Association Between Apo Lipoprotein B Levels at Admission of Patients and Short-term Morbidity and Mortality After Myocardial Infarction

Sepideh Sokhanvar1, Amirhossein Khoshi2, Sanaz Hajiaghaei1, S.Nouraddin Mousavinasab1, Zahra Golmohammadi1*

1Department of Cardiology, Zanjan University of Medical Sciences, Zanjan, Iran
2Department of Clinical Biochemistry, Kerman University of Medical Sciences, Kerman, Iran
3Madani Heart Hospital, Tabriz University of Medical Sciences, Tabriz, Iran

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ABSTRACT

Introduction: Dyslipidemia is an important risk factor in cardiovascular diseases. Different studies have shown that Apolipoprotein B (Apo B) is one of the best predictors in determining cardiovascular diseases and patients follow up after cardiovascular events. We hypothesized that there is a relation between Apo B levels and cardiovascular events in patients who have myocardial infarction (MI). In addition, Apo B may be an appropriate marker for following these patients after MI. Methods: In this study, 220 patients with acute myocardial infarction were allocated at their admission to the hospital. They were followed for three months after MI and their morbidity and mortality rates were evaluated. Apo B levels were measured immunoturbidimetrically. Results: Apo B levels were significantly higher in patients with the events including coronary artery bypass grafting (CABG), percutaneous coronary intervention (PCI) and malignant arrhythmias (P = 0.001). Conclusion: Apo B levels can be an appropriate indicator of cardiovascular events in patients after MI.

Introduction

In most countries, coronary artery disease (CAD) is the leading cause of death.1 Increased amounts of low-density lipoprotein cholesterol (LDL-C) are mostly introduced as one of the major risk factors in atherosclerotic cardiovascular diseases.2 Although plasma LDL-C is proven as a predictor of CAD, it might not be the most appropriate circulatory marker. Epidemiological studies have shown that apolipoprotein B-100 (Apo B), with or without Apo A-I, is a better predictor than LDL-C and other non-HDL lipoproteins in predicting coronary artery diseases.3-5 Prospective studies in different countries reported that cardiovascular mortality rates vary from 5% in Japan to 15% in Europe, according to cholesterol levels about 5.43mmol/l (210 mg/dl). This wide range of mortality rates is due to different sizes of LDL particles; as small dense LDLs (sd LDL) are more atherogenic than others.6,7 High plasma levels of Apo B, especially elevated Apo B/Apo A-I ratio, have been established as a risk factor for CAD−; however, the relationship between Apo B levels and the short-term outcome after acute myocardial infarction are yet to be studied. This study aims to investigate the relationship between the Apo B levels at admission and the mortality and morbidity rates after acute myocardial infarction. Such a relation indicates that the elevated serum Apo B levels in myocardial infarction may be a marker necessitating secondary preventive measures.

Materials and methods

Sampling

All patients admitted to coronary care unit at Vali-asr and Mousavi hospitals in Zanjan, Iran from January 2008 to December 2008 with diagnosis of acute myocardial infarction based on WHO criteria were eligible participants. In studies of disease prevalence by the World Health Organization (WHO), MI was defined by a combination of two of three characteristics: typical symptoms (i.e., chest discomfort), enzyme rise and a typical ECG pattern involving the development of Q waves.8 The final study population consisted of 220 patients. Written informed consents were obtained from all the patients. Interviews were conducted and the clinical data were collected using a common protocol. Serum Apo B levels ≥1.2 g/L were defined as high Apo B.9 Hypertension was defined as resting systolic blood pressure ≥140 mmHg and diastolic blood pressure ≥90 mmHg. Cigarette smoking was defined as ever versus never smoked. Diabetes was defined as fasting blood glucose ≥7mmol/L or a diagnosis of diabetes needing diet or drug therapy. Total cholesterol ≥5.18mmol/L or triglycerides ≥2.26mmol/L and LDL ≥2.59mmol/L or HDL ≤1.16mmol/L and non-HDL ≥
Lipid profile analysis
Cholesterol and triglycerides were measured enzymatically (Colorimetric, Pars Azmun Co., Iran) by autoanalyzer (Selectra E2 Chemistry Analyzer, Vital Scientific Co., Netherland). In addition, HDL-C was determined after precipitation of Apo B-containing particles by phosphotungstic acid-MgCl2 (Randox Co, UK/ Hitachi 902 autoanalyzer, Japan). LDL-C levels were estimated using Friedewald equation.

Apo B was assayed by an automated immunoturbidimetric method (XL-300 Biochemistry Analyzer. Erba Co., Germany) with Apo B kit from Randox. Co, UK (Inter Assay: 4.2-7.6%, Intra Assay: 3.7-7.5%)

Determination of morbidities in patients
All patients were followed for up to three months after myocardial infarction and later they were followed by telephone interviews with the survivors. Information on hospitalization for congestive heart failure, angina pectoris, nonfatal reinfarction, percutaneous coronary intervention (PCI), coronary artery bypass grafting (CABG), arrhythmias were collected. Each event was recorded only once. Information on mortality and causes of death were obtained from hospital records. Reinfarction was defined as an infarct with an onset >72 hours after the index infarct that caused prolonged initial or a new hospitalization.

Congestive heart failure (CHF) was defined as an ejection fraction (EF) < 50% and classified into three groups of severe left ventricular dysfunction (LVD) with EF ≤ 30%, moderate LVD with EF: 31-40% and mild LVD with EF: 41-50%. Major cardiovascular events were defined as CABG, PCI, malignant arrhythmias, reinfarction and death.

