12	27
• Pulmonary valve	2	5
Stenotic	4	8
• Mitral valve	2	50
• Aortic valve	1	25
• Tricuspid valve	0	0
• Pulmonary valve	1	25
Mixed	4	8
• Mitral valve	4	100

Details regarding the mWHO classification of the studied patients as shown in Figure 1 revealed that 15 (18%) patients were classified as modified WHO class 4 where there is a significant risk of maternal morbidity and mortality.

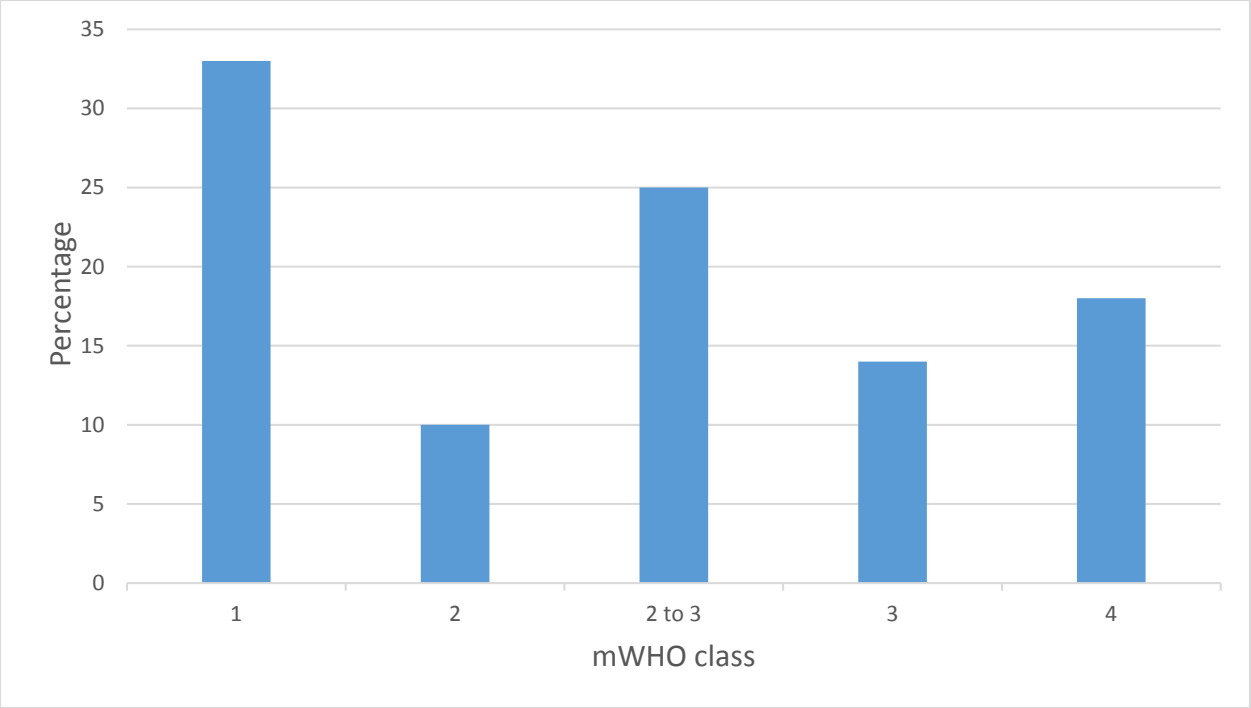


Figure 1: Modified WHO classification for pregnant cardiac patients

Of the 83 deliveries conducted with an anaesthetic technique, 36 (43%) were done under GA, and 47 (57%) under neuraxial anaesthesia. The type of anaesthetic technique is shown in Table V. Continuous spinal anaesthesia and local anaesthesia techniques were not used for Cesarean section in this study.

Table V: Type of anaesthetic technique

Type of anaesthetic technique	Number	Percentage
General anaesthesia	36	43
• Standard GA	28	78
• High opioid-based GA	8	22
Neuraxial anaesthesia	47	57
• Graded epidural	33	70
• Standard epidural	2	4
• Single-shot spinal	12	26

An epidural for labour analgesia was inserted in 10 (12%) patients. Of the 10 patients, 1 (10%) patient had a normal vaginal delivery, and 9 (90%) patients delivered by Cesarean section. Labour epidurals for these patients were topped up in the operating room to an adequate level of anaesthesia for Cesarean section.

Half of the patients, 22 (50%), with regurgitant valvular cardiac disease delivered with a standard GA, 9 (20%) patients with a single-shot spinal anaesthesia, 9 (20%) with a graded epidural and 4 (9%) with a high opioid-based GA. Regarding patients with stenotic valvular cardiac disease, 2 (50%) patients delivered with a graded epidural, and 2 (50%) patients with a high opioid-based GA. Of the 4 patients with mixed mitral valve disease, 2 (50%) patients delivered with a standard GA and 2 (50%) with a high opioid-based GA.

Of the 13 patients with peripartum cardiomyopathy, 4 (31%) delivered with a single-shot spinal anaesthesia, 3 (23%) with a graded epidural, 1 (8%) with a standard epidural, and 5 (38%) with a standard GA. Of the 4 patients with a dilated cardiomyopathy, 1 (25%) delivered with a standard GA, 1 (25%) with a high opioid-based GA, 1 (25%) with a standard epidural, and 1 (25%) with a graded epidural anaesthesia. Of the 2 patients with hypertrophic cardiomyopathy, 1 (50%) delivered with a graded epidural and the other with a standard GA.

