University of Khartoum
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THE QUALITY OF LIFE AFTER INTERVENTIONAL TREATMENT FOR CONGENITAL HEART DISEASE IN SUDANESE CHILDREN

By
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May 2007

Supervisor

Assistant Professor Mohammed Osman Mutwakil
MBBS, MD (U of K)
DEDICATION

TO THE SOULS

OF MY

FATHER & BROTHER
بسم الله الرحمن الرحيم

الرحمن (1) علم القرآن (2) خلق الإنسان (3) علمه البيان (4)

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To those who helped me not to give in

Department of medical record in SHC,

My patients & their caregivers,

My friends,

and My family.
Interventional cardiac treatment has important effects on different aspects of the quality of life (QOL) of children with the congenital heart disease, so a hospital based cross sectional study was conducted at Sudan Heart Centre, during the period from March to September 2006. It included 72 children with congenital heart disease with a mean age of 7 year (range: 6months-18years). These children received interventional cardiac treatment (66.7% of them had surgical procedures while 26.4% had therapeutic catheterization and 6.9% had both surgical and catheter treatment), and their quality of life was studied in different aspects. The mean follow-up period was 1.08 year.

It was found that (52.8%) of these children had interventional treatment at age > 5 years. The majority of these children (97.3%) felt that their general health was good or very good after treatment. Eighty six percent of these patients had no further hospitalization, (68.1%) of them stopped medication, while (19.4%) decreased their use, and (9.7%) had more medications after treatment. Most of the patients showed much improvement in their symptoms (51.39%), nutritional intake (79.2%), social interaction and physical activity (91.7%). A considerable number of children suffered from parents over protection as (52.7%) were given the same or even more family attention. There was improvement of the children weight gain and height in (69.4%) after treatment. A quality of life (QOL) score was formulated consisting of; (1) signs
and symptoms (2) general well-being (3) frequency of hospitalization (4) growth state (5) social interaction (6) physical activity (7) dependency on family. It showed that (88.89%) of these children had good QOL after interventional treatment, while (11.11%) of them had poor QOL.

Although interventional cardiac treatment in Sudan had been recently introduced this study had shown that, most children benefited from this treatment and enjoyed a better QOL. With improving early diagnosis and treatment this percentage is expected to increase.
ملخص الطرح:

- إنّ الهدف من الطرح هو تحليل نموذج داء التصلب المتعدد في السودان خلال الفترة من سبتمبر 2006 إلى 2018.

- تضمنت الدراسة 52.8% من الحصص، وتشمل هذه العوامل المخبرية ونوعية الحياة، والتماسك، والصحة، والعادات، والنشاط الاجتماعي.

- تشير النتائج إلى أن 97.3% من المرضى تلقوا جراحة في القلب، و66.7% من الجراحات، و26.4% من العلاجات، و6.9% من جراحة علاجية، و87.9% من المرضى بصفة جيدة.

- نتائج الدراسة تظهر أن 52.7% من المرضى تلقوا العلاج في السودان، و11.11% تلقوا العلاج في الخارج.

- يُرجى النظر إلى النتائج المفصلة في الدراسة المذكورة في النص الذي يحتوي على 대부분 من المعلومات المذكورة في الطرح.
<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>ACE</td>
<td>Angiotensin converting enzyme</td>
</tr>
<tr>
<td>AR</td>
<td>Aortic regurgitation</td>
</tr>
<tr>
<td>AS</td>
<td>Aortic stenosis</td>
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<tr>
<td>ASD</td>
<td>Atrial septal defect</td>
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<tr>
<td>AV block</td>
<td>Atrioventricular block</td>
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<tr>
<td>AVSD</td>
<td>Atrioventricular septal defect</td>
</tr>
<tr>
<td>CHD</td>
<td>Congenital heart disease</td>
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<tr>
<td>CHF</td>
<td>Congestive heart failure</td>
</tr>
<tr>
<td>COA</td>
<td>Coarctation of the aorta</td>
</tr>
<tr>
<td>CXR</td>
<td>Chest x-ray</td>
</tr>
<tr>
<td>DORV</td>
<td>Double outlet right ventricle</td>
</tr>
<tr>
<td>ECHO</td>
<td>Echocardiography</td>
</tr>
<tr>
<td>FO</td>
<td>Foramen ovale</td>
</tr>
<tr>
<td>GH</td>
<td>Growth hormone</td>
</tr>
<tr>
<td>HLHS</td>
<td>Hypoplastic left heart syndrome</td>
</tr>
<tr>
<td>LA</td>
<td>Left atrium</td>
</tr>
<tr>
<td>L-R shunt</td>
<td>Left-to-right shunt</td>
</tr>
<tr>
<td>LV</td>
<td>Left ventricle</td>
</tr>
<tr>
<td>MPA</td>
<td>Main pulmonary artery</td>
</tr>
<tr>
<td>PA</td>
<td>Pulmonary artery</td>
</tr>
<tr>
<td>PBF</td>
<td>Pulmonary blood flow</td>
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<tr>
<td>Acronym</td>
<td>Description</td>
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<tr>
<td>---------</td>
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<tr>
<td>PDA</td>
<td>Patent ductus arteriosus</td>
</tr>
<tr>
<td>PS</td>
<td>Pulmonary stenosis</td>
</tr>
<tr>
<td>PVOD</td>
<td>Pulmonary vascular obstructive disease</td>
</tr>
<tr>
<td>QOL</td>
<td>Quality of life</td>
</tr>
<tr>
<td>RA</td>
<td>Right atrium</td>
</tr>
<tr>
<td>R-L shunt</td>
<td>Right-to-left shunt</td>
</tr>
<tr>
<td>RV</td>
<td>Right ventricle</td>
</tr>
<tr>
<td>RVH</td>
<td>Right ventricular hypertrophy</td>
</tr>
<tr>
<td>RVOT</td>
<td>Right ventricular out flow tract</td>
</tr>
<tr>
<td>SHC</td>
<td>Sudan heart centre</td>
</tr>
<tr>
<td>TGA</td>
<td>Transposition of great arteries</td>
</tr>
<tr>
<td>TOF</td>
<td>Tetralogy of fallot</td>
</tr>
<tr>
<td>TR</td>
<td>Tricuspid regurgitation</td>
</tr>
<tr>
<td>TS</td>
<td>Tricuspid stenosis</td>
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<tr>
<td>VSD</td>
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1. INTRODUCTION AND LITERATURE REVIEW

1.1. Definition:

Congenital heart disease (CHD) are defects that affect the heart and it is major blood vessels before birth, as a result of failure of the heart or the blood vessels near it to develop normally. These defects are ranging in severity from simple to complex abnormalities (1).

1.2 HISTORICAL BACKGROUND:

Since the sixteenth century many abnormalities of the hearts and blood vessels had been disclosed by post-mortem examination. The last 50 years of the 20th century was witnessed of staggering advances in virtually all aspect of paediatric cardiac medicine and surgery. In 1930; Dr Helen Taussing, characterized the clinical and fluoroscopic finding of wide variety of CHD, and published the material in a two volumes textbook in 1960 (2). In 1936 Dr Maude Abbott of Montreal had published an Atlas of congenital heart defects that helped in giving clinical diagnosis
and surgical correction of CHD. In 1938 successful ligation of the ductus arteriosus was accomplished and was a signal achievement in the era of surgery for CHD. In 1945, Crafoord and Nylin successfully repaired the coarctation of the aorta. Legendary Blalock-Taussing anastomosis had a tremendous impact on the emergency field of cardiac surgery (3, 4, 5). In 1954; Andref, Cournand and others shared the Nobel prize in medicine and physiology" for their discoveries concerning heart catheterization pathological changes in circulatory system". John H.Gibbon`s heart/lung by pass machine which was developed in the early 1950s, set the stage for intracardiac surgery; a mechanical pump-oxygenator that permitted "accurate visualization of structure within the heart for a period sufficient to permit precise corrective measure. Each of these innovations addressed congenital cardiac malformation and heralded one of the most successful rehabilitation programs in medical history. The last half of the 20th century witnessed remarkable diagnostic and therapeutic development in this field; the introduction of the M-mode cardiography and the other technique modalities and was the introduction of the catheter based therapy (6, 7, 8).
The late 1990s, has witnessed major change in cardiac surgical treatment in Sudan. That was the introduction of open-heart surgery in Ahmed Gassim hospital. In the year 2000a tertiary cardiac centre (which is Sudan heart centre (SHC)) was then established. Interventional paediatric cardiac treatment was introduced in SHC first in 2001as surgical intervention then, in 2004 cardiac specialized paediatric cardiac catheterization was started (9). Many of our children with congenital heart disease were offered the chance, the thing that stimulates us to have a look at their quality of life after such treatment.

1.3. Epidemiology:

1.3.1. General view:

Congenital heart disease affects 5 to 8 infant per 1000 live births(10). The incidence is higher among still born (2%), abortuses (10-20%) and premature infants (2%) excluding patent ductus arteriosus. There are no racial differerance in the incidence rate of congenital heart disease, although some differences in the type of the lesions do occur (11).
The outlook of CHD depends on the nature and severity of the lesion, the presence of associated abnormalities, and the availability of surgical or catheter-based intervention. The mortality rate for untreated CHD is high, and prior to the introduction of modern surgery, a study of babies born live with heart disease reported that up to one third would die within the first month of life and 60% before the end of the first year (12). Congenital heart disease-related mortality was decreased by 39% from 1979-1997, and the age of death increased for most of the defects (13). Recent figures indicate that 85% of newborns with congenital heart disease are expected to survive to adult life (14).

There is no evidence of major variations in incidence of CHD based on racial, geographical, and socio-economic factors in developing countries (15,16). The last two decades in Africa, showed a growing awareness towards CHD as an important cause of morbidity and mortality (17). In Tanzania the incidence was reported to be 7 per 1000 live birth, and it was found to be 1.7 per 1000 live birth in Kenya (18,19).
1.3.2. Situation in Sudan:

Sudan is similar to other African countries in its situation about congenital heart disease. The prevalence of CHD was found to be 2.3 per 1000 live birth, in a study conducted in 1996 by Ibtisam Ibrahim (20). The pattern of congenital heart disease among Sudanese children studied in 2004, and was found to be comparable to pattern reported in other parts of the world (21). A recent study however, reported that the frequency of Ebstein malformation of Tricuspid valve (TV) was four times that reported in west literature (22). Elhag found in a study conducted over a period of two year (1991-1993) that almost all types of CHD was present in Sudanese children, and the most common being VSD (23). Ethnic, residence distribution of CHD children studied in 2005 and found that the majority were belong to Arab tribe and were from urban areas (24).

1.4. Perinatal Cardiac Physiology:

The understanding of the physiology of the unique nature of fetal and neonatal circulation, as well as the concept of the transitional circulation had a profound impact on the development of treatment modalities in paediatric cardiology. Rudolph and his
colleagues have fully characterized the fetal circulation demonstrating the flow pattern of the great veins, the fetal channels including ductus venosus and ductus arteriosus, and the obligatory right-to-left shunt at the level of the foramen ovale (FO) occurring in the fetus. The inefficient separation of the uptake and delivery circulation of the fetus is replaced by two distinct circulations in series after birth. This parallel circulation is achieved by the closure of the arterial duct and the ductus venosus, the separation from the umbilical circulation, and the cessation of the right-to-left flow through the foramen ovale. Coincident with these changes, are a substantial increase in pulmonary blood flow and an increased output from each ventricle. Clearly, ventilation, oxygenation, and umbilical cord occlusion are the gross events responsible for the transition from the fetal circulation pattern to the circulation pattern of the newborn. These phenomena are mediated by neurohormonal, mechanical, and environmental factors(25-27).
1.5. Cardiac Anatomy and the Nosology of Congenital Heart Disease:

Dr Maurice Lev and his colleagues described and characterized the entire spectrum of congenital malformed hearts and produced a number of classifications of various cardiac anomalies. Lev, Anderson, and Becker also provided detailed information about the specialized conduction tissue in the normal and malformed heart. Richard Van Praagh and his colleagues, provided in the early 1960s the framework for segmental analysis of (CHD) \(^{28-30}\). The three segments identified were; the atria, the ventricular loop, and the great arteries. There are two schools of cardiac nomenclature; one by Van Praagh and his colleagues emphasizing the infundibular anatomy of both normal and congenitaly malformed hearts. The other by Dr Robert Anderson and his colleagues using the segmental approach\(^ {31-33}\).
1.6. **Classification of Congenital Heart Disease:**

Congenital cardiac defects can be divided into two major groups based on the presence or absence of cyanosis: Acyanotic Lesions, Cyanotic Lesions.

