Overview of ECP

External Counterpulsations

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ASPECTS

Overview of ECP

The Place of ECP in the Medical Arena

Economic Impact of ECP & Cost Benefits

Academic Impact of ECP and Job Creation
Introduction to External Counterpulsation Therapy (ECP)

• Non-invasive, non-surgical outpatient treatment for patients suffering from coronary artery disease, heart failure and other co-morbidities.

• Clinical studies show most patients experience a reduction in angina and are able to return to an active lifestyle with a single course of ECP.
**History of ECP**

**1950's** - Kantrowitz and Kantrowitz started the idea of counterpulsation by describing the principle of "phase shift" diastolic augmentation.

**EARLY 1960's**
Birtwell and Clauss produced counterpulsation by inventing the IABP

**LATE 1960's**
Scientists attempted the non-invasive technique using hydraulic systems.

**1970's**
Hydraulic device developed in Chicago called CardiAssist.
1980’s

• Zheng & Assoc produced ECP device achieving long-term symptomatic relief from chronic angina.
• 6,000 ECP patients were treated with favourable results in 1800 ECP centres in China.
• U.S. scientists began to rethink their approach to external counter pulsation.

1987

• ECP cleared for the first time in the USA by the FDA.

1990's

• Zheng device used extensively in New York.
1995

- Another American company began importing the Chinese device following the FDA's clearance to market it. This was based on equivalence to the CardiAssist device.
- ECP machine patented in the USA as Enhanced External Counterpulsation Therapy (EECP). This is just a trade name and not a new form of ECP. SECP is practiced in India ("S" - super)

2002

- ECP cleared again by FDA
- Congestive Heart Failure added as an indication.
- Medicare approved reimbursement for angina patients.
History of ECP (cont’d)

Today

Zheng Device

Pneumatic ECP Machine from China
Endorsements & Certification

- SFDA Certification
- CE Certification
- ISO German Equipment Safety Law Certification
- Exportation Certificate
How Is ECP Treatment Performed?

- Patients lie on a bed containing sets of adjustable pressure cuffs that are connected to patient’s calves, thighs and buttocks.

- Cuffs are triggered by ECG and inflated sequentially to augment blood flow into the heart during diastole.

- Video
Principles of Operation

**Diastolic Inflation**
Sequential inflate three sets of cuffs at the end of systole

- Effects:
  - Diastolic Augmentation
  - Increase Venous Return
  - Increase Coronary Perfusion
  - Increase Cardiac Output

**Systolic Deflation**
Simultaneously deflate all three sets of cuffs at the end of diastole

- Effect:
  - Systolic Unloading
  - Reduce Cardiac Workload
  - Increase Cardiac Output

**Diastolic Augmentation**
- Increase Venous Return
- Increase Coronary Perfusion

**Systolic Unloading**
- Reduce Cardiac Workload
- Increase Cardiac Output
Duration of ECP Treatment

• One-hour sessions daily, five days a week, for seven weeks to complete 35 sessions.

• Alternatively, 2 one-hour sessions, 30 minutes apart, to complete 35 sessions in 18 days.

• Patients may require more than 35 sessions for optimal benefits.
What Does ECP Do?

Causes immediate and sustained increase in coronary blood flow by:

- Dilating coronary blood vessels
- Opening dormant collateral vessels
- Stimulating the release of growth factors
- Establishing shunts from other vessels
- Forming new blood vessels
Indications for ECP

- Angina Pectoris (Stable and Unstable)
- Acute myocardial infarctions (MI)
- Cardiogenic shock
- Congestive heart failure
- Ischaemic heart disease in patients with an ejection fraction < 40 %
Other Indications for ECP

- Diabetes mellitus (Type 2)
- Chronic fatigue syndrome
- Erectile dysfunction
- Chronic Hypertension
- Strokes (CVA)
Contra-Indications for ECP

- Severe arrhythmias
- Bleeding diathesis
- Active thrombophlebitis
- Severe lower extremity vascular occlusive disease
- Presence of a documented aortic aneurysm requiring surgical repair
- Pregnancy
- Severe pulmonary hypertension/oedema (pulmonary artery > 50 mm Hg)
- Uncontrolled systemic hypertension (> 180/110 mm Hg)
- Severe aortic insufficiency
- Warfarin therapy with INR>3.0
Pathophysiology of Cardiovascular Disease

Risk Factors
- Hyperlipidemia
- Hypertension
- Diabetes
- Smoking
- Obesity
- Aging
- Physical Inactivity

Endothelial Dysfunction
- Smooth Muscle Cells Proliferation
- Nitric Oxide ↓, Endothelin ↑, Intimal Hyperplasia

Inflammation/Neurohormonal Activation
- Arterial Stiffness, LV Hypertrophy
- Atherosclerosis
- Thrombosis

Target Organ Damage
- Ischemic Heart Disease
- Myocardial Infarction
- Stroke
- Renal Insufficiency
- Peripheral Arterial Disease

Organ Failure
- Heart Failure
- End Stage Renal Disease

Disease Progression
- Pathological Remodeling
- Plaque Rupture

Death
Mechanism of Action

Hemodynamic Effects
- Systolic Unloading (cardiac workload↓)
- Diastolic Augmentation (coronary blood flow↑)
- Increase Cardiac Output (organ perfusion↑)