The intraoperative anaesthetic complications as shown in Table VI reveal that the majority, 75 (90%), of patients in this study underwent anaesthesia without any complications. Patients who had either a failed spinal or a failed epidural anaesthesia were converted to a GA. Two patients (2%) who were not previously in cardiac failure went into cardiac failure intra-operatively. They both received a GA and belonged to mWHO class 4.

Table VI: Intraoperative complications

Complications	Number	Percentage
None	75	90
Failed neuraxial	3	4
• Failed spinal	2	67
• Failed epidural	1	33
Cardiac Failure	2	2
Others	3	4
• Intrapartum haemorrhage	1	33
• Postpartum haemorrhage	1	33
• Metabolic acidosis	1	33

Among the 83 patients who had delivered with an anaesthetic technique, there were no deaths reported in the first 24 hours' post-operative. The destination of patients post-delivery is shown in Table VII.

Table VII: Destination of patients post-delivery

Ward	Number	Percentage
General intensive care	17	20
General high-care	3	4
Obstetric high-care	46	55
Post-natal	17	20

Discussion

It has been demonstrated that cardiac disease in pregnancy can lead to an increase in maternal morbidity and mortality [12-15] and that the profile of cardiac disease in pregnant women differs between developed and developing countries. [16-23] The majority of literature in this regard is from developed countries. This study provides a profile of obstetric cardiac patients receiving a GA and/or a neuraxial anaesthesia for delivery at CHBAH. CHBAH offers antenatal care for pregnant patients including those with cardiac disease, not only for the Soweto community but also for patients referred from other hospitals.

It is concerning that 42% of the patients' records were missing due to poor record keeping systems. This despite this group of patients being high risk patients as well as the increased number of litigations observed in obstetric patients. [24, 25]

The occurrence of cardiac disease in pregnant women is 0,49% in this study. This occurrence is within the range 0.2 – 4% described worldwide. [17, 26-30] In Canada, Goldszmidt et al [28] found that cardiac disease occurred in 0.4 % of pregnant women in 2010. In the United States of America, Warrick et al [31] reported an incidence of 0.6% in 2015. In Pretoria, Soma-Pillay et al [18] reported an occurrence rate of 0.94%. In 1993 Hsieh et al [32] found an occurrence of 0.25% in Taiwan.

The mean age of patients in this study was 30 years with no patients aged less than 18 years of age. This is similar to the ages reported by Ford et al [2] (28 years) in the United States of America and Fu and Lin [14] (28 years) in China. However, in this study 34% of patients were multiparous, 33% primiparous, and 24% nulliparous patients. In the Ford et al [2] study 65% of patients were nulliparous and in the study by Fu and Lin [14] 78% of patients were primiparous. This is possibly due to the fact that women from developed countries give birth late irrespective of

their underlying diseases. A further reason is that this population does not appreciate the consequences of pregnancy despite their underlying cardiac disease.

This study confirmed that the disease profile is different to that seen in developed countries as 65% of patients had acquired cardiac disease and 35% had congenital cardiac disease. In Canada, Siu et al, [33] in 2001, reported that 74% of patients had congenital and 26% had acquired cardiac disease. Curtis et al [22] in the United Kingdom, in 2001, stated that 77% of patients had congenital and 23% had acquired cardiac disease. In India, a developing country like South Africa, Arora et al [34] in 2015 found that only 16% of patients had congenital and 84% had acquired cardiac disease.

Regarding the type of acquired cardiac disease, our study found that rheumatic cardiac disease was the most prevalent (41%). This is contrary to the findings made in Canada in 2011 by Jastrow et al [21] who reported a prevalence of 4%. In China, Fu and Lin, [14] in 2015, found that 15% of patients had rheumatic cardiac disease. This is possibly due to the fact that rheumatic fever is still a major public health problem in South Africa whilst it has been almost eradicated in developed countries. [35, 36]

The most prevalent congenital cardiac disease in this study was the shunt-type disease (69%). In the United States of America, Warrick at al, [31] in 2015, reported a similar prevalence of shunt-type cardiac disease (76%). In China, in 2016, Fu and Lin [12] reported a lower prevalence of 40% of shunt-type of cardiac disease. A possible explanation is that shunt-type congenital cardiac disease is still dominant, even in the paediatric population.

The mean PAP was 49 mmHg. Pulmonary hypertension was present in 19% of patients in our study which is high compared to the findings from other studies. Siu et al [33] reported an incidence of 4% and Liu et al [37] of 3%. The incidence of pulmonary hypertension observed in our study is possibly due to the high number (50%) of patients with regurgitant mitral valve disease.

Further echocardiographic data revealed that there were more regurgitant (85%) than stenotic (8%) valvular cardiac lesions. In Spain, Pijuan-Domenech et al [38] found that regurgitant valvular diseases (54%) were more prevalent than stenotic (8%) valvular diseases. In Pretoria, Soma-Pillay et al, [18] in 2008, found that 28% of patient had regurgitant valvular lesions and 21% had stenotic valvular lesions. We were not able to find the explanation for the difference between our findings and Soma-Pillay et al findings.

The majority (33%) of patients in our study were in mWHO class 1. However, 18% of the patients were included in mWHO class 4 where pregnancy is not advised and 14% were in mWHO class 3 where there is a significant risk of maternal morbidity and mortality. The intraoperative complication rate in this study was 10%. Two (2%) patients had cardiac complications and these patients were in mWHO class 4. In the United Kingdom a study by Cauldwell et al, [15] in 2017, concluded that the majority of maternal adverse events were observed in patients who were in mWHO 3 and 4. Fu et Lin [12] in China, in 2016, found that 38% of patients were in mWHO class 3 and 15% of those in mWHO class 4 had cardiac complications. This show that the mWHO classification is an important tool in predicting maternal adverse events in pregnant cardiac patients.