1.6.1. **Acyanotic lesions:**

This group is further subdivided into:

1.6.1.1. **Lesions resulting in increased volume load:**

The most common of these being, lesions causing left-to-right shunt including; Atrial septal defect (ASD), Ventricular septal defect (VSD), Atrio-ventricular septal defect (AVSD, AVcanal) and Patent ductus arteriosus (PDA).

1.6.1.2. **Lesions resulting in increased pressure load:**

The most common are obstruction to ventricular out flow like Pulmonary stenosis (PS), Aortic stenosis (AS), and Coarctation of the aorta (COA). Less common lesions are obstruction to ventricular inflow like Tricuspid or Mitral atresia and Cor triatrium.
1.6.2.1. Cyanotic lesions:

This group is further subdivided into:

1.6.2.1.1. Lesions with decreased pulmonary blood flow (PBF):

These lesions include both an obstruction to PBF, at tricuspid valve, right ventricle(RV) or pulmonary valve level, and aright- to-left( R-L) shunt ,(via patent foramen ovale( FO),ASD or VSD). Common lesions in this group include: Tricuspid atresia(TA), Tetrology of fallot (TOF), and various forms of a single ventricle with PS.

1.6.2.1.2. Lesion with increased pulmonary blood flow:

In this group there is no obstruction to pulmonary blood flow and cyanosis is caused by total mixing of systemic venous and pulmonary blood within the heart or by an abnormal ventricular-arterial connection, like transposition of great arteries (TGA). The total mixing lesions includes those with common atria or ventricle, Total anomalous pulmonary venous return (TAPVR), and Truncus arteriosus. The nine lesions which together make up (90%) of all cases are VSD, ASD, AVSD, PS, PDA, AS, COA, TOF and TGA, the remaining (10%) are rarer complex anomalies (11,34).
1.7. Pathophysiology of Congenital Heart Disease:

The anatomic and physiological changes in the heart and circulation due to any specific congenital cardio circulatory lesion are not static but rather progressive from prenatal life to adulthood. Thus, malformation that are benign or escape detection in childhood may become clinically significant in the adult \(^{(35)}\).

1.7.1. Pathophysiology of a cyanotic lesions:

1.7.1.1. Left-to-right (R-L) shunt lesions:

Examples of this group:

A. Ventricular Septal Defect (Vsd):

A VSD may be located in the perimembranous septum or in the muscular septum. PDA and COA are frequently associated defects. In sub arterial or supracristial VSD, the aortic valve may prolapse through the VSD, with resultant aortic regurgitation (AR). The defects vary in size, ranging from a small defect without hemodynamic significance to large defects with pulmonary hypertension and congestive heart failure. In VSDs with small to moderate L-R shunt, a volume overload is placed on the LA and LV. PBF is increased to a varying degree, and pulmonary
hypertension may result. With long-standing large VSD, pulmonary vascular obstructive disease (PVOD) develops, with severe pulmonary hypertension and cyanosis from a R-L shunt.

**B. Patent ductus arteriosus (PDA):**

There is a persistent patency of normal fetal structure between the pulmonary artery (PA) and the descending aorta. The magnitude of the L-R shunt is determined by the diameter and length of the ductus and the level of pulmonary vascular resistant (PVR) with a long-standing large ductus, pulmonary hypertension and PVOD may develop with a R-L shunt and cyanosis\(^{36,37}\).

1.7.1.2. Lesions resulting in increased pressure load:

An example of this group:

**Pulmonary stenosis (PS):**

Pulmonary stenosis may valvular(90%), or subvalvular (infundibular or supra valvular). Dysplasia of the pulmonary valve is frequently seen with Noonan’s syndrome. Isolated infundibular PS is uncommon, it is usually associated with a large VSDas in TOF. Post stenotic dilatation of the main pulmonary artery (MPA) usually develops in valvular PS. Depending on the severity of the PS, a varying of degree of right ventricular
hypertrophy (RVH) is present; Dilatation of RV on the chest x-ray (CXR) does not result unless congestive heart failure (CHF) supervenes, which is usually very late.

1.7.2. Pathophysiology of cyanotic congenital heart disease:

Example of this group:

a. Transposition of Great Arteries (TGA):

TGA is the most common cyanotic CHD in newborn. The aorta arises anteriorly from RV, and the PA arises posteriorly from the LV. This result in complete separation of the two circuits, with hypoxemic blood circulating in the body and oxygenated blood circulating in the pulmonary circuit. Defects that permit mixing of these circulations; such as ASD, VSD and PDA, are necessary for survival. A VSD is present in (40%) of these cases and PS (valvular or subvalvular) occur in (30%-35%) of patients had VSD. In neonates with poor mixing of the two circulations, progressive hypoxemia and acidosis develop, with resulting in early death if no intervention was offered. CHF develop in the first week of life in many patients. The RV is the systemic ventricle.

B. Tetrology of Fallot (TOF):
The original description of TOF includes four abnormalities: a large VSD, right ventricular outflow tract (ROVT) obstruction, RVH, and overriding of the aorta. However, only two abnormalities are important: a VSD large enough to equalize pressure in both ventricles and an RVOT obstruction. The RVOT may be in the form of infundibular stenosis, pulmonary valve stenosis or a combination of the two. In the most severe form of the anomaly the pulmonary valve is atretic (10%). Right aortic arch is present in (25%) of cases. Because of the nonrestrictive VSD, systolic pressures in the RV and the LV are identical. Depending on the degree of the RVOT obstruction, either an L-R or R-L shunt is present. With mild to moderate RV outflow obstruction and balanced shunt across the VSD (acyanotic TOF) occurs, and with a more severe degree of obstruction, an R-L shunt occurs (cyanotic TOF). The major heart murmur audible in cyanotic TOF originates from the RVOT obstruction, rather than the VSD\textsuperscript{(11)}.

1.8. Diagnosis of Congenital Heart Disease:

Cardiac catheterization became a reality in 1940s, as it was first used to diagnose the right side of the heart, and in 1940-1950s, it became available for infants and children for left sided lesions.
Single fixed-plane angiographic equipment evolved to biplane equipment by 1970s. Bargeron and his colleagues by mid 1970s introduced the axial angiography\(^{38,39}\). M-mode echocardiography was introduced in the 1970s, and in the early 1980s it was developed to the cross-sectional type. The color Doppler technology added yet another dimension to these non invasive imaging modalities. The transesophageal approach to cross-sectional echocardiology has now extended to be used in very small infants. Contrast echo-cardiac CT, MRI, Single photon emission CT perfusion imaging, stress echocardiography, Tissue Doppler characterization, 3D-echo, and intravascular U|S are new imaging modalities\(^{40}\). With these new modalities, considerable information about cardiac structure, function, myocardial perfusion and tissue characterization can be obtained. Fetal echocardiography has provided a new frontier for diagnosis, counseling and treatment.

1.9. Interventional Treatment

(Catheter and Surgical Based)

1.9.1. Interventional catheterization:
The primary role of interventional procedures in the management of some CHD is established and their clinical utility broadens every day. Improvements and new developments in specifically designed paediatric equipment have played a significant role. It has clear implication on cost, as most of non-surgical techniques are cheaper than surgery, and hospitalization is much shorter\(^{(41)}\). In 1953 Rubio-Alvarez, described the technique by which pulmonary stenosis could be relived using a catheter technique\(^{(42)}\). Quarter of a century later, Semb et al, using an inflated balloon-tipped angiographic catheter that reduced the outflow gradient of the main pulmonary artery\(^{(43)}\). However, the introduction of static balloon dilation by Kan and his colleagues fostered the application of these therapeutic modalities. Over the last two decades, the technique has become the "treatment" of choice for pulmonary valve stenosis at any age and with any valve morphology. The safety and efficacy of the technique has been confirmed by numerous studies by Mccrindle and Kan\(^{(44,45)}\). But catheter-based therapy for CHD was clearly focused by the approach of Rashkind and Miller, who in 1966 demonstrated the role of balloon atrial septectomy as maneuver to promote mixing
at the atrial level in patient with TGA\textsuperscript{46}. The application of this technique has changed the outcome of those patients. Postmann et al first advocated a percutaneous technique for permanent closure of the arterial duct, which could be achieved via femoral artery in the late 1960s, but this technique, was not widely used\textsuperscript{47}. The 1980s had witnessed a virtual explosion of catheter-based therapy. Balloon dilation was offered to patients with aortic stenosis, valvular and sub valvular and a wide range of acquired obstruction (Mustard and Senning baffles, etc)\textsuperscript{48}. The use of catheter-introduced devices to closed CHD has produced good results, where catheter closure of the arterial duct with any type of catheter-delivered devices or coils became a standard practice. Currently, several devices (Clamshell, Helex, Button) are undergoing clinical trials for closure of small to moderate sized ASD also an double-umbrella device (i.e., lock clamshell occluder) for a trial septal defect had been use\textsuperscript{49}. In the late 1980s and throughout the 1990s, there was increased experience with catheter closure of the muscular ventricular septal defect (VSD). In 1999 Transcatheter closure of VSD with the use of Amplatzer occluder was introduced\textsuperscript{50}. Other application of this technique includes
dilation of pulmonary out flow tract as in (TOF) and also used in tricuspid atresia. The introduction of endovascular stents has afforded a considerable improvement. Today, there are relatively few areas of cardiovascular system that have not been explored by the interventional paediatric cardiologist.

1.9.2. Complications of interventional catheterization

Over the last decade the paediatric interventional laboratory, while continuing to play a significant role in the anatomic and hemodynamic diagnosis, has evolved a therapeutic function (51, 52). All such procedures, both diagnostic and interventional are associated with some risk. To this end, a number of studies have addressed the risk of each of invasive procedure (53, 54), but they were either retrospective or had reviewed relatively a small number of patients. To achieve understanding of the relative risk of all such procedures a prospective 7-year study was undertaken by Renato in Toronto, Canada to determine the incidence of adverse effects and predisposing factors associated with paediatric intervention and diagnostic cardiac catheterization. The study analyzed 4,952 cardiac catheterization performed at a medium age of 2.9 year, with 55% being a male 45% being a female.
It was found that one or more complications occurred in 436 cases (8.8%), and were classified as major in 102 and minor in 458. Arrhythmic complications were the most common major complication occurred in 128 cases (2.6%) the most common arrhythmic event was atrioventricular block, 5 patients needed pacing during the procedure. Death occurred in seven cases (0.14%) as a direct complication of the procedure and was more common in infants (n=5). Other complication found to be, cardiac arrest, arterial thrombosis, venous thrombosis, bleeding, cardiac perforation, cardiac tamponade, air embolus, and infections. Independent factors for complications included a young patient's age undergoing interventional procedure\(^{(54)}\).

1.9.3. **Cardiac Surgery:**

Surgical intervention was first offered for CHD in 1930s, and prior to that few children survived to adulthood\(^{(55)}\). By 1950, some form of surgical palliation for CHD were firmly entrenched. "Palliative" surgery offered relief of major circulatory disturbances, and includes: PA banding Blalock-Taussing shunt, Blalock-Hanlon operation, Waterston's shunt, Pott's operation, Gore-Tex interposition shunt and Noorwood procedure.
'Definitive' surgery attempts to restore the cardiac anatomy to normal, and includes: Rastelli repair, Rashkind procedure, Senning procedure, Fontan procedure, Glenn shunt, Jatene procedure and Mustard technique\(^{(56)}\). Pulmonary artery banding has been introduced in 1950s\(^{(57,58)}\), and the introduction of cardiopulmonary bypass was in the mid 1950s\(^{(59)}\). In 1970s was the intracardiac repair for most of CHD was carried out by deep hypothermic circulatory arrest\(^{(60)}\). In the early days of open heart surgery, the old children undergone primary repair procedures, and young children usually palliated. Then after the introduction of open heart surgery, the infants were able to undergo definitive repairs. Primary repair for most conditions was introduced by Castaneda and his colleagues at the children hospital in Boston. The Period 1950-1959, had witnessed the palliation of babies with TGA, with either Blalock-Hanlon arterial septectomy or one of partial venous switch operation\(^{(61)}\). Mustard in 1950s, attempted an arterial switch operation with relocation of one coronary artery, but none of his patient survived\(^{(62)}\). The contribution by Sennjng in 1959, was a complete venous switch had the potential for saving the severely cyanotic baby with complete transposition, but most
surgeons were unable to reproduce it with an acceptable surgical mortality\(^{(63)}\). Then in 1963 William Thornton Mustard, performed his successful inflow switch operation, but it could not be performed in young infants. In the next 10-15 years, after the successful introduction of Mustard or Sennjng procedure, a "Pandora's box" of complication was catalogued. Dr Adib Jatene from, Brazil had accomplished the anatomic repair that failed by Mustard\(^{(64,65)}\). By late 1970s an arterial switch operation had become the procedure of choice for most patient of TGA with VSD. In the early 1980s Castaneda and his colleagues introduced the concept of neonatal arterial switch, and this soon become the procedure of choice\(^{(66-69)}\). Similar drama can be found in the surgical history of TOF, complex pulmonary atresia with VSD, the hypoplastic left heart syndrome (HLHS) and other complex anomalies\(^{(70)}\). Fontan and Baudet carried out a successful total right heart by pass in patients with tricuspid atresia, and provided long term palliation for that malformed heart not amenable for biventricular repair\(^{(71-73)}\).