Improve Endothelial Function
- Vasodilation ↑
- Intimal Hyperplasia ↓
- Nitric Oxide production ↑

Collaterals Development
- Blood flow to ischemic region ↑
- Capillary density ↑

Improve Neurohormonal Factors
- BNP ↓ and ANP ↓
- Angiotensin II ↓

Reduce Arterial Stiffness
- Blood pressure ↓
- Vascular resistance ↓
- Cardiac efficiency ↑
Blood Flow in the coronary arteries before and after ECP
Clinical Evidence Demonstrating the Safety & Effectiveness of ECP

- 60% of the patients with Acute MI’s found remarkable improvement in their ECG after the 1st hour of treatment.
- 96% of the patients with severe chest pain found relief within 30 mins of ECP.

- Investigated the long term prognosis of patients who underwent ECP over a 5 year period.
- 64% of the patients remained alive and without major adverse cardiovascular events.
- Revascularization procedures not required 5 years post ECP.

- ECP significantly improved anginal symptoms assessed by reduction in mean sublingual nitrate use per day
- ECP improved endothelial function


Evaluated the safety and efficacy of ECP patients with refractory angina and severe left ventricular dysfunction with an ejection fraction <35%.

Findings showed:

- 72% of 363 patients improved from severe angina to mild/no angina.
- ECP is safe in patients with SLVD who are not candidates for PCI or CABG.
- 52% of 363 patients stopped using nitroglycerin and had significant improvement in quality of life.
2 year follow up:

- Angina reduction was maintained in 55% of patients
- Survival rate - 83%
- Event free survival - 70%
- No cardiac hospitalization - 43%
- No heart failure events - 81%

Soran et al (2007)

- Assessed the impact of ECP on emergency department visits and hospitalization rates at 6 month follow-up. The mean number of emergency department visits per patient decreased from 0.9 to 0.2 at 6 months. Mean number of hospitalizations were reduced from 1.1 to 0.3.
Change in CCS (angina) Classification

Percentage of Patients improved after ECP Treatment

- Improved 3 Classes
  - 22.0% (From Class IV to Class I)

- Improved 2 Classes
  - 39.5% (From Class IV to Class I or II from Class III to Class I)

- Improved 1 Class
  - 73.4% (From Class IV to Class I, II or III from Class III to Class I or II from Class II to Class I)

N=2,289 patients

Advantages of ECP for the Patient

- Simple, non-invasive treatment
- Safe and risk free – no surgery or hospital stay
- No recovery period required
- Treatment does not disturb patient’s daily routine
- Cost effective treatment in exchange for a more healthier and productive life
- Increases life expectancy
The Place of ECP in the Medical Arena

Cardiac Patient

- Angina
- Myocardial Infarction
- Cardiogenic Shock
- Congestive Heart Failure
**Angiogram and stent**
- Invasive procedure under anaesthesia
- Involves opening of old vessels
- Symptomatic relief from angina
- In hospital stay
- Recovery period minimum 3 days

**Cardiopulmonary Bypass**
- Grafts are used to re-establish flow
- Invasive procedure under general anaesthesia
- High risk procedure
- Only a selected number of vessels can be grafted
- Recovery period 6 weeks
- After care required
- Scar tissue formation

**External Counterpulsation**
- Non invasive procedure with no anaesthesia
- Involves establishing collaterals vessels
- Symptomatic relief from angina
- Done on an out patient basis
- No recovery period required

**Sustained Benefits of Bypass**
- Grafts could last between 1 day to 15 years
- Patients commonly still experience pain on exertion after cardiac bypass surgery
- No or little reduction in medication requirements

**Sustained Benefits of ECP**
- Benefits of ECP has shown to last for 5 years
- Patients are symptom free after a single course of ECP treatment
- Significant reduction in the dose of medication required
- Reduced hospital visits
Academic Impact of ECP and Job creation
Scope of Practice

- Clinical technologist are involved in performing organ system support, diagnostic, therapeutic and corrective procedures

- Clinical Technologist specialising in Cardiovascular Perfusion and Cardiology are the most suitable to provide this service due to their background

- Intra Aortic Balloon Pump (IABP)
Qualification

Current Qualifications
3 year Diploma – supervised practice
4 year B Tech Degree – independent practice
  - Registration with Board of Healthcare Funders
Masters Degree
Doctorate Degree (PhD)

ECP Qualifications
Four year Bachelors Degree in Clinical Technology
Fifth year - Post graduate advanced Diploma in ECP
  - registration with HPCSA as ECP Technologist
Masters Degree
Doctorate Degree (PhD)
Job Creation

- Creation of jobs for Clinical Technologists
- Creation of jobs for subsidiary staff (admin, reception, domestic, etc)
- Franchise opportunity from the company for sustainable services to all parts of RSA in the future
CURRENT ECP CENTRES IN KZN

Umhlanga

Central Durban

Pietermaritzburg

Richards Bay
News

Experts of EECP

Exhibitions

Users Home and Abroad