More than half (57%) of the deliveries in our study were conducted with neuraxial anaesthesia. In the United States of America, Warrick et al [31] in 2015, reported a higher rate of neuraxial anaesthesia (86%). In Canada, in 2009 Goldszmidt et al [28] found that 80% of Cesarean sections were done under neuraxial anaesthesia. The rate of insertion of epidurals (12%) for labour analgesia was lower in our study compared to other studies. In Holland, Hink et al, [20] in 2010, reported a rate of epidurals for labour analgesia of 36% and 49% in the Chia et al [39] study in Bangladesh, in 1998. The reason for the low rate of neuraxial anaesthesia and labour epidural analgesia in this study is possibly due to the lack of a 24-hours epidural service at CHBAH. During the study period there was a single anaesthetist responsible for labour epidurals from Monday to Friday during the daytime (08:00 to 16:00) only.

It was difficult to find literature from both developed and developing countries detailing specific anaesthetic management of each type of cardiac disease. Half of the patients (50%) with regurgitant valvular cardiac disease

delivered with a standard GA in this study. Although the 2011 ESC guidelines [40] recommend the use of an epidural anaesthesia for Cesarean section in asymptomatic patients, Chestnut and Wong [41] stated that both general and neuraxial anaesthesia can be safely used in these patients.

Overall, 46% of patients with peripartum cardiomyopathy in our study delivered with a single-shot spinal anaesthesia. The 2011 ESC guidelines [40] recommend a combined spinal epidural and epidural anaesthesia for Cesarean section. In the United Kingdom, Pryn et al [42] in 2006, reported that an incremental combined spinal-epidural provided effective anaesthesia in patients with peripartum and hypertrophic cardiomyopathies. Two patients with hypertrophic cardiomyopathy in our study delivered with a graded epidural and the remaining two delivered with a standard GA. The 2011 ESC guidelines [40] state that the choice of the type of anaesthesia is determined by the severity of the left ventricular outflow obstruction. Therefore, an epidural anaesthesia can still be used in less severe cases. In the United States of America, Ashikmina et al, [43] in 2015, reported the use of a single-shot spinal anaesthesia and a combined spinal-epidural anaesthesia for Cesarean sections in patients with hypertrophic cardiomyopathy.

In this study, 2% of patients had cardiac complications intraoperatively, 1 under GA and 1 under neuraxial anaesthesia. In Canada, Robertson et al [44] reported a similar rate of cardiac complication (2%). However, in 2015, Warrick et al [31] and Fu and Lin [14] described a higher incidence of cardiac complications (11%) in the United States of America and in China respectively. The difference between this study and the previous studies is possibly due to the fact that we only described cardiac complications that had occurred intraoperatively.

In our study, 14% of the patients were admitted to ICU following delivery. In Canada, in 2010, Goldszmidt et al, [28] reported an ICU admission rate of 13%. In the United States of America, Warrick et al [31] in 2015, reported an ICU admission rate of 3%.

This study was contextual in nature and may therefore, not be generalisable to cardiac patients having Cesarean section in other contexts. A further limitation was that the study was done retrospectively and therefore relied on information already documented and follow up was not possible.

Conclusion

This audit demonstrated that acquired cardiac disease was more prevalent than congenital. Rheumatic valvular disease is still the most common cause of acquired cardiac disease in pregnancy. Neuraxial anaesthesia was the most used anaesthetic technique for delivery in these patients.

Conflict of interest

We declare that we have no financial or personal relationships which may have inappropriately influenced us in writing this paper.

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SECTION 4: Appendices

Appendix 1: Ethics approval

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

R14/49 Dr LT Lushiku and Ms H Perrie

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
CLEARANCE CERTIFICATE NO. M160105

NAME: (Principal Investigator)	Dr LT Lushiku and Ms H Perrie
DEPARTMENT:	School of Clinical Medicine Department of Anaesthesiology Chris Hani Baragwanath Academic Hospital
PROJECT TITLE:	Profile of obstetric cardiac patients delivered with an anaesthetic intervention at an academic hospital
DATE CONSIDERED:	29/01/2016
DECISION:	Approved unconditionally
CONDITIONS:	Title change noted on 04/04/2018
SUPERVISOR:	Professor J Scribante
APPROVED BY:	CB Penny Professor CB Penny, Chairperson, HREC (Medical)
DATE OF APPROVAL:	22/04/2016

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary on 3rd floor, Phillip V Tobias Building, Parktown, University of the Witwatersrand, Johannesburg.
I/We fully understand the conditions under which I am/we are authorised to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated from the research protocol as approved, I/we undertake to resubmit to the Committee. **I agree to submit a yearly progress report**. The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed. in this case, the study was initially reviewed in **January** and will therefore be due in the month of **January** each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).

Principal Investigator Signature _____ Date _____

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

Appendix 2: Post-graduate approval

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

Private Bag 3 Wits, 2050
Fax: 027117172119
Tel: 02711 7172076

Reference: Mrs Sandra Benn
E-mail: sandra.benn@wits.ac.za

01 April 2016
Person No: 1482294
PAG

Dr LT Lushiku
P.O Box 2199
Ruimsig
Johannesburg
1732
South Africa

Dear Dr Lushiku

Master of Medicine: Approval of Title

We have pleasure in advising that your proposal entitled *Profile of obstetric cardiac patients delivered with an anaesthetic intervention at an academic hospital* has been approved. Please note that any amendments to this title have to be endorsed by the Faculty's higher degrees committee and formally approved.