Lupoglazoft J .M and his colleagues carried out a study and they found that VSD with L-to-R shunt mortality is 5% and that all
inter ventricular communication with major pulmonary hypertension should be operated during the first year of life. For atria L-to-R shunts, surgery should be done before the age 4 to 5 years. They also found that results of TOF repair is excellent with survival of more than 30 years in 86% of the simple form, and that total correction of TGA improve the survival to more than 90%. They concluded that all operable cardiac malformation should be performed before the end of the second year of life, allowing for nearly normal life both at home and school\(^\text{(74)}\). CHD related mortality was decreased by 39% since 1978-1997 and the age at death was increased for most defects\(^\text{(13)}\). However, with increased sophistication of surgical and medical management, mortality is becoming a less prominent issue and the focus most shifts towards morbidity, functional status, quality of life and resource demands in both the short and long term outcome\(^\text{(75)}\).

1.9.4. Post interventional treatment course:

The field of cardiac intensive care is rapidly evolving with nearly simultaneous advances in surgical techniques and adjunctive therapies, respiratory care technology and monitoring, pharmacological research and development, computer and
electronics(76). The post operative course depends on numerous factors, the severity of congenital heart defect, the age, the condition of the patient prior to surgery, the event in the operating room, and the quality of post operative care(11).

1.10. Quality Of Life (QOL) After Interventional Treatment

In the international symposium on "Quality of life after open heart surgery" presented the experience in more than 20,000 patients; Issues like early identification, operation of pre morbid personalities, psychological counseling before and after the operation, explanation of the true risks were stressed. Other points like, educational programs in redefinition of family roles, stressing the important of returning to normal activity in education, employment and society, financial support though health insurance to cover the high cost of open heart surgery, and formulation of socioeconomic policies which encourage returning to work yield improvement in all patient groups. For CHD, emphasis was lead to the need to educate parents about the disease, the importance of open discussion between parent, patient and the paediatric cardiologist, and the role of the parent self
groups. Lastly, general awareness of patient abilities will facilitate their social integration and improve quality of life\(^{(77)}\).

1.10.1. The effect of interventional treatment on the clinical presentation

1.10.1.1. Symptom and Signs: Children with congenital heart disease can either present with symptoms of: (a) congestive heart failure; breathlessness (particularly after exertion of feeding or crying), sweating, poor feeding, recurrent chest infection, failure to thrive and cyanosis (b) can be asymptomatic discovered during routine examination\(^{(34)}\).

Symptoms of specific type of congenital heart disease are as follow:

a- Clinical feature of L-R shunt lesions: quick tiring, slow growth, susceptibility to pneumonia, rapid or difficult breathing. If the duct is small, there may be no symptom.

b- Clinical feature of Obstructive defects: cyanosis, chest pain, tiring easily, dizziness or fainting, congestive heart failure, and high blood pressure.
c- Clinical feature of cyanotic defects: may present with cyanosis, sudden rapid breathing or unconsciousness and shortness of breath and fainting during exercise\(^{(78)}\).

1.10.1.2 Physical Examination:

The presence of cyanosis, respiratory distress, and stunted growth, associated malformation and chromosomal syndromes which are suspected by the presence of dysmorphic features, all are indicative for the presence of CHD. The presence or absence of a heart murmur is unreliable as basis for the diagnosis of CHD\(^{(79)}\). In older children, clubbing of digits, and squatting to rest are indicative of right-to-left shunts, while fatigue with exercise, tachycardia, dyspnea, orthopnea and pedal edema are signs of heart failure. Femoral and brachial pulses should be palpated, as they may be absent in infants with some obstructive lesions of the left sided of the heart, sometimes femoral pulses maybe palpable, but one or both brachial pulses may not be palpable\(^{(80)}\). Suspicion of cyanosis should by confirmed by the nitrogen washout test (Hyperoxia test). The infant is placed in (100%) oxygen for ten minutes. If the right radial arterial PO2 is less than113mmhg after
this test, a diagnosis of CHD can be confidently made, assuming lung disease and pulmonary hypertension of the new born have been excluded\(^{(81)}\). Accurate assessment of height, weight and head circumference and plotting them on standard growth charts is essential as both chronic HF and chronic cyanosis usually result in failure to thrive. Growth failure is usually manifested by poor weight gain. In a study conducted in U.K in children and adult with CHD, it was found that \((89.7\%)\) were symptomatic and \((26.8\%)\) reported at least one symptom that was relatively disabling. Breathlessness and palpitation were the most common symptoms, others found to have dizziness, depression, and cyanosis\(^{(82)}\). Two other studies from Unit States (U.S) examining health-related quality of life (QOL), reported conflicting results regarding the symptom experience. One study found that children with CHD were more likely to experience symptom-related distress than control\(^{(83)}\). The second study however, detected no significant difference between children with CHD and normal control in symptom experience\(^{(84)}\). An a third one carried among a heterogeneous group of adult with CHD found that \((9.8\%)\) reported disability as indicated by New York heart association.
criteria (NYHAC) class III or IV functional classification\(^{(14)}\). In Canada in a high risk group of adult with single ventricle or systemic right ventricle, more patients reported disability with (13.3\%) in class III and (4.3\%) in class IV\(^{(85)}\). In Australia a study carried out by Tefuarani and his colleagues in the period between 1978-1994 to assess the outcome in 125 children who had cardiac surgery and 31 who were found to be unsuitable for surgery. Results showed survival rate of 99\%, 79\% respectively. On reviewing those survivors, they found that 93\% of the surgical patients were asymptomatic and all fulfilled the (NYHAC) class I or II. Mild pulmonary hypertension or residual defects of no hemodynamic significance were present in 44\%. In contrast, all survivors from the 18 children originally classified having inoperable lesion were symptomatic, all in NYHAC class III, IV \(^{(86)}\).

1.10.1.3. Health maintenance and general well-being:

Health is state of complete physical, mental, and social well being and not merely the absence of disease or infirmity\(^{(87)}\). To maintain the health of a child with CHD, regular visits should be scheduled to multidisciplinary team. The frequency of visits should be individualized depending on the condition of the child.
In these visits several issues should be discussed with the parents. These include the nature of their child's CHD, treatment options, nutrition, vaccination, endocarditic prophylaxis and recommendation for physical activity\(^{(88)}\). Meijboom.F, from Netherlands studied 176 infants and children undergone surgical closure for VSD at younger age in 1968-1980. Their results showed that, the main interval after operation was \(14.5 \pm 2.6\) years. 84% of the patients were assessed to have good or very good health and 89% had been free of medical or surgical intervention since the operation. At examination all patient were in good health. 84% of the patients had normal exercise capacity. Echocardiography demonstrated a small residual VSD in seven patients (6%) with no signs of pulmonary hypertension. No patient had symptomatic arrhythmia, and it was concluded that personal health assessment is comparable to that of normal population\(^{(89)}\). In Finland a study conducted by Heta and his colleagues to assessed the psychosocial outcome of finish patient who had been operated on for CHD during childhood, with median time of follow-up of 25.6 year (range 9-45) in part of there results 2227 of the patients (77%) described their general health as good, 22% as moderately good
and 1% as poor. Poor health attributed to a condition unrelated to the cardiac defect or its treatment. 5 patients with PDA considered being in poor condition because of their cardiac defect, and surprisingly no patient with TGA reported poor health. The commonest lesions were found to be PDA, COA, ASD TOF, TGA, PS and AS\textsuperscript{(90)}.

1.10.2. The effect of interventional treatment on cardiac morbidity:

Agnoletti.G and his colleagues conducted a study, to identify the predictive factors of interventional paediatric catheterization. They analyzed 1022 interventional procedures, considering several patient related variables like, age, weight, gender, etc. They analyzed variables linked to the environment, specifically the date of the examination, whether the operator remained in training, any break down in the installation, and error made by the operator. They found that the incidence of complications was 4.1%. Of those patients, 4 were died, 7 needed urgent surgery, 5 needed elective surgery, 3 were hospitalized in the ICU and 8 were recatheterized. They concluded that variables related to either patient or the environment of catheterization are
associated with increased risk of procedural complication, so knowledge of risk factors can improve paediatric interventional treatment\(^{(91)}\). Hortkotte D and his colleagues, studied 246 consecutive patients, mean age 11.9±6.7 years with primary or secondary complete repair of TOF between 1961 and 1972. They found that 46 of the patients were re-operated, and 21 had late death. Complications were arrhythmia, HF, and infective endocarditis. The hazard of arrhythmia was inconstant and increased with time from the initial operation, and young age at surgery result in significantly better long-term prognosis \(p=0.03\) \(^{(94)}\). Dysrhythmias are important source of morbidity and mortality in patient with CHD after interventional treatment, and are especially common in individuals who have undergone arterial switch repair for TGA, TOF or Fontan palliation for single ventricle, as reported by Le Roy\(^{(94)}\).

1.10.3. The effect of interventional treatment on the use of Cardiac Medication

Therapeutic measures are aimed at control of heart failure symptoms and the maintenance of normal growth. These measures can be either;
• Supportive therapy: is important to increase tissue oxygen supply and correct metabolic abnormalities.

• Medical therapy: These include correction of hypoglycemia, acidemia, and administration of antibiotic if infection is a contributing factor.
  - Inotropic agents: like (dopamine, digoxin)
  - Diuretics: like frusmide.
  - Vasodilators: those are angiotensin converting enzyme ACE inhibitors like Captopril and Enalpril\(^{(94,95)}\).

Other measures include a well balance diet, prevention of anemia, prophylaxis against bacterial endocarditis, and the usual immunization programmed. All the previous measures still of consideration post interventional therapy mainly in case of procedures complications, with especial attention to immunization schedule where measles-mumps-rubella vaccine should not be given with in 10 days of surgical procedure. It is best to avoid all immunization the week before and 6 week after heart surgery\(^{(96)}\).

In one study conducted in the Czech Republic, it was found that 26.8\% of CHD children aged 8-13 years, require medication\(^{(97)}\).
In a study conducted by Meijboom and his colleagues in 1968-1980, it was found that 89% of the operated CHD children had been free from any medical or surgical intervention since the operation (89). In Belgium a study conducted by Moons and his colleagues in a group of adult CHD patients, and they found that 27% of them still using cardiac medication post the procedure (98).

1.10.4. The effect of interventional treatment on the physical activity:

Most patients who have mild CHD require no treatment, so parents and children should be made aware that normal life is expected and no restriction of the child activities is necessary. Even those of moderate to severe heart disease need not to be markedly restricted in their physical activity, and they can modify it according to their capacity to participate. Massin and his colleagues studied the physical activity pattern of 52 unselected children aged 7-14 years, after neonatal switch operation for TGA, and 35 children with repaired atria or ventricular defect and aged matched to 127 healthy controls. They found that both cardiac groups were significantly less active than the control group when considering moderate and vigorous activity. After operation; only
27% of children engaged in more than 30 minutes a day of moderate activity, and 19% of them in 20 minutes a day of vigorous activity. Concluded that children after arterial switch operation just like other cardiac children, do not meet the guideline for physical activity. They recommended regular activity to offset adult sedentary behavior and to prevent cardiac atherosclerotic disease\(^{99}\). In a study done in the Czech Republic study, poor exercise tolerance was reported by 3.2% of school aged children with CHD, however 59.5% of them reported participation in recreational sports, and 6.7% in competitive sports\(^{97}\).

Guidelines regarding activity level and sport participation for CHD children have been developed which is shown below in (1.10.4.1).

1.10.4.1. Recommendation for physical activity in CHD children:

The recommendation is categories into;

**Category-1**: No restriction for physical activity for patients with; ASD, VSD, PDA (without pulmonary obstruction), mild PS and AS.
Restriction of activity is not recommended for those with COA who are surgically repaired with normal BP and for children with TOF who surgically repaired with RV pressure < 50 mmHg.