Yours sincerely

Mrs Sandra Benn
Faculty Registrar
Faculty of Health Sciences

UNIVERSITY OF THE WITWATERSRAND
18 APR 2016
FACULTY OF HEALTH SCIENCE
YORK ROAD, PARKTOWN
2193
JOHANNESBURG

Appendix 3: Approval from CHBAH Medical Advisory Committee

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

MEDICAL ADVISORY COMMITTEE
CHRIS HANI BARAGWANATH ACADEMIC HOSPITAL

PERMISSION TO CONDUCT RESEARCH

Date: 16 March 2016

TITLE OF PROJECT: Profile of obstetric cardiac patients delivered with an anaesthetic intervention at an academic hospital

UNIVERSITY: Witwatersrand

Principal Investigator: LT Lushiku

Department: Anaesthesiology

Supervisor (If relevant): J Scribante

Permission Head Department (where research conducted): Yes

Date of start of proposed study: March 2016
Date of completion of data collection: Dec 2017

The Medical Advisory Committee recommends that the said research be conducted at Chris Hani Baragwanath Hospital. The CEO /management of Chris Hani Baragwanath Hospital is accordingly informed and the study is subject to:-

- Permission having been granted by the Human Research Ethics Committee of the University of the Witwatersrand.
- the Hospital will not incur extra costs as a result of the research being conducted on its patients within the hospital
- the MAC will be informed of any serious adverse events as soon as they occur
- permission is granted for the duration of the Ethics Committee approval.

.....
Recommended
(On behalf of the MAC)
Date: 16 March 2016

.....
Approved/Not Approved
Hospital Management
Date: 20/03/16

Appendix 4: Approval from CHBAH Head of Anaesthetic Department

GAUTENG PROVINCE
REPUBLIC OF SOUTH AFRICA

CHRIS HANI BARAGWANATH ACADEMIC HOSPITAL
DIRECTORATE - ANAESTHESIA
Enquiries: Prof AC Lundgren
Tel. number: (011) 933-9334
Fax number: 086 553 2529
Email: chris.lundgren@wits.ac.za

19th November 2015

TO WHOM IT MAY CONCERN

RE: PERMISSION FOR TOMS LUSHIKU TO CONDUCT A RESEARCH STUDY AT CHBAH

I have received a request from Dr. T. Lushiku to conduct a research study at Chris Hani Baragwanath Academic Hospital aimed at evaluating the Profile of obstetric cardiac patients receiving anaesthesia for delivery at Chris Hani Baragwanath Academic Hospital. I am aware of his study and believe it will benefit our hospital.

I would like to support his application for permission to conduct the study at the hospital.

Kind Regards.

PROF. A C LUNDGREN
CHIEF ANAESTHETIST AND HEAD
DEPARTMENT OF ANAESTHESIOLOGY
CHRIS HANI BARAGWANATH ACADEMIC HOSPITAL
UNIVERSITY OF THE WITWATERSRAND

ACL/st

SECTION 5: Proposal

Profile of obstetric cardiac patients delivered with an anaesthetic intervention at an academic hospital

Lunganga Toms Lushiku

1482294

Supervisor: Juan Scribante

Department of Anaesthesiology

Co-supervisor: Helen Perrie

Department of Anaesthesiology

Co-supervisor: Estie Mostert

Department of Anaesthesiology

1. Introduction

The progress made in medical and surgical management of patients with congenital heart disease has resulted in more women with cardiac disease surviving to the childbearing age (1-3). Therefore, the number of pregnant patients with cardiac disease requiring the anaesthetist services is rising as well.

Pregnant women undergo anatomical and physiological changes necessary in coping with the increase metabolic demands of pregnancy (4). Whilst these adaptive changes are well tolerated by healthy pregnant women, those with heart disease can decompensate resulting in significant morbidity and mortality (5).

The World Health Organization (WHO) defines a maternal death as “the death of woman while pregnant or within 42 days of termination of pregnancy, irrespective of the duration and the site of pregnancy, from any cause related to or aggravated by the pregnancy or its management but not from accidental or incidental causes”.

Maternal mortality can have a direct, an indirect cause or both. Direct obstetric deaths are those resulting from obstetric complications of pregnancy while the indirect obstetric deaths are those resulting from previously existing disease such as cardiac disease (6).

Although maternal mortality rate is decreasing in the United Kingdom according to the report from the Centre for Maternal and Child Enquiries (CMACE), the deaths that do occur are increasingly related to indirect obstetric causes. The second most common indirect obstetric cause is cardiac disease (7).

In the United States of America, there were 1 102 maternal deaths among 7 785 583 births between 2003 and 2011 and the overall maternal mortality was estimated to be

1.42 per 10 000 pregnancies. Maternal mortality due to cardiac disease represent 18.4% of all maternal deaths (8). In South Africa, the report released by the Confidential Enquiries into Maternal Death in 2014 (9) revealed a fall in the institutional maternal mortality ratio from 176.22 per 100 000 live births between 2008 to 2010 to 154.06 per 100 000 live births between 2011 to 2013. The indirect causes of maternal death represent approximately 44% of the overall maternal mortality, of which 34.3% were related to cardiac disease. A prospective cohort study done at a single tertiary hospital in Cape Town has shown that there is a mortality rate of 5.92% among pregnant women with cardiac disease (10).

Due to the complexity of their cardiac lesion coupled with the significant increase in morbidity and mortality, pregnant patients with cardiac disease need to be managed by a multidisciplinary team including the obstetrician, the cardiologist, the anaesthetist, and the intensivist (11, 12). The anaesthetist is in an ideal position to coordinate the multidisciplinary team due to their background in critical care combined with perioperative medicine knowledge (12).

2. Problem statement

Pregnant women with cardiac disease present some of the greatest challenges to the anaesthetist due to their cardiac lesion and the physiological changes occurring in pregnancy (1, 11, 12). The peripartum period combined with anaesthesia can be an unpredictable period for the pregnant women with cardiac disease (1).

In developed countries data is more readily available as to the incidence of pregnant women with cardiac disease, the type of anaesthetic used as well as the maternal cardiac and obstetric outcome (8, 13). Data from South Africa on pregnant cardiac patients is scanty. A 2014 audit at a single tertiary care centre in Cape Town had shown

that the profile of cardiac disease in pregnancy is markedly different to that seen in the developed countries (10).

The profile and the anaesthetic management of obstetric patients with cardiac disease presenting at Chris Hani Baragwanath Academic Hospital (CHBAH) is not known.

3. Aim

The aim of this study is to describe the profile of obstetric cardiac patients who had delivered with an anaesthetic technique at CHBAH.

4. Objective

The objectives of this study are to:

- document the total number of deliveries and the number of obstetric cardiac patients who had delivered with an anaesthetic technique during the study period
- describe the cardiac disease in these patients
- describe the echocardiographic findings in these patients
- classify patients according to the modified WHO risk classification scale for pregnant women with cardiac disease
- describe the anaesthetic management of these patients
- describe the intraoperative anaesthetic complications
- describe the anaesthetic maternal outcome at 24 hours post-delivery.

5. Research assumptions

The following definitions will be used in the study.

Anaesthesia: refers to the anaesthetic that the cardiac obstetric patient receives for delivery. This may be neuraxial, local or general anaesthesia. Neuraxial anaesthesia will be either a spinal, an epidural or a combination of both.

Anaesthetist: a qualified doctor who is currently working in the Department of Anaesthesiology, including medical officers, registrars and consultants.

Medical Officers: a qualified registered medical doctor practicing anaesthesia under specialist supervision. Career medical officers with more than 10 years' experience will be regarded as consultants.

Registrar: a qualified medical doctor who is registered with the Health Professional Council of South Africa in the specialty of Anaesthesiology as a trainee anaesthetist.

Consultant: any anaesthetist who has completed the required South African College of Medicine examinations, and all other criteria to become a specialist in Anaesthesiology. Career medical officers will also be included in this category.

Records: will include the labour admission book, cardiac obstetric anaesthetic assessment form, the intraoperative anaesthetic form and the epidural form. The term record will be used in this report.

Maternal outcome: refers to the outcome of the cardiac obstetric patients at 24 hours post-delivery i.e. dead or alive, and if alive whether the patient is in the intensive care unit, high care area or post-natal ward.

6. Demarcation of the study field

This study will be conducted in the Department of Anaesthesiology of CHBAH. CHBAH is a 2888 beds tertiary hospital, located in Soweto, Gauteng, and is affiliated to the University of the Witwatersrand. The hospital has 25 operating theatres of which two are dedicated maternity theatres that operate 24 hours a day. There are more than 20 000 newborns delivered per year at CHBAH.

7. Ethical considerations

Approval to conduct the study will be obtained from the Graduate Studies Committee and the Human Research Ethics Committee (Medical) of the University of Witwatersrand. Approval to conduct the study will also be obtained from CHBAH Medical Advisory Committee (Appendix 1). Approval to access the records will be obtained from the gatekeeper, Head of the Department of Anaesthesiology at CHBAH (Appendix 2).

This study will be done retrospectively. A list of patient's names, hospital numbers and their corresponding study number will be generated and filed separately. Neither the name of the patient nor the name of the anaesthetist will be recorded on the data collection sheet. Only the researcher and supervisors will have access to the raw data. These measures will ensure anonymity and confidentiality. All data will be stored securely for six years following the completion of the study.

This study does not involve any drug or therapeutic management, and will be conducted by adhering to good clinical research practice as set out in the South African Good Clinical Practice Guidelines (14) and the Declaration of Helsinki (15).

8. Research methodology

8.1 Research design

The design of a study is the template for the study and its purpose is to maximise the probability of obtaining valid answers to the research questions (16). It determines the methods by which the data are collected, analysed and the results interpreted (16, 17).

The research design used in this study is that of a retrospective, contextual, descriptive study (17).

A retrospective study measures variables that have been recorded in the past (16), and is applicable to this study as the data will be obtained from January 2014 to December 2015 (17).

A contextual study is centered on a particular group of people or a “small scale world” (18). This study is contextual as it will only examine the records that originate from CHBAH.

A descriptive study is intended to describe the characteristics of the variables under investigation, and the researcher does not manipulate any variable (16). This study will describe recorded parameters following neuraxial anaesthesia or general anaesthesia on obstetric cardiac patients at CHBAH.

8.2 Study population

The study population will be the records of the obstetric cardiac patients who delivered with an anaesthetic intervention at CHBAH.

8.3 Study sample

8.3.1 Sample size

The sample size will be determined by the number of obstetric cardiac patients who delivered with an anaesthetic intervention at CHBAH during the period 1 January 2014 to 31 December 2015.