**Category-11:** Those are allowed moderate exercise, regular physical education classes, tennis and basketball. This group includes TGA, TA surgically repaired.

**Category-111:** Those allowed light exercise. This group includes; ASD, VSD and PDA (with mild to moderate pulmonary obstruction), moderate AS, COA with hypertension, TOF (surgically repaired with RV pressure > 50 mmHg or marked cardiomegaly), TA palliated or inoperable.

**Category-1IV:** Moderate limitation (no participation in physical education classes) is recommended for children with; severe AS and PS. ASD, VSD, and PDA (with moderate to severe pulmonary obstruction).

**Category-V:** Extreme limitation. Home or wheelchair bound.

1.10.5. The effect of interventional treatment on the education and social interaction of CHD children

1.10.5.1. Education
CHD is often associated with intellectual, developmental, and academic late effects related to the disease itself or its treatment. It appears that children with CHD, and particularly those with cyanotic CHD, are at risk of significant impairment in visual spatial skills, visual motor skills and overall developmental progress speed. Early neurocognitive interventions, especially with younger children, may prove beneficial for remediation of some of these deficiencies\textsuperscript{(101)}. Intellectual development is likely to be compromised in some children who had developed chronic illness early in life\textsuperscript{(102)}. Impaired (central nervous system, developmental, and cognitive) have been widely reported in children with CHD\textsuperscript{(103,104)}. Feeding problems, resulting in failure to thrive are common in infants and young children with CHD, and can result in impaired development and intellect\textsuperscript{(105)}. Surgical intervention for CHD can results in significant increases in IQ scores, particularly among older children\textsuperscript{(106)}, and more specifically in those children with cyanotic lesions\textsuperscript{(107)}. However even after correction of cyanotic lesions, considerable neurodevelopment and cognitive deficiencies may remain\textsuperscript{(108,109)}. There is some evidence that postponing the repair of cyanotic lesions is associated with
progressive impairment in cognitive function. In children with acyanotic lesion, no relation has been found between age at surgery and cognitive impairment\(^{105,106}\). In 1999 Wary and his colleagues compared intellectual and developmental impairment in children with CHD children awaiting surgery, children waiting for bone marrow transplantation, and a control. The Results showed preoperatively, the cardiac and transplant groups showed intellect and development deficits compared to control. Postoperatively, continuing developmental deficits were significant only in children with cyanotic lesions. They concluded that before corrective surgery, chronic illness itself appears to have a predominant influence on development. Postoperatively, cyanotic and a cyanotic lesions are associated with different short term outcomes, where the cyanotic group showed significant deterioration in locomotors and personal/social functioning, the a cyanotic showed improvement in the above subscale that not reach statistical significant\(^{110}\). In a recent U.S study, 94% of adults with complex CHD had finished their high school education, and 62% of them finished college\(^{111}\). In other countries, however, academic problems have been reported in children with CHD, including
delayed school attendance in 35.5% and poor academic performance in 6.9% as found by Samanek (97).

10.5.2. Social interaction: In several studies, adolescents and young adults with CHD have consistently been reported to be feeling different from their peers (111). Despite this, even adult with complex CHD reported "normal childhoods" and normal teen years. Nonetheless, the same subject how were reported "normal", also described to have feeling of social isolation and limitation in peer's interactions. Some researchers described this as denial, while others describe it as normalizing, strategy to deal with situation (112). An old study compared problems of behavior in children with complex CHD and those with innocent murmurs. It was found that children with complex CHD were more withdrawn, experienced more social problems, and engaged in fewer activities (113). Turkish researcher identified worsening and severity of hemodynamic status, older age group at surgical repair, and others as predictive factors of behavioral problem; like depression, anxiety... etc (114). Mccrindle and his colleagues studied 537 patients; their mean age was 11.9 year assessing their health state after Fontan procedure. They reported morbidities include
deficits in vision in 33%, speech in 27% and hearing in 7%, as well as problem with attention in 46%, learning in 43%, behavior in 23%, anxiety in 17% and depression in 8% (115). In a study conducted to examine the psychosocial outcome of Finish patients who had been operated on for CHD during childhood, Heta and others found that they were living in steady relationship as often as the general population (90).

1.10.6 Psychosocial impact on the children and their families post intervention:

Chronisity of the disease reported to produce both negative and positive effects on the patient's life (116). In many studies, good coping has resulted in excellent QOL, even for severely physically disabled patient (117). In a European study conducted to assess the long term behavioral problems, among CHD children had repair surgery, they found that high score of problem was among the age group 10-14 year. They related it to many factors; like numbers of cardiac procedure, prematurity, older age at surgical repair...etc (118).

Difficulties in leading independent life was the most common negative effect reported by Utens and his colleagues (119)
as long term results of CHD surgically corrected. Knowledge of parents of CHD children, about their child heart disease, treatment, prevention of complications, type of interventional procedure they needed and its risk, and the post interventional course, may likewise promote a better health related behavior in their children by reinforcement of the positive, normal attributes of their children that help these families seeing their children as an individual with many of the same needs as healthy children. Children with cardiac defects may have entirely wrong concepts of their disease (120). In Sudan 2005 a study conducted, to asses parental knowledge, attitudes and practice towards their children heart disease and its impact on their growth, the result showed that 64% of the parents had poor knowledge(24). Another study conducted by Beeri and his colleagues to assess parental knowledge and attitudes among outpatients at a hospital paediatric cardiology clinic. They found 68% of the families turn to non-medical personnel for medical advice(121). Andresova and other, in Czecholovakia investigated training attitudes of 18 mothers of children age 6-14 years, operated during preschool age for CHD. All mothers preferred democratic training with
stimulation of the children's activities. They refused authoritative and restricting attitudes. Mothers did not display excessively centered relation to the child, nor exaggerated protectiveness\(^{(122)}\). An a study conducted in UK by Noll S, and his colleague to characterize the source of additional medical information acquired by the parents and to verify how much information is correctly interpreted and remember correctly. The conclusion was that parents commonly obtain additional medical information, however this information does not necessarily improve parent's understanding of the child's operative risk and long-term problems. In addition parents` perception of having adequate medical information often is incorrect\(^{(123)}\).

Families must be included as a part of the health care team, to assure that they have accurate information for making decisions about their child treatment\(^{(124)}\). Consultation with a mental health professional may enable the family to recognize and build on strength that will help them cope with this challenge that might interfere with their coping abilities\(^{(125)}\). Physician awareness of community resources such as parent support groups and respite care is helpful to parents. When this process occurs the family
focuses on the child rather than on the condition. Reinforcing family's successes helps them build the confidence and desire to address and manage future issues\(^{(126)}\).

**1.10.6. The effect of interventional treatment on the growth State and development progress of CHD children:**

Children with CHD often grow and develop more slowly than other children, i.e. their height and weights are in lower "percentiles", and their development milestones such as (rolling over, sitting...etc), may be slower than healthy children. Falling behind in the growth and development in such children has several reasons; the inadequate nutrition that does not meet the body energy requirement, allowing for proper growth, and causing them tiring quickly to be physically keeping up with their peer of the same age. The illness and frequent or prolonged hospitalization may prevent the child from receiving stimuli that help with the development, such as being played with, talked to or touched.

**1.10.6.1. The effect on the growth:** Growth impairment of CHD children is directly proportional to the presence of cyanosis
and to the severity of the hemodynamic disturbance (127). Acyanotic lesions tend to jeopardize weight gain rather than height, whereas cyanotic lesions tend to affect both height and weight (128, 129). Linde and his colleagues found amore pronounced retardation in both weight and height in children with cyanosis than those with acyanotic lesions (130). Boys are usually more malnourished than girls (127, 129). Much of the research on malnutrition and growth failure in CHD children are rather old and may not reflect outcomes with current medical and surgical technology. In a U.S study performed in the last decade, 52% of young children with CHD had weight below the third percentile, 37% had their height below the third percentile, and 12%-25% had their skin fold thickness lying below the third percentile (131). A similar study carried out in Turkey revealed growth failure in more than 50% of children with CHD, and it identified cyanosis, pulmonary hypertension, and congestive heart failure to be significant factors for growth failure and malnutrition (132). In another study, Foster and his colleagues noted that these problems persist into adulthood, and that adult with CHD continue to struggle with physical appearance issues related to small
stature\textsuperscript{133}. Delay of surgical repair of CHD can lead to worsening of nutrition and growth status of patients. Several reports have documented more encouraging results of early repair of critical CHD in symptomatic neonates and infants compared to those of palliative operations\textsuperscript{134}. The effects of the interventional treatment on both weight and height of CHD children have been studied. Sasaki and his colleagues in Japan assessed seven short prepubertal children with CHD, who had complete surgical correction and treated with recombinant human growth hormone (GH). Their growth rate increased from a mean of 4.3cm/year before treatment to a mean of 7.8cm/year in the first year and to a mean of 6.3 cm/year in the second year of treatment. Their mean standardized height also improved. They came to conclusion that recombinant GH increases the growth rate in children with congenital heart disease and in those with prepubertal growth retardation\textsuperscript{135}.

In a study conducted in 2005 in Sudan, Leila El Mahadi found that more than half of CHD patients (55%) had weight below the 3\textsuperscript{rd}. On the other hand (40%) had moderate to severe malnutrition, and (24%) had mild malnutrition. Thirty one patients
(31%) were found to be failing to thrive. The study included both CHD children had interventional treatment and those did not had it(24).

1.10.6.2 Developmental Progress:

The developmental progress of infant requiring early open heart surgery is currently being defined. Overall, severe neurological squeal are uncommon; however, mild to moderate developmental disabilities are prevalent. Functional limitation, academic achievements and health-related quality of life are areas that deserve further attention(136). The use of cardiopulmonary by pass and/or deep hypothermic circulatory arrest intraoperatively increases the risk of neurodevelopmental abnormality(137). In a prospective study conducted in Canada by Limperopoulos and his colleagues, to determine the prevalence of persistent developmental impairments in children with CHD, 131 infants age less than 2 years, were assessed before surgery and again 12-18 month later with stander developmental assessment and formal neurological examination. Results showed that the mean age at follow up testing was19.1±6.6 months, assessment indicated, that 41% had abnormal neurological examination. Gross and/or fine
motor delays were documented in 42%, and 23% demonstrated global developmental delay. They concluded that children with CHD commonly have ongoing neurological, motor, and developmental deficits which continue well after surgical correction\textsuperscript{(138)}.

In 2001 Weinberg and his colleagues found that more than 46% of children with surgical or catheter intervention scored abnormal ratings on developmental screening. Those children were significantly more likely to be rated as abnormal, than children with hemodynamically insignificant congenital heart disease. They also reported gross motor, personal and social skill delays\textsuperscript{(139)}.

Wray and his colleagues looked into intellectual impairment among children with CHD. They compared three groups aged below three and half years; a group with CHD awaiting surgery, another waiting for bone marrow transplant, and a healthy group for control. Results showed that although the mean of the three groups were within normal range, preoperatively the cardiac and transplant groups showed some deficits on the locomotor area, personal/social, and speech and
hearing scale. Postoperatively continuing developmental deficits were significant only in the children with the cyanotic lesions\(^{110}\). In assessing the neurodevelopmental outcome and lifestyle in 143 school-aged and adolescent children with HLHS, William and his colleagues found that 47.8% had fine motor abnormalities, 39.1% had gross motor abnormalities and 17.4% met the criteria for cerebral palsy (CP). Hemiparesis was noted in all 4 subjects with CP. No patient was found to have spastic quadriplegia\(^{140}\).

1.10.7. The effect of interventional treatment on the hematological indices:

Treatment of iron deficiency anemia is especially important in cyanotic patients who will show improved exercise tolerance and general well-being with adequate hemoglobin levels; on the other hand, these patients should also be carefully observed for excessive polycythemia. Cyanotic patients should avoid situations in which dehydration occur, which might lead to increased viscosity and increased risk of stroke. High altitudes and sudden changes in the environment should be avoided. Phlebotomy with volume replacement should be carried out in symptomatic
patients with severe polycythemia (hematocrit > 65%)(11). There are no studies available on this issue.

JUSTIFICATION AND OBJECTIVES

Justification:

1. Congenital heart disease is a common health problem with a great burden on children.

2. Interventional treatment for congenital heart disease (surgical or catheter-based) which has been introduced recently in Sudan has important effects on the quality of life of these children.