8.3.2 Sampling method

Consecutive, convenience sampling will be used in this study. Convenience sampling uses the most readily accessible individuals in a study while a consecutive sampling is a method whereby the researcher attempts to include all accessible individuals records into the sample (19). In this study consecutive, convenience sampling means that every record fulfilling the inclusion criteria will be included in this study.

8.3.3 Inclusion and exclusion criteria

The inclusion criteria in this study are the records of the obstetric cardiac patients who underwent:

- caesarean section or vaginal delivery

- under neuraxial, local or general anaesthesia
- in the operating theatre or labour ward.

The exclusion criteria are:

- illegible records
- missing records.

8.4 Data collection

8.4.1 Record generation and storage

CHBAH uses duplicated, pre-printed obstetric cardiac anaesthetic assessment forms that are completed manually by the consultant assessing the pregnant cardiac patients at the cardiac clinic during their 37 weeks' gestational visit. The top page is kept in a file in the anaesthetic tea-room and the bottom page is attached to the patient's file.

A single page, pre-printed epidural record is completed manually by the anaesthetist performing the epidural. After a normal vaginal delivery, the epidural record is placed in a file on the epidural trolley and then collected by the consultant responsible for overseeing the epidural service and placed in the epidural record file.

Anaesthetic records are pre-printed carbonated forms that are completed manually by the anaesthetist in theatre. After a caesarean section, the anaesthetic record is taken with the patient to the recovery room, the high care area or intensive care unit. In the recovery room, the vital signs are recorded by the recovery nurses on the anaesthetic record until they are satisfied that the patient is stable for transfer to the ward. The top page of the anaesthetic record is kept in a box in the recovery room for filing while the

bottom page is placed in the patient's file. The anaesthetic record is completed and the top page is placed in the collection box by the anaesthetist escorting the patient. The collection boxes from each theatre complex are taken to the departmental secretaries on a daily basis for filing of the top page of the anesthetic record, which will then be filed based on the date and stored in a secure place in the anaesthetic department. Anaesthetic records can therefore easily be located.

8.4.2 Data collection method

Data will be collected from CHBAH once all the approvals have been obtained. The labour ward admission book will be used to determine the number of deliveries during the duration of the study. The number and identified information of obstetric cardiac patients will be obtained from the obstetric cardiac clinic records. The number of obstetric cardiac patients' normal vaginal deliveries who required an epidural will be determined from the Department of Anaesthesiology epidural record file. The number of obstetric cardiac patients who had caesarean sections will be determined from the operating theatre records.

Patients' data will be entered directly onto a Microsoft Excel® spreadsheet (Appendix 3).

The data collection sheet will contain the following information:

- demographics
    - age
    - parity
    - gestation
- cardiac pathology
- classification according to the modified WHO risk classification for pregnant women with cardiac disease
- echocardiography

    - ejection fraction
    - valve
    - pulmonary artery pressure
- anaesthetic management
    - type of anaesthesia
- maternal intraoperative complications
- 24-hour patient outcome
    - dead or alive
    - intensive care unit
    - high care unit
    - postnatal ward.

The capturing of data will take place in the Department of Anaesthesiology and the records will not be removed from the hospital premises.

8.5 Data analysis

Collected data will be analysed using Microsoft Excel® using descriptive statistics. Categorical data will be summarised using frequencies and percentages. Means and standard deviation will be utilised for continuous variables that are normally distributed while medians and interquartile ranges will be used for variables that are not normally distributed.

9. Significance of the study

The healthcare system in general and CHBAH in particular are not spared from the growing number of obstetric cardiac patients. These patients present a great challenge to the anaesthetist, the obstetrician, and the cardiologist (20).

The cardiovascular changes occurring in pregnancy may put additional stress upon a heart with reduced reserve (21). Many studies have shown that cardiac disease is among the leading indirect cause of maternal morbidity and mortality (10, 12, 13, 21-24).

The spectrum of cardiac disease in pregnant women from developing countries appears to differ from developed countries (10, 22). There is a paucity of evidence-based data describing cardiac disease in pregnant women from the developing countries as well as their anaesthetic management (10). The results from this study will describe the profile of obstetric cardiac patients at CHBAH and will contribute to the South African knowledge base of obstetric cardiac patients.

10. Validity and reliability of the study

According to Botma et al (25) the validity of a study refers to “the degree to which a measurement represents a true value” and the reliability of a study “represents the consistency of the measure achieved”. Measures that will ensure the validity and the reliability of this study are the following:

- the use of an appropriate study design
- using appropriate data collecting techniques
- data being collected by a single researcher
- having a representative sample
- application of inclusion and exclusion criteria during record recruitment
- double checking every data entry point at time of data capturing to ensure accuracy.

11. Potential limitations

Limitations are defined by Burns and Grove (17) as restrictions or problems that reduce the assumptions that can be made from the results of a study.

This study is contextual in that the population is limited to obstetric cardiac patients at CHBAH. Thus, the results may not be generalisable to other obstetric cardiac patients.

The retrospective nature of this study has potential limitations such as some patient's files may be missing and the information may be illegible or incomplete due to poor record keeping. Furthermore, unbooked patients will not have cardiac obstetric anaesthetic assessment forms.

12. Project outline

12.1 Time frame

	Nov 2015	Dec 2015	Jan 2016	Feb 2016	Mar 2016	Apr 2016	May 2016	Jun 2016	Jul 2016
Proposal									
Chapter 1-3									
Proposal submission									
Ethic committee approval									
Postgraduate committee approval									
Data collection									
Data analysis									
Chapter 4,5									
Editing									
Submission									

12.2 Financial plan

All the costs related to printing and paper will be incurred by the Department of Anaesthesiology, University of the Witwatersrand.