3. No similar study was done in Sudanese children before.

OBJECTIVES:

1. General objective:
   - To evaluate the quality of life after interventional treatment for CHD children.

2. Specific objective:
   - To evaluate the effect of interventional treatment on the following:
     - Clinical symptoms and signs.
• General well-being.
• Cardiac morbidity (Hospitalization and cardiac complications).
• The use of cardiac medications
• Physical activity.
• Education and Social interaction.
• Family's caring and children dependency.
• Growth state (weight & height) and developmental progress.
• Hematological indices (Hemoglobin & Packed cell volume).
Chapter Two

2. Patients and Methods

2.1. Nature of the Study:

This is a hospital based, cross sectional descriptive study.

2.2. Study Area:

The study is conducted in Sudan Heart Centre (SHC); which is a tertiary paediatric cardiac center. It is located in Erkwit-Khartoum, and is established in 2000. It is running three paediatric clinics per week by two paediatric cardiologist and one general paediatrion. In addition there is paediatric surgical clinic run by one cardiac surgeon and one junior staff. There are two operating theatres; one is for open heart surgery. The catheter laboratory, where different procedures are available includes: diagnostic and therapeutic cardiac procedure. The combined (ICU/CCU) has 10 monitored beds and 45 beds with central oxygen, suction, compressed air and other necessary equipment. There where about
300 operations per year and more than 1000 cardiac catheterization per year; 150 of these is paediatric procedure.

2.3. Study Duration:

From first of March to the end of July 2006.

2.4. Study population:

The study population is composed of children from six months to eighteen years attending Sudan Heart Centre (SHC) with Congenital Heart Disease (CHD) for which they had interventional treatment 6 months or more prior the time of interview.

2.5. Case Definition:

Interventional treatment: Refer to cardiac catheterization or heart surgery for CHD.

2.6. Inclusion Criteria:

All Children age between six months and eighteen years attending Sudan Heart Centre (SHC) with CHD for which they had interventional treatment 6 months or more prior the time of interview, were included.
2.7. Exclusion Criteria:

1. Syndromic children.
2. Children and parents who refused to participate in the study.

2.8. Sample Size:

According to the equation below:

\[ N = \frac{Z^2 \times PQ}{D^2} \]

- \( N \) = Sample size
- \( Z \) = Statistical certainty 1.96 (at 95% of confidence)
- \( P \) = Prevalence = 5%
- \( Q \) = Probability of failure = 1.0 - \( P \)
- \( D \) = Desired margin of error = 0.05 = correction factor

The sample size was calculated to be 72 children.

2.9. Ethical Approval:

- Approval of the study was taken from our local committee of paediatric and child health university of Khartoum.
- Approval from the consultants taking care of the patients.
• Verbal informed consent was obtained from the children or their parents after explaining the objectives of the study.

2.10. Study Technique and Tools:

2.10.1 Research team:

• The Author.

• A Paediatric cardiologist

• A Laboratory technician.

2.10.2. Research tools:

Pre-structured questionnaire, to be filled by the author after explaining the purpose to child caretaker, and after taken a verbal consent at the outpatient clinic.

2.10.2.1. The Questionnaire was containing the following data:

- Personal data of the patient such as name, age, gender, tribe, and residence.

- Symptoms and signs of congenital heart disease before interventional treatment compared to those after treatment.

- Number of hospitalization to be compared before and after treatment.
- From the medical records the following data was collected; past history of cardiac complications, diagnosis, type of procedure, date of procedure, and post treatment complications.

- **Developmental assessment using**: Denver developmental assessment (Denver 11). It is a tool for screening of the apparently normal child between the ages 0-6 years. It allows the practitioner to identify those children who may have developmental delay. The test screens the child in four areas: personal- social, fine motor, gross motor, and language(141).

- **Education**: assessed by the level of education and school attendance which was evaluated by the number of days of absences per week. Academic performance was evaluated in four degree as excellent, good, fair or poor and was compared to that before treatment.

- **Social interaction**: was assessed by the child interaction with peer and surrounds, and was compared to that before treatment.
- **Physical activity:** was assessed by being compared to that before treatment, either better, less or remain the same in his/her activity. This is by asking the parents, and by assessing the degree of dyspnea according to the New York Heart Association Classification (NYHAC);

**Class 1:** No breathlessness.

**Class 11:** Breathlessness on sever exertion.

**Class 111:** Breathlessness on mild exertion.

**Class 1v:** Breathlessness at rest.

- **Family caring for the child:** assessed by asking if remained the same to before treatment, becoming less or giving more care.

- **The child's dependency on the family:** assessed by asking if it remained the same, less or becoming more dependant after treatment.

- **The nutritional history:** was evaluated by comparing to that before treatment.

- **Drug history:** assessed the numbers of medications before and after treatment.
The socioeconomic status of the patients was classified to low, moderate, and high state according to the national Sudanese income.

2.10.2.2. **Physical examination:**

Through physical examination was conducted including:

2.10.2.2.1. **General examination:** for pallor, plethora, cyanosis, and lower limb edema.

2.10.2.2.2. **Anthropometric measurements (weight and height):**

**Weight:** Weights of children were measured with light clothing without shoes and the error of weighting the children with underwear was corrected by subtracting 0.1kg.

**Supine length:** was done up to the age of 2-3 years on a flat surface, was measured by holding the child under the mandible with the vertex against the head board and another person stretching the extended legs, with the foot board against the soles of the infant's feet.
**Standing height:** done for children who are older than two year. It was taken without shoes, with child standing with heels against backstop with straight legs. Gentle pressure applied to mastoids to the extend neck and keep external auditory meatus and lower rim of orbit in a horizontal line while the child is looking slightly downwards. The upper part of the height scale is applied to the vertex of the skull at right angles to the back rest using a measure box (Shorr Board ™ USA)

*Nutritional status are classified according to the following:*

**Table:**

<table>
<thead>
<tr>
<th>Malnutrition Indicator</th>
<th>$Z &lt; -1.0$</th>
<th>$Z &lt; -2.0$</th>
<th>$Z &lt; -3.0$</th>
</tr>
</thead>
<tbody>
<tr>
<td>HAZ</td>
<td>Mild Stunting</td>
<td>Moderate Stunting</td>
<td>Severe Stunting</td>
</tr>
<tr>
<td>WAZ</td>
<td>Mild Underweight</td>
<td>Moderate Underweight</td>
<td>Severe Underweight</td>
</tr>
<tr>
<td>WHZ</td>
<td>Mild Wasting</td>
<td>Moderate Wasting</td>
<td>Severe Wasting</td>
</tr>
</tbody>
</table>

**HAZ:** Is height for age.

**WAZ:** Is weight for age.

**WHZ:** Is weight for height.
2.10.2.2.3. **Cardiovascular examination:** The children were examined while they were calm and in a comfortable position. The examination include measurement of the blood pressure using an appropriate paediatric cuff covering two third of the upper left arm and plotted against normal for age. The pulse characteristic including rate, volume, and character were determined from the radial artery and from the brachial artery in infants. The femoral artery is examined for a radio-femoral delay. The pericordium was then examined to locate the apex beat, presence of left parasternal heave, thills, and murmurs. Oxygen saturation assessed by using pulse oximetry. The lung bases were auscultated for basal crepitations.

2.10.2.2.4. **Abdominal examination:**

Examination of the abdomen including palpation for hepatomegaly, splenomegaly and percussing for ascites.

2.10.2.2.5. **Central nervous system examination:**

This included examination of the cranial nerves, upper limbs and lower limbs for power, tone and reflexes.

All the physical finding were compared to the data recorded before interventional treatment in the medical records.
2.10.3. **Investigations**: The following investigations were done post-operative and compared with preoperative results:

1. Hemoglobin level and packed cell volume (PCV).
2. Echocardiography.
3. Cardiac Catheterization Results (in selected patients) are recorded. All the investigations were done in the SHC.

Echocardiography and cardiac catheterization was performed by a paediatric cardiologist before and after the treatment.

2.10.4. **Data entry and statistical methods:**

The questionnaire was coded, and a master sheet was constructed to arrange the raw data. The tables were then drown and descriptive statistics measured. Data was analyzed using computer program the Statistical Package for Social Sciences System (SPSS). Data was expressed as percentage. Univariate analysis to assess for association between demographic and clinical variable with selected items of clinical presentation, general well-being, cardiac morbidity, education, social interaction, and physical activity, use of medication, growth and
developmental progress was performed with the Chi-square test. Level of significance was set at p value <0.05.

EPI-Info 2000 Statistical Package Computer Program was used to determine the nutritional status of children (boys and girls), by using the below indicators\(^{(133)}\).

**Indicators produced were:**

WHZ (weight for height or length Z-score)

SD (Standard Deviation)

\[ Z = \frac{(\text{Observed value}) - (\text{median reference value})}{\text{Standard deviation of reference population}} \]

**IF** WHZ was > -2SD, i.e. mild malnutrition.

**IF** WHZ was > -3SD, i.e. moderate malnutrition.

**IF** WHZ was < -3 SD, i.e. sever malnutrition\(^{(142)}\)
Scoring system was also used to assess the quality of life in different aspects; like signs and symptoms, general well-being, frequency of hospitalization, growth, physical activities, social interaction, and dependency on families after interventional therapy. Using score of two for better outcome in the QOL and one for the same outcome, and zero for poor outcome. The total of the outcome results were analyzed and a cut-off point of (70%) was used to divide the outcome to good or poor QOL. Score of more than (70%) were considered as good quality of life and score equal or below (70%) were consider as poor QOL.

2.10.5. Potential difficulties:

- Insufficient data on out patient medical records.
3. RESULTS

A total of seventy two patients with an interventional treatment done six months or more before the interview were included in this study. Parents and children (old age group) were interviewed using a questionnaire (attached as supplement) and data obtained.

3.1. Socio-demographic Character of the Study:

3.1.1. Age and gender distribution of the study group:

The age of the patients in the study group range between (6 months - 18 years). Children (<1 year) age were 6 (8.3%), between (1-<5) years were 21 (29.2%), between (5 <10 years) were 22 (30.6%), and between (10-18 years) were 23 (31.9%). Male to female ratio was 2:1. (Figure 1, 2).
3.1.2. Age at diagnosis of the study group:
Children diagnosed of age below one month were 8 (11.1%), one month to less than one year were 26 (36.1%), between 1 year to less than 5 years were 30 (41.7%), from 5 to less than 10 years were 4 (5.6%), and 4 (5.6%) children were in the age group of 10 to 18 years at time of diagnosis. (Figure 3).

### 3.1.3. Tribe distribution of the study group:

The majority of children in our study were from Arab tribe represented 52 (72.2%), 7 (9.7%) were Khordofani, 6 (8.3%) were Darfori, 4 (5.6%) were Bija, 2 (2.9%) were Nuba and one patient (1.4%) belong to equatorial tribes. (Figure 4).

### 3.1.4. Residence distribution of the study group:

Twenty eight children in the study groups were from urban areas and represented (38.9%), 27 (37.5%) were from rural areas, and the remaining 17 (23.6%) were from suburban areas. (Figure 5)
3.1.5. Socioeconomic status of the study group:

Thirty eight (52.8%) of the patients were of low socioeconomic state, 33(45.8%) were of moderate state, one patient (1.4%) belong to high social class (Figure 6).

3.2. History and Clinical data Before and After the Interventional Treatment in the Study Group:
The study showed that the major symptoms before treatment were; dyspnea, cough, and recurrent chest infections and those represented 55(76.4%), 53(73.6%), 53(73.6%) respectively. After treatment 37 patients (51.39%) had no symptoms. Fifteen (20.8%) of the symptomatic patients were found to had cough. Dyspnea and recurrent chest infections represented 8(11.1%) and 6(8.3%) respectively, (p=0.008). Other symptoms were; easy fatigue in 45(62.5%), 42(58.3%) had failure to gain weight, 37(51.4%) had cyanosis, 32(44.4%) had palpitation, 27(37.5%) had difficulty in feeding, 27(37.5%) had frontal sweating, 27(37.5%) had a history of squatting during the attack of cyanosis, 14(19.4%) had chest pain, and 8(11.1%) had convulsion before the treatment. After the treatment
easy fatigue were 7(9.7%), 4(5.6%) had failure to gain weight, those with cyanosis were 10(13.9%(p=001), palpitation were 4(5.6%), one(1.4%) had difficulty in feeding, 12(16.7%) had frontal sweating, 2(2.8%) remained to have squatting position, one(1.4%) had chest pain, and one had convulsions, as shown in (Table 1).

3.3. Health Maintenance and General Well-being:

The study showed that 48(66.7%) expressed that their health and general well-being after treatment as good, 22(30.6%) as very good and, and two patient(2.7%) did not feel well, as shown in (Table 2).