Item	**Price**	**Number of pages**	**Copies**	**Total**
Proposal	R1 per page	20	10	R200
Ethic form	R1 per page	10	25	R250
Postgraduate form	R1 per page	1	6	R6
Completed report	R1 per page	100	4	R400
Binding	R200 per copy		3	R600
TOTAL				R1456

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Appendix 1: Approval from the Medical Advisory Committee at CHBAH

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

MEDICAL ADVISORY COMMITTEE
CHRIS HANI BARAGWANATH ACADEMIC HOSPITAL

PERMISSION TO CONDUCT RESEARCH

Date: 16 March 2016

TITLE OF PROJECT: Profile of obstetric cardiac patients delivered with an anaesthetic intervention at an academic hospital

UNIVERSITY: Witwatersrand

Principal Investigator: LT Lushiku

Department: Anaesthesiology

Supervisor (If relevant): J Scribante

Permission Head Department (where research conducted): Yes

Date of start of proposed study: March 2016
Date of completion of data collection: Dec 2017

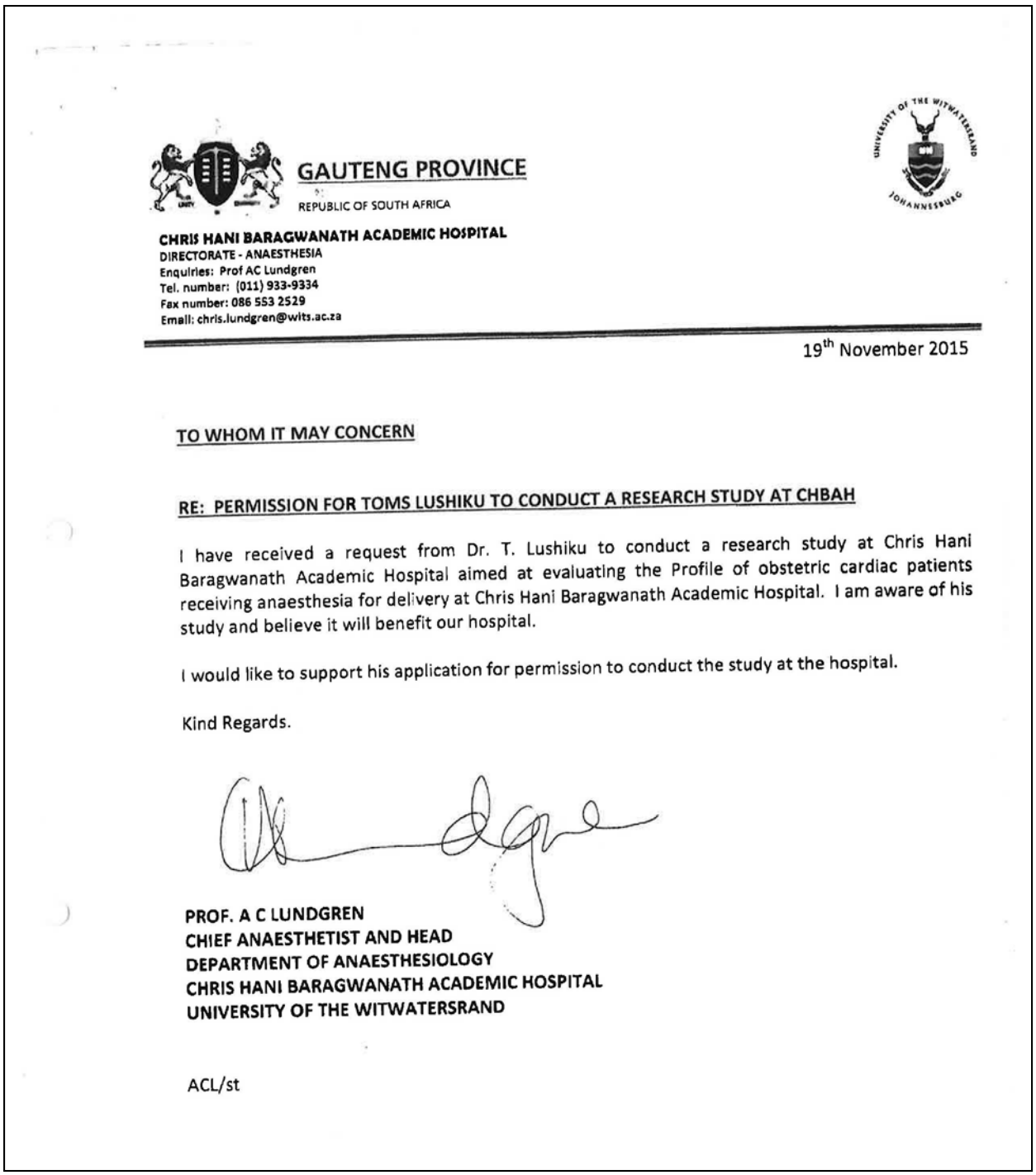
The Medical Advisory Committee recommends that the said research be conducted at Chris Hani Baragwanath Hospital. The CEO /management of Chris Hani Baragwanath Hospital is accordingly informed and the study is subject to:-

- Permission having been granted by the Human Research Ethics Committee of the University of the Witwatersrand.
- the Hospital will not incur extra costs as a result of the research being conducted on its patients within the hospital
- the MAC will be informed of any serious adverse events as soon as they occur
- permission is granted for the duration of the Ethics Committee approval.