3.4. Number of Hospitalization and Cardiac Complications:

The frequency of hospital admission after treatment were as follow: No further hospitalization for 58(80.6%) compared to 17(23.6%) not being admitted before treatment (p=0.02), 11(15.3%) had decreased frequency of hospitalization, and 3(4.2%) remained with a comparable frequency of hospitalization. Before treatment
history of heart failure (HF) was found in 11 (15.3%), one patient had cerebrovascular accident (CVA) and one had sub acute bacterial endocarditis (SBE) represented (1.4%), and no history of arrhythmia was found before treatment. After treatment two
patients (2.8%) had HF, two (2.8%) developed arrhythmia, and no history of CVA or SBE recorded after treatment as seen in (Figure 7,8).

3.5. Diagnosis:

Results showed that from the 72 studied patient 24 (33.3%) were TOF, 15 (20.8%) were VSD, 5 (6.94%) were PS, 5 (6.94%) were PDA, 5 (6.94%) were ASD, 4 (5.6%) were AS, 12 (16.7%) had multiple cardiac lesions and one patient (1.4%) had AVSD (Table 3). The type of cardiac lesions was found to be affected by the gender of the patients (p=0.02), where male patients represented (66.7%), while female were (33.3%) and the majority were cyanotic lesions. The type of lesion, had no effect on the patient's social interaction, physical activity, dependency, schooling, nutritional state, family caring and cardiac complications neither the growth state after the treatment (p>0.05).
3.6. Type, Number and Complications of Interventional Treatment:

Patients who underwent surgical procedures were 48 (66.7%), two of them were palliative, while interventional catheterization patients were 19 (26.4%). Interventional treatment included patients who had devices closure of VSD, PDA and ASD represented 2 (10.53%), 5 (26.32%), 5 (26.32%) respectively, where 5 patients (26.32%) with PS had balloon dilatation, and 2 patients (10.53%) had balloon septostomy. Five patients (6.9%) had both surgical treatment and interventional catheterization. Sixty-four patients (88.9%) had one procedure throughout their period of treatment follow up while 8 patients (11.1%) had two procedures (Figure 9). 60 (83.3%) of the patient had no further complications after treatment while 12 (16.7%) developed complications which were; complete atrioventricular block needing permanent pacemaker insertion in 4 patients (5.6%), pleural effusion 4 (5.6%), 2 patients
(2.8%) had pericardial effusion and 2 patients (2.8%) had septicemia. Period of hospitalization post interventional catheterization was
24-36 hours compared to 7 days in the surgical intervention. 58 of the patients (80.6%) were hospitalized for less than 7 days while 14 patients (19.4%) stay more than 7 days post procedures including one patient who had catheter intervention (Figure 10). Post interventional treatment complications seem to had no effect on the medication used by the patient (p=0.4).

3.7. Duration of Follow-Up after the Interventional Treatment:

Children selected for the study had been follow-up for 6 months to 4 years; the mean was 1.08 years (1.08±0.725SD). Duration of follow-up after treatment showed no affect on the health state and general well-being of patients (p=0.5), but had a significant effect on both weight gain (p=0.01), and patient's height (p=0.05).

3.8. Education Level, School Attendance, Days of Absents and Academic Performance in the Study Group:
Before treatment thirty four of the patients (47.2%) were not attending school or stopped schooling, 7 (9.7%) were in kinder garnet, 29 (40.3%) were basic school pupils, and two (2.8%) were
secondary school pupils (Figure 11). Before treatment 20 (52.6%) of those who attended school had good school attendance while 18 (47.4%) had a poor attendance. After interventional treatment 32 (84.2%) were found to have good attendance, whereas 6 (15.8%) remained to have poor attendance (p=0.1). Regarding academic performance; before treatment 17 (44.7%) had good performance, 9 (23.7%) had fair performance, 8 (21.1%) had excellent performance, and 4 (10.5%) had poor performance. After treatment the percentage remained the same for those with good and excellent performance and increased in fair performance to 12 (31.6%) while one patient (2.6%) remained with poor performance (p=0.00) (Figure 12). 21 (55.3%) of those attending school had a frequency of absentism of more than 4 days per week, while 5 (6.9%) used absent themselves for 2-4 days per week, and 12 (31.6%) for less than two days per week before treatment. After treatment 32 patients (84.2%) had less than two days of absentism and 6 (15.8%) had more than 4 days of absentism (Figure 13).
3.9. Physical Activity after the Interventional Treatment in the Study Group:
From the 72 patients of our study group, 66 (91.7%) of them showed better activity while 4 patients (5.6%) remained with the same activity and two (2.8%) had less physical activity. According to the NYHA classification the majority of the patients before treatment were in NYHA class I and represented 39 (54.1%) while 8 (11.1%) were in class 1, 7 (9.7%) were in class III, and 3 (4.2%) were in NYHA class IV and 15(20.9%) had no dyspnea. After treatment 7 (9.7%) of them remained in NYHA class I, 27 (37.5%) were in class I, and 1 (1.4%) was in class III, while 37 (51.4%) had no dyspnea (p=0.008).

3.10. The Social Interaction after the Interventional Treatment in the Study Group:

Sixty six of the patients (91.7%) developed better interaction while two patients (2.8%) were depressed and two (2.8%) remained at the same level of interaction. Both physical activity and hemoglobin level were found to have an effect on the child's social interaction (p=0.00) (p=0.01), respectively(Figure 14).
3.11. Family Care of the Child after the Interventional Treatment:

The family offered less care compared to that before treatment for 34 patients (47.2%), 24 (33.3%) had more care from
family and 14 (19.4%) remained to have same care. Family caring of the child had no effect on his/her social interaction (p=0.6) (Figure 15).

3.12. The Child Dependency on the Family after the Interventional Treatment:

Forty-three of the patients (59.7%) became less dependant on their families, 21 (29.2%) remained with the same dependency while 8 (11.1%) became more dependent. No effect of the child's dependency was reported on his/her social interaction (p=0.12) (Figure 16).
3.13. The Nutritional Intake after the Interventional Treatment:

The study showed that 57 (79.2%) of the patients had increased nutritional intake, 9 (12.5%) had the same intake and 6 (8.3%) had fewer intakes compared to that before the treatment. (Figure 17)

3.14. Medications:
The study showed that 49(68.1%) had no more medical therapy after the interventional treatment, 14(19.4%) had decreased number of medication, 7(9.7%) had more medication and two patient remained to have the same medical treatment (Figure 18).

3.15. Developmental Progress:

Before treatment gross motor delay was found in 25(34.7%) of the patients, fine motor delay in 19 (26.4%), 4 patient (5.6%) had social delay and 3 patient (4.2%) had language delay. After treatment nine patients (12.5%) remained with gross motor delay, 5 (6.9%) had fine motor delay, 3 patient (4.2%) had language delay and no patient had social delay (p=0.032) (Figure 19).
3.16. Physical Examination:

3.16.1. General examination:

Before treatment 65 patients (90.3%) looked ill while 6 (8.3%) remained ill after treatment. Fourteen patients (19.4%) were pale, and 30 (41.7%) had cyanosis, two patient had plethora and two had lower limb edema each represented (2.8%). After treatment two patients (2.8%) were pale, 12(16.7%) patients were cyanotic and no patient was found to have plethora or lower limb edema.

3.16.2. Vital signs:
3.16.2.1. **The pulse**: Before treatment, from the 72 patients studied, 5 (6.9%) were found to have abnormal heart rate (tachycardia), with no abnormality in rhythm. The pulse volume was found to be small in 5 patients (6.9%), collapsing in 9 patients (12.5%), 7 patients (9.7%) lost the synchronicity of the pulse, 5 (6.9%) had radio femoral delay and 3 patients (4.2%) had absent femoral pulses. After treatment 4 patients (5.6%) had tachycardia, 4 patients (5.6%) developed irregular rhythm and they need permanent pacemaker. All patients had normal volume, synchronous pulse with no radio femoral delay.

3.16.2.2. **Blood pressure (BP)**:

Before treatment 65 patients (90.3%) had a normal BP, 4 patients were (5.6%) found to have a high BP, and 3(4.2%) had a low BP. None of the patients had abnormal BP after the treatment.

3.16.3. **Anthropometric measures by Z-score**:

3.16.3.1. **Height for age before the interventional treatment**:

The study showed that 11 patients (15.3%) were (<-3) z-score, 12 (16.7%) were, (-3 to -2.01) z-score, 18 (25%) were (-2 to -1.01) z-score, 20 (27.8%) were (-1.00 to 0.00) z-score, 7 (9.6%) were (0.01 to-
1.00) z-score 2(2.8%) were (1.01to-2.00) z-score, 2(2.8%) were (>2.00) z-score (Table 4).

3.16.3.2. Height for age after the interventional treatment:

After treatment 10 patients(13.9%) were (<-3) z-score, 12 (16.7%) were (-3- -2.01) z-score, 21 (29.2%) were (-2to-1.01) z-score, 20 (27.8%) were (-1.00-0.00) z-score, 7 (9.6%) were (0.01-1.00) z-score, 1 (1.4%) was (0.01-2) z-score, 1(1.4%) was (>2.00) (p=0.00) (Table 4).
3.16.3.3. **Weight for age before the interventional treatment:**

The study showed that 16 patients (22.2%) were (<-3) z-score weight for age, 23 (31.9%) were (-3 to -2.01) z-score, 19 (26.4%) were (-2 to -1.01) z-score, 12 (16.7%) were (-1.00 to 0.00) z-score, 1 (1.4%) was (0.01 to 1.00) z-score, 1 (1.4%) was (>2.00) z-score (Table 5).

3.16.3.4. **Weight for age after the interventional treatment:**

Nine patients (12.5%) were (<-3) z-score, 18 (25%) were (-3 to -2.01) z-score, 22 (30.6%) were (-2 to -1.01) z-score, 20 (27.8%) were (-1.00 to 0.00) z-score, 1 (1.4%) was (0.01 to 1) z-score, one patient (1.4%) was (1.01 to 2) z-score, and one patient (1.4%) was (>2.00) z-score (p=0.001) (Table 5).

3.16.3.5. **Weight for height before interventional treatment:**
Nine patients (12.5%) were (<-3) z-score, 18(25%) were (-3 to -2.01) z-score, 12(16.7%) were (-2 to -1.01) z-score, 26(36.1%) were (-1.00 to 0.00) z-score, 5(6.9%) were (0.01 to 2.00) z-score, 1(1.4%) were (1.01 to 2.00) z-score, 1(1.4%) were (>2.00) z-score (Table6).

3.16.3.6. Weight for height after the interventional treatment:

Four patients (5.6%) were (<-3) z-score, 10(13.9%) were (-3 to -2.01) z-score, 13(18.1%) were (-2 to -1.01) z-score, 34(47.2%) were (-1.00 to 0.00) z-score, 8(11.1%) were (0.01 to 1) z-score, and 3 patient (4.2%) were (1.01-2) z-score (p=0.00) (Table 6).
3.16.4. Cardiovascular examination (CVS):

Before treatment; the study showed 11(15.3%) of the patients had abnormally located apex beat, 7(9.7%) had a abnormal beat character, 4(5.6%) had left a Para sternal heave (LPH), 33(45.8%) had a thrill and 67(93.1%) had a murmur, and 4(5.6%) were found to have basal lung crackles. After treatment 6(8.3%) had a abnormally located apex, 4(5.6%) had an abnormal character, one patient(1.4%) had a LPH, 5(6.9%)had a palpable second heart sound , 22 patients (30.6%) had a thrill and 55(76.4%) had a murmur, no patient was found to have basal lung crackles, and 67(93.1%)had improved oxygen saturation after the treatment, as the saturation was ranging from (65%-100%)before treatment to(91%-100%) after treatment.

3.16.5. Abdominal examination:
Before treatment; liver enlargement was found in 9 patients (12.5%) while one patient had a splenomegaly and one patient had ascites, each represented (1.4%). After treatment none of the patients showed abnormal abdominal findings.

3.16.6. Central nervous system examination (CNS):

Before treatment; it was found that three patients (4.2%) had an abnormal CNS examination. Two out of three patients (2.8%) had generalized hypotonia and one (1.4%) had a hemiplegia. After treatment one patient remained hypotonic and one hemiplegic, each represented (1.4%), while one patient developed a new spastic quadriplegia (1.4%).