.....
Recommended
(On behalf of the MAC)
Date: 16 March 2016

.....
Approved/Not Approved
Hospital Management
Date: 20/03/16

Appendix 2: Approval from the Head of Department of Anaesthesiology at CHBAH



GAUTENG PROVINCE
REPUBLIC OF SOUTH AFRICA

CHRIS HANI BARAGWANATH ACADEMIC HOSPITAL
DIRECTORATE - ANAESTHESIA
Enquiries: Prof AC Lundgren
Tel. number: (011) 933-9334
Fax number: 086 553 2529
Email: chris.lundgren@wits.ac.za

19th November 2015

TO WHOM IT MAY CONCERN

RE: PERMISSION FOR TOMS LUSHIKU TO CONDUCT A RESEARCH STUDY AT CHBAH

I have received a request from Dr. T. Lushiku to conduct a research study at Chris Hani Baragwanath Academic Hospital aimed at evaluating the Profile of obstetric cardiac patients receiving anaesthesia for delivery at Chris Hani Baragwanath Academic Hospital. I am aware of his study and believe it will benefit our hospital.

I would like to support his application for permission to conduct the study at the hospital.

Kind Regards.

PROF. A C LUNDGREN
CHIEF ANAESTHETIST AND HEAD
DEPARTMENT OF ANAESTHESIOLOGY
CHRIS HANI BARAGWANATH ACADEMIC HOSPITAL
UNIVERSITY OF THE WITWATERSRAND

ACL/st

Appendix 3: Data collection sheet

TOTAL NUMBER OF CARDIAC PATIENTS	

STUDY NUMBER			
DEMOGRAPHICS			
Age			
Gestation			
Parity			
Mode of delivery	C/S	NVD	
Echocardiographic findings			
CARDIAC PATHOLOGY			
Congenital	Corrected	Uncorrected	
Diagnosis			
Acquired			
Diagnosis			
MODIFIED WHO RISK STRATIFICATION			

TYPE OF ANAESTHESIA	**GA**	**Neuraxial**		**Local**
	Standard	**Spinal**	**Epidural**	
	High opioid	Standard	Standard	
	Ketamine	Continuous	Graded	

MATERNAL INTRAOPERATIVE COMPLICATIONS	
24 HOURS MATERNAL OUTCOME	
Alive or dead	
Postnatal ward	
Intensive care unit	
High care unit	

Appendix 4: World Health Organization (WHO) modified pregnancy risk score.

- Conditions in which pregnancy risk is WHO class 1: risk not relatively higher than the general population
    - ◦ Uncomplicated small ventricular-septal defect
    - ◦ Mild pulmonary stenosis
    - ◦ Small patent ductus arteriosus or mitral valve prolapse with mild mitral regurgitation
    - ◦ Successfully repaired simple lesions (secundum atria-septal defect, ventricular septal defect, patent ductus arteriosus, anomalous pulmonary venous connection)
- Conditions in which pregnancy risk is WHO class 2: small increase risk of maternal mortality or moderate increase in morbidity
    - ◦ Unrepaired atrial septal defect or ventriculo-septal defect
    - ◦ Repaired tetralogy of Fallot
- Condition in which pregnancy risk is WHO class 2 to 3 (depending on the individual)
    - ◦ Unoperated atrial septal defect
    - ◦Repaired tetralogy of Fallot
    - ◦ Mild systemic ventricular impairment (ejection fraction less than 55%)
    - ◦ Native or tissue valvular heart disease not considered WHO 1 or 4
    - ◦ Marfan syndrome without aortic dilatation (aortic size less than 40 mm)
    - ◦ Aorta less than 45 mm in association with bicuspid aortic valve disease
    - ◦ Repaired coarctation of the aorta
- Conditions in which pregnancy risk is WHO class 3: significantly increased risk of maternal morbidity and mortality compared with the general population
    - ◦ Mechanical valve replacement
    - ◦ Systemic right ventricle
    - ◦ Fontan circulation

    - Unrepaired cyanotic heart disease
    - Other complex congenital heart disease
    - Aortic dilatation 40 to 45 mm in Marfan syndrome
    - Aortic dilatation 45 to 50 mm in bicuspid aortic valve disease
- Conditions in which pregnancy risk is WHO class 4: extremely high risk of maternal morbidity and mortality; patients should be counseled against pregnancy
    - Pulmonary arterial hypertension from any cause
    - Severe systemic ventricular dysfunction from any cause (ejection fraction less than 30%, New York Heart Association class 3 to 4 symptoms)
    - Severe mitral stenosis
    - Severe symptomatic aortic stenosis
    - Marfan syndrome with dilated aorta more than 45 mm
    - Bicuspid aortic valve disease with dilated aorta more than 50 mm
    - Native severe coarctation of the aorta.

(Adapted with the permission from Dr Jonathan N. Ginns et al.)

Appendix 5: Request for use of mWHO risk classification table

From: "Ginns, Jonathan N." <jng2125@cumc.columbia.edu>

Date: 16 November 2015 at 4:01:47 AM SAST

To: Toms Lushiku <lushiku_toms@yahoo.fr>

Subject: Re: Permission for the use of a table

Sure. Fine with me

On Nov 15, 2015, at 4:13 PM, "Toms Lushiku" <lushiku_toms@yahoo.fr> wrote:

Good evening Dr Ginns

I am Dr Toms Lushiku, a resident in the Department of Anaesthesiology in South Africa. I am conducting a

research on cardiac pregnant patients. I would like to use a table on WHO risk classification for cardiac pregnant

patient that I've discovered in one of your article (Adult congenital heart disease and pregnancy; do I number:

10.1053).

Kind Regards