3.17. Hematological Indices (Hb%, PCV) and Post Interventional treatment cardiac investigations:

3.17.1. Hematological indices (Hb%, PCV):

Abnormal hematological indices before treatment were found in 33 (45.8%) of the patients, as 20 of them (27.8%) were found anemic and 13 (18%) polycythemic. After treatment 5 patients had abnormal indices (6.9%), all were found to be anemic
and none had polycythemia (Table 7). The blood indices showed improvement that was not statistically significant, and were found to have no effect on the growth state after treatment (p=0.5).
3.17.2. Cardiac investigations; (Echocardiography and catheter results):

After treatment echocardiography was abnormal in 21 patients (29.2%) with a mild shunt residual in 10(13.9%) and with significant shunt residual in 11 patients (15.3%). Two patients (2.8%) where recatheterized after treatment; one had surgical pulmonary valvotomy and post operative catheterization showed severe pulmonary stenosis, and the other had palliative pulmonary artery band and post operative catheterization showed high pressure gradient of the main pulmonary artery (i-e loose band).

The residual cardiac lesions after the interventional treatment was found to affect the social interaction (p=0.01), but showed no significant effect on NYHA classification (p=0.2), the child's physical activity (p=0.2), his dependency on his family (p=0.7), his nutritional intake (p=0.4), his general well-being (p=0.8) or his growth state (p=0.4).
3.18. Quality of Life Scores:

A QOL score consisting of: (1) signs and symptoms (2) general well-being (3) frequency of hospitalization (4) growth state (5) social interaction (6) physical activity (7) dependency on the family.

The possible maximum score for the QOL was 10. The attained outcome score ranged from 2 to 10. Sixty four of the patients (88.89%) had a good QOL in the different aspects mentioned above, as they score more than (70%), while poor QOL outcome was found in eight patients (11.11%) as shown in (Figure 20).
Chapter four

4. DISCUSSION

The study was designed to evaluate the quality of life after cardiac interventional treatment in different aspects; including general well-being, complications, frequency of hospitalization, growth and developmental progress, physical activity, social interaction, education and academic performance, family caring and child dependency on the family; all compared to those before interventional treatment.

4.1. Socio-Demographic Characteristic of the Study Group:

4.1.1. Age and gender distribution of the study group:

Large number of the patients (31.9%) was between 10-18 years. The median age at the time of the study was 7 years, the range being 6 months to 18 years. That was different from McCrindle study which reported median age of 2.9 years, ranging from one day to 20 years (115). This may be due to the recent introduction of cardiac interventional treatment in Sudan and that surgery is done at an older age due to late diagnosis and limited
technical facilities as surgery for patients weighting less than 7kg needs specialized post operative intensive care facilities. This is currently not available in Sudan and open heart surgery is not usually done below 7kg. Regarding gender distribution, the study showed that 66.7% were males and 33.3% were females. This goes with the findings of the previous study.

4.1.2. Age at diagnosis and Age at intervention of the study group:

Although there was some improvement in detecting patients with CHD in Sudan, a large percentage of patients (41.7%) were diagnosed after one year of age, and (52.8%) had interventional treatment after age of 5 years which was late compared to Western literature as in Renato study (54)

4.1.3. Tribe distribution of the study group:

The study includes most of the ethnic groups and showed that 72.2% of the patients were from Arab tribes, reflecting the representation of this ethnic group in the community, and is consistent with previous studies in Sudan(21,24).
4.1.4. **Residence Distribution of the Study Group:**

The majority of the study group came from urban areas. This was consistent with the fact that, urban population benefited most from health services, and is consistent with previous study in Sudan\(^{(24)}\).

4.1.5. **Socioeconomic status of the study group:**

Most of patients (52.8%), were of a low socioeconomic status in contrast to the findings in a previous study which showed (51%) of the patients belong to moderate social class (24). This reflects the availability of such treatment to all community classes inspite of its cost. Fortunately this socioeconomic background did not influence children's social interaction post intervention (p=0.7), this reflects sociality as part of our culture in the community.

4.2. **Clinical Data Before and After the Interventional Treatment in the Study Group:**

The study showed that 72.2% of the patients had no symptoms after treatment. The most frequent pretreatment symptoms were; dyspnea, cough and recurrent chest infections and had improved significantly after treatment (p=0.008). This
result was different from the Australian result as 93% of their patients found to be asymptomatic after treatment\textsuperscript{(86)}. These differences are explained by the differences in the set-up of the centre in developed countries, however our results are acceptable when we consider our limited facilities.

The general physical examination of the study group was acceptable after treatment as (91.7%) of them looked well. There was ongoing neurological deficit in 2.4% which was consistent with research findings from Canada by Limperopoulos\textsuperscript{(138)}.

4.3. Health Maintenance and General Well-Being:

Most of the patients in the study group (97.3%) felt that their general health was good and very good after treatment which was higher than results obtained from Netherlands by Meijboom, where 84% were in good health\textsuperscript{(89)}. It can be explained by the long duration of follow-up after the procedure as it was 14.5±2.6 year in the study mentioned above, compared to maximum of 4 year in our study group and the fact that in the latter study more complex surgery was done and patients were younger.

4.4. Number of Hospitalization and Cardiac Complications:
The study showed that there was significant improvement in patient frequency of hospitalization \((p=0.02)\) as 80.6% had no further admissions. Hospitalization due to cardiac complication was also improved as 2.8% developed HF compared to 15.3% before treatment, with no more CVA or SBE among them. This result was acceptable according to our set up in Sudan.

4.5. Diagnosis:

The most common diagnosis was TOF which represented 33.3%, others diagnosis were VSD, ASD, PDA, PS, AS, multiple cardiac lesions and AVSD. This is not consistent with the results from Finland where the acyanotic group were the most common lesions\(^{(110)}\). It reflects the fact that TOF patients tend to be diagnosed late and survive longer. The type of the cardiac lesion had significant correlation with the gender of the patients \((p=0.02)\), as most of the cyanotic patients were male with a ratio of 2:1. We found that there was no direct effect of the type of the cardiac lesion on the child interaction, playing activity, dependency, family caring, nutritional intake, school level and attendance or performance neither on the complication, growth or development in all its aspects \((p>0.05)\). This is probably due to the short follow-
up period in our study group, and the insignificant residual together with the improvement in the blood indices after treatment.

4.6. Type, Number and Complications of Interventional Treatment:

The study showed that 88.9% of the patients had one procedure throughout the period of treatment and follow up, and only 8 patients had a second procedure. 12 patients (16.7%) developed complication after intervention, this incidence was higher compared to 4.1% reported by Agnoletti from France (91) and to 8.8% reported by Renato from Toronto (54), although they interfere in large number of patients compared to that in our study. The major complication was found to be complete heart block represented 5.6% compared to (0.41%) in the previous study (54). This complication needed life long follow up as the pacemaker will need change every 8 to 10 years which is a burden on the child and family. Pleural effusion represented 5.6%, and 19.4% of those patients needed admission for more than one week after treatment, however, this is usually a transient complication. The results was found to be comparable to the findings by
Meijboom from Netherlands where 89% of the patients were found to be free of a second intervention, but in their study the number of patients was larger and period of follow-up was long (14.5 year) (89), compared to maximum of 4 years in our study. Post interventional complication had no effect on the use of cardiac medication (p=0.4), as most of these complication were transient apart from those needed pacing. The duration of follow up was found to have no significant effect on the general well-being of the patients (p=0.5). This might be explained by the immediate improvement of hemodynamic state after intervention.

4.7. Education Level, School Attendance, Days of Absence and Academic Performance in the Study Group:

Before treatment 34 patients (47.2%) were not attending school before treatment, that was higher than found by Samanek were (35.5%) had delay school attendance (97). This is probably
due to the impact of the illness before treatment, and to family's overprotection, that reflects negatively on their schooling and self dependency.

Many of our study group were basic school pupil (40.5%), among them (27.8%) had good attendance. Although there was post interventional improvement in their attendance (43.1%), it did not reach statistical significance (p=0.1). 23.6% of the children had good performance, 12.5% were fair, and 11.1% were excellent, while poor performance were 5.6%. They showed significant improvement after treatment (p=0.00), where one patient remained with poor performance 1.4%.

4.8. Physical activity after the Interventional Treatment in the Study Group:

The majority of the patients (91.7%) showed better activity, (5.6%) remained in the same activity and (2.8%) became less active. The majority of the patients were in NYHA class 11 and showing significant improvement after treatment (p=0.033). This is consistent with findings from Australia by Tefuarani. They
related their symptoms to the presence of mild pulmonary hypertension and the presence of residual defects. The small number of patients in our results can be related to the increased incidence of residual defects or to lack of education regarding the physical activities guide line, unlike the case in Martil’s results\(^{(99)}\), where they found restriction of patients activities after the procedure which was not standardized by the guide line of activities.

4.9. Social Interaction after the Interventional Treatment:

Sixty six of the patients (91.7\%) developed better interaction, while two patient (2.8\%) were depressed and two (2.8\%) remained at the same level of interaction. This is not consistent with the findings of Mccrindle where behavior problems were found in (23\%) of the patients, anxiety in (17\%), and depression in (17\%)\(^{(115)}\). It could be explained because less number of interventions was performed in our study group, and the shorter interval period of follow-up. The improvement of the hemodynamic status and physical activity, influence children interaction significantly (p=0.01) (p=0.00). This can be explained by the Turkish researchers findings where they identified worsening
and severity of the hemodynamic status at surgical repair as predictive factors of behavioral problem\textsuperscript{(114)}.

4.10. Family Care of the Child after the Interventional Treatment:

Before treatment (52.7\%) of the patients families paid the same or more care towards their child's health state, while (47\%) received less attention. This reflects the need to involve the family as an important part of the management and to insure having accurate information, and to reinforce the positive, normal contribution towards their children's management.

4.11. The Child Dependency on the Family after the Interventional Treatment:

Many of our study group (40.3\%) was still dependant on their families after treatment. This goes with the findings of Utens (119), who reported that leading a dependant life was the most common negative effect. Our results reflect the need to encourage families to guide their children toward independency and to have a positive contribution toward their daily life. This dependency
did not affect their social interaction (p=0.12), probably due to the improvement of their general health state.

4.12. The Nutritional Intake after the Interventional Treatment:

The study showed that 57 (79.2%) of the patients had increased nutritional intake, 9 (12.5%) had the same intake and 6 (8.3%) had less intake compared to that before the treatment. This reflects the degree of improvement in general well-being and physical state.

4.13. Medications:

The study showed that 49 (68.1%) had no more medical therapy after interventional treatment, and that was not consistent with the result found by Meijboom from Netherlands where 89% had been free of medications\(^{109}\). This might be related to the higher incidence of residual lesions in our study group.

4.14. Developmental Progress:

After treatment (12.5%) of the patients had gross motor delay, (6.9%) had fine motor delay and (4.2%) had language delay. The results showed deficiency in the GM/FM and language
which was consistent with the findings reported by Wray, Limeripoulos and Weinberg\textsuperscript{(110,138,139)}. This might be related to maternal overprotection that hinders their motor progress. There was significant improvement in the social component (p=0.032). We found no significant correlation of the duration of follow up after the intervention and the developmental progress (p>0.05) in all its aspect. This in fact reflects the nature of such lesions.

4.15. Anthropometric measures by Z-score:

The study showed that before treatment severe malnutrition was reported in 37.5% (WHZ >-3), and moderate to mild malnutrition in 62.5%. After treatment, these figures dropped to 30.5% for severe malnourish, and 69.4% became moderate malnutrition. The results reflects significant improvement in their weights, and heights after treatment (WAZ, WHZ, HAZ) (p=0.001), (p=0.00), (p=0.00), respectively. The duration of follow-up after treatment had positive correlation with the weight (p=0.01) and weight for height (p=0.05). No difference between the type of cardiac diagnosis on the different aspects of the growth (p>0.05), and the growth found to have no effects on children's
gender (p>0.05) after treatment. This probably due to the improvement of their general well-being, hematological indices and the insignificant shunt residual after treatment in both sexes.

4.16. Hematological Indices (Hb%, PCV) and Post Interventional Treatment Cardiac Investigations:

4.16.1. Hematological indices (Hb%, PCV):

Abnormal hematological indices were found in (45.8%) of the patients; (27.8%) of them were anemic and (18%) were polycythemic. Improvement after treatment was notice but did not reach statistical significant (p>0.05).Where (6.9%) of the patients had abnormal indices; anemia was found in (5.6%) and none of the patients had polycythemia. There was no correlation between the hemoglobin state and the growth (p>0.05) after treatment. This reflects the fact that many other factors contributed to growth process, like for psychological state.

4.17.2. Cardiac investigations; (Echocardiography and Catheter results):
Residuals lesions were found in (29.2%) of the patients after treatment; (15.3%) of these residuals were insignificant. The study showed positive correlation (p=0.01) of the shunt residual on the interaction, but not on the physical activity, child dependency on family, the nutritional intake or the general wellbeing (p>0.05). This could be explained by the fact that most of these residual lesions were insignificant.

4.17. Quality of Life Scores:

The majority of the patients (88.89%) were found to have good QOL; that was done by evaluating the aspects of signs and symptoms, general well-being, frequency of hospitalization, growth state, social interaction, physical activity, and dependency on family of the study group. While 11.11% of the patients were found to have poor QOL. The results were encouraging especially in our current set-up, but more efforts are needed to improve QOL of these children. Early diagnosis and early establishment of medical and interventional treatment is vital to improve QOL. This needs increasing awareness of physicians and pediatricians about CHD and also needs availability of catheterization and surgery at affordable cost. After treatment, social and nutritional advice
should continue to consolidate the general wellbeing that follows treatment. Parents can be encouraged to form support groups to discuss the problems of their children with each other and with health care providers.

4.2. CONCLUSION

- Most children with congenital heart disease were diagnosed late after the age of one year, and almost half of them had interventional therapy after the age of five.
- Interventional cardiac treatment (catheter based and surgical) for most of the common CHD is available to children in Sudan even to those of low socioeconomic class inspite of its cost.
- There was significant improvement of QOL regarding general well-being, health state and frequency of hospitalization after treatment.
- The majority of the patients showed much improvement in their physical activity, social interaction and 68.1% needed no more medication after intervention.
- Interventional therapy had significant positive effects on the weight and height of the patients.
• There was improvement on the motor development that was not statistically significant after treatment.

• Disappointingly, family over caring hindered children's schooling and leading of independent life.
4.3. RECOMMENDATIONS

1. Early detection of CHD by increasing awareness of medical staff and improving the rate of referral to the cardiac centres.

2. Awareness of preventive measures helps in decrease the prevalence of congenital heart disease.

3. Improving and upgrading of the available cardiac interventional facilities to include larger numbers of patients; younger age groups and wider range of interventions at affordable cost.

4. Introduction of cardiac services for the management of these patients in both large cities and suburban areas.

5. Promotion of parents' health education directly or through support groups to ensure their cooperation and full understanding of their children conditions.

6. Long-term follow-up studies of these children are needed to look at their QOL.
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59. Lillehei CW, Cohen M, Warden HE. The direct vision intracardiac correction of congenital anomalies by controlled cross circulation: Results in 32 patients with ventricular


84. Krol Y, Grootenhuis MA., Destree-Vonk A, Lubbers LJ, Koopman HM, Last BF. Health related quality of life in


95. Grag R, Yusuf S. The collaborative on ACE inhibitor trials. Overview of randomized trial of angiotensin converting


113. Casey FA, Sykes DH, Craig BG, Power R, Mulholland HC. Behavioral adjustment of children with surgically palliated


142. Z-score.
http://ww.cdc.gov/epi_info/
### 0- Study DATA

<table>
<thead>
<tr>
<th>serial No.</th>
<th>Tel No.</th>
<th>Date</th>
</tr>
</thead>
</table>

### 1- Personal data

1-1 Name: 
1-2 Age: 

<table>
<thead>
<tr>
<th>Age group</th>
<th>Option</th>
</tr>
</thead>
<tbody>
<tr>
<td>a- (6/12 üù &lt; 1 y)</td>
<td>b- (1 y üù &lt; 5y)</td>
</tr>
<tr>
<td>c- (5 üù &lt; 10)</td>
<td>d- (10 üù 18)</td>
</tr>
</tbody>
</table>

1-3 Age at Diagnosis: 

<table>
<thead>
<tr>
<th>Option</th>
</tr>
</thead>
<tbody>
<tr>
<td>a- (&lt; 1 month)</td>
</tr>
<tr>
<td>c- (1y üù 5y)</td>
</tr>
<tr>
<td>e- (10 üù 18)</td>
</tr>
</tbody>
</table>

1-4 Gender: 

<table>
<thead>
<tr>
<th>Option</th>
</tr>
</thead>
<tbody>
<tr>
<td>a- (male)</td>
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1-5 Ethnic group: 

1-6 Residence: 

<table>
<thead>
<tr>
<th>Option</th>
</tr>
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<tr>
<td>a- Rural</td>
</tr>
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### 2- Symptoms at time of interview versus symptoms before treatment

<table>
<thead>
<tr>
<th>Symptom</th>
<th>before treat.</th>
<th>After treat.</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-0 Dyspnoea</td>
<td>a- yes</td>
<td>b- no</td>
</tr>
<tr>
<td>2-1 NYHA</td>
<td>a- class I</td>
<td>c- class III</td>
</tr>
<tr>
<td>2-2 cough</td>
<td>1- yes</td>
<td>2- no</td>
</tr>
<tr>
<td>2-3 Bluish discoloration</td>
<td>1- yes</td>
<td>2- no</td>
</tr>
<tr>
<td>2-4 Recurrent chest infection</td>
<td>1- yes</td>
<td>2- no</td>
</tr>
<tr>
<td>2-5 palpitation</td>
<td>1- yes</td>
<td>2- no</td>
</tr>
<tr>
<td>2-6 Difficulty in Feeding</td>
<td>1- yes</td>
<td>2- no</td>
</tr>
<tr>
<td>2-7 Frontal Sweating</td>
<td>1- yes</td>
<td>2- no</td>
</tr>
<tr>
<td>2-8 Squatting</td>
<td>1- yes</td>
<td>2- no</td>
</tr>
<tr>
<td>2-9 Easy Fatigue</td>
<td>1- yes</td>
<td>2- no</td>
</tr>
<tr>
<td>2-10 Failure to gain wt</td>
<td>1- yes</td>
<td>2- no</td>
</tr>
<tr>
<td>2-11 increase wt gain</td>
<td>1- yes</td>
<td>2- no</td>
</tr>
<tr>
<td>2-12 convulsion</td>
<td>1- yes</td>
<td>2- no</td>
</tr>
<tr>
<td>2-13 chest pain</td>
<td>1- yes</td>
<td>2- no</td>
</tr>
<tr>
<td>2-14 Is he/she generally well being?</td>
<td>1- yes</td>
<td>2- no</td>
</tr>
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### 3- Past History from medical records

<table>
<thead>
<tr>
<th>Option</th>
</tr>
</thead>
<tbody>
<tr>
<td>a- increased</td>
</tr>
</tbody>
</table>

| Number of hospital admission after treatment | 1-increased | 2-decreased | 3-none |
3-2 history of heart failure a- yes b- no
3-3 H of Arrythmia a- yes b- no
3-4 H of stroke (CVA) a- yes b- no
3-5 H of SBE a- yes b- no
3-6 other specify ………………..
3-7 No and Types of intervention treatment received:

<table>
<thead>
<tr>
<th>Type</th>
<th>Surgery</th>
<th>Catheter</th>
</tr>
</thead>
</table>

2- Number ………………………

3- Complication a- yes b- no

4- Hospital stay a- ≤7 days b- >7 days

5-period after treatment……

4- Development history

<table>
<thead>
<tr>
<th>Development</th>
<th>Before</th>
<th>After</th>
</tr>
</thead>
</table>

4-1 Early childhood development a- normal b- delay
4-1-1 Gross motor a-normal b-delay
4-1-2 Fine motor a- normal b- delay
4-1-3 Social a- normal b- delay
4-1-4 Language a- normal b- delay

4-2 School level:

<table>
<thead>
<tr>
<th>School Level</th>
<th>Kindergarten</th>
<th>Basic School</th>
<th>Secondary School</th>
</tr>
</thead>
</table>

4-3 School attendance a- poor B- good

4-5 School performance a- Excellent b- good c- Fair d- poor

4-6 No. of days absent from school per week a- < 2 days b- 2-4 days c- > 4 days

6- Diagnosis:

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>VSD</th>
<th>ASD</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>AVSD</td>
<td>PDA</td>
</tr>
<tr>
<td></td>
<td>PS</td>
<td>TOF</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

7- Social history & personal

7-1 Interaction after treatment

<table>
<thead>
<tr>
<th>Interaction</th>
<th>depress</th>
<th>interact</th>
<th>The same</th>
</tr>
</thead>
</table>

7-2 Playing activity after treatment

<table>
<thead>
<tr>
<th>Activity</th>
<th>less</th>
<th>the same</th>
<th>better</th>
</tr>
</thead>
</table>

7-3 Family care to the child after treatment compare to before treatment

<table>
<thead>
<tr>
<th>Family Care</th>
<th>same</th>
<th>less</th>
<th>more</th>
</tr>
</thead>
</table>

7-4 Child dependency on family after treatment compare to before treatment:

<table>
<thead>
<tr>
<th>Dependency</th>
<th>same</th>
<th>less</th>
<th>more</th>
</tr>
</thead>
</table>

7-5 Nutritional intake after treatment compared to before treatment

<table>
<thead>
<tr>
<th>Nutritional Intake</th>
<th>same</th>
<th>less</th>
<th>more</th>
</tr>
</thead>
</table>

7-6 Socioeconomic state a- low b- moderate c- high

8. Drug history:

8.1 Number of medication after treatment:

<table>
<thead>
<tr>
<th>Number</th>
<th>None</th>
<th>decreased</th>
<th>the same</th>
<th>increased</th>
</tr>
</thead>
</table>

9. Physical examination:

9.1 Anthropometric measurements:

9.1.1 weight

<table>
<thead>
<tr>
<th>Weight</th>
<th>wt before treatment</th>
<th>wt after treatment</th>
</tr>
</thead>
</table>

9.1.2 height /length

1- before treatment cm

2- after treatment cm

9-1-3 Wt / Ht Z score before treatment a- mild b- moderate c- sever
9.2 Developmental assessment:

<table>
<thead>
<tr>
<th></th>
<th>1) Normal</th>
<th>2) Abnormal</th>
<th>before</th>
<th>after</th>
</tr>
</thead>
<tbody>
<tr>
<td>a- GM</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>b- FM</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>c- Social</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>d- Language</td>
<td></td>
<td></td>
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</table>

9-3 General

<p>| | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
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<th></th>
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<tbody>
<tr>
<td>a- Look</td>
<td>1- well</td>
<td>2- ill</td>
<td></td>
<td></td>
</tr>
<tr>
<td>b- Anaemia</td>
<td>1- yes</td>
<td>2- no</td>
<td></td>
<td></td>
</tr>
<tr>
<td>c- Cyanosis</td>
<td>1- yes</td>
<td>2- no</td>
<td></td>
<td></td>
</tr>
<tr>
<td>d- Plethora</td>
<td>1- yes</td>
<td>2- no</td>
<td></td>
<td></td>
</tr>
<tr>
<td>e- L.L oedema</td>
<td>1- yes</td>
<td>2- no</td>
<td></td>
<td></td>
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</table>

9-3 CVS  9-3-1 pulse ..............

<p>| | | | | |</p>
<table>
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<td>a- normal</td>
<td>b- tachycardia</td>
<td>c- bradycardia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>a- regular</td>
<td>b- irregular</td>
<td>c- large</td>
<td></td>
<td></td>
</tr>
<tr>
<td>a- yes</td>
<td>b- no</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>a- yes</td>
<td>b- no</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>a- yes</td>
<td>b- no</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>a- yes</td>
<td>b- no</td>
<td></td>
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</table>

9-3-10 Chest: basal crackle

<p>| | |</p>
<table>
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<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>a- yes</td>
<td>b- no</td>
</tr>
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</table>

9-3-11 abdomen

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>i- Spleen</td>
<td>1) present</td>
</tr>
<tr>
<td>ii- Liver</td>
<td>1) present</td>
</tr>
<tr>
<td>iii- Ascites</td>
<td>1) present</td>
</tr>
</tbody>
</table>

9.3.12 CNS

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>a- Normal</td>
<td>b- Abnormal</td>
</tr>
</tbody>
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9.4 Investigation:

<p>| | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Hb:          a. normal</td>
<td>b. abnormal</td>
<td>1-highy</td>
<td>2-low</td>
<td></td>
</tr>
<tr>
<td>b. PCV ........  a- normal</td>
<td>b. abnormal</td>
<td>1-highy</td>
<td>2-low</td>
<td></td>
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9.1 Echo finding (after treatment):

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>I) shunt residual:</td>
<td>1. Yes</td>
</tr>
<tr>
<td>II) If yes,</td>
<td>1. Significant</td>
</tr>
</tbody>
</table>
| e. Catheter result in those need post-operative catheterization.................