Ethical approval
We state that our study complies with the Declaration of Helsinki, that the locally appointed ethics committee has approved the research protocol. This study with reference number: 630, was approved by Zanjan ethical committee. All authors observe ethical principles related to references. Written informed consents were obtained from all patients.

Statistical analysis
Statistical analyses were performed with SPSS for windows version 16.5. The main statistical comparisons were performed between patients who survived and the ones who died, between survivors with and without nonfatal reinfarction, between patients with and without CHF and between patients with and without a major cardiovascular event. Differences between groups were tested with Mann Whitney Test. Differences were considered significant if P values were ≤ 0.05, all P values are two tailed.

Multivariate analyses were carried out by multiple logistic regression analysis. Odds ratios were adjusted for factors known to be associated with CAD such as age, diabetes, cigarette smoking.

Results
The baseline characteristics of the 220 patients are given in Table 1. The mean age of the patients was 63±11 years and 157 subjects (71%) were male. At hospital admission, the mean plasma Apo B level was 1.22±0.36 g/L. The patients were extensively treated during the hospitalization. Thirty-nine (17%) patients underwent PCI and 23 (10%) underwent CABG during 3-month follow up period.

Apo B levels in patients who had coronary artery bypass grafting were about 156 mg/dl; a significant relation was found in patients without morbidity (P = 0.0001). However, the Apo B levels had no significant correlation with the patients with arrhythmias and reinfarction and the participants who did not suffer from these morbidities. A total of 10 (4.5%) patients died; 6 of patients died during the initial hospitalization and 4 during the remaining follow up period. Two hundred-two (91%) of patients had LVD and were divided into three groups: mild LVD 65 (29%), moderate LVD 55 (25%), and severe LVD 82 (37%). Six of patients (2.7%) had a nonfatal reinfarction. As shown in Table 2, in univariate analysis, Apo B levels were significantly higher in patients with one of the major cardiovascular events; Apo B 1.31±0.41 g/L (P = 0.0001). As previously stated, several baseline characteristics apart from Apo B levels predicted the outcome. If their univariate P value was <0.2, these variables were entered into multivariate logistic regression model together with Apo B plasma level.

The resulted multivariate analysis showed that there is a significant correlation between Apo B and major cardiovascular events (P = 0.0001). There was a significant correlation between the male sexuality and major cardiovascular events, hypercholesterolemia and CHF, increased non-HDL-C lipoproteins and death rate in

<table>
<thead>
<tr>
<th>Total</th>
<th>Morbidity and Mortality</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes</td>
<td>NO</td>
</tr>
<tr>
<td>N</td>
<td>220</td>
<td>114</td>
</tr>
<tr>
<td>Age</td>
<td>63±11</td>
<td>63±12</td>
</tr>
<tr>
<td>Male</td>
<td>157 (71)</td>
<td>84 (73)</td>
</tr>
<tr>
<td>HTN</td>
<td>66 (30)</td>
<td>38 (33)</td>
</tr>
<tr>
<td>Smoker</td>
<td>74 (33)</td>
<td>42 (36)</td>
</tr>
<tr>
<td>DM</td>
<td>100 (45)</td>
<td>53 (50)</td>
</tr>
<tr>
<td>Apo B ≥1.2 g/L</td>
<td>124 (56)</td>
<td>76 (66)</td>
</tr>
<tr>
<td>TC ≤5.18 mmol/L</td>
<td>84 (38)</td>
<td>44 (38)</td>
</tr>
<tr>
<td>LDL ≥2.59 mmol/L</td>
<td>122 (55)</td>
<td>65 (61)</td>
</tr>
<tr>
<td>HDL &lt;1.16 mmol/L</td>
<td>125 (56)</td>
<td>68 (59)</td>
</tr>
<tr>
<td>Non HDL ≥2.85 mmol/L</td>
<td>107 (72)</td>
<td>61 (75)</td>
</tr>
</tbody>
</table>

Data are means ± SD or n (%). TC: total cholesterol, DM: diabetes mellitus, HTN: hypertension, LDL: low density lipoprotein, HDL: high density lipoprotein
Association between Apo B and morbidity and mortality

Table 2. Association between cardiovascular risk markers at admission of patients and short-term morbidity and mortality after myocardial infarction

<table>
<thead>
<tr>
<th>Parameter</th>
<th>CABG or PCI</th>
<th>P value</th>
<th>CHF</th>
<th>P value</th>
<th>Non fatal reinfarction</th>
<th>P value</th>
<th>Death</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex (M)</td>
<td>77(49)</td>
<td>0.03</td>
<td>146(93)</td>
<td>0.3</td>
<td>31(2)</td>
<td>0.2</td>
<td>7(4.5)</td>
<td>0.9</td>
</tr>
<tr>
<td>Smoking</td>
<td>38(51)</td>
<td>0.1</td>
<td>69(93)</td>
<td>0.5</td>
<td>11(1.4)</td>
<td>0.3</td>
<td>2(2.7)</td>
<td>0.3</td>
</tr>
<tr>
<td>DM</td>
<td>42(42)</td>
<td>0.4</td>
<td>94(94)</td>
<td>0.2</td>
<td>3(3)</td>
<td>0.8</td>
<td>2(2)</td>
<td>0.09</td>
</tr>
<tr>
<td>TC ≥2.6mmol/L</td>
<td>38(45)</td>
<td>0.8</td>
<td>73(86)</td>
<td>0.03</td>
<td>3(3.6)</td>
<td>0.5</td>
<td>2(2.4)</td>
<td>0.2</td>
</tr>
<tr>
<td>LDL ≥2.59mmol/L</td>
<td>48(39)</td>
<td>0.08</td>
<td>111(91)</td>
<td>0.6</td>
<td>5(4.1)</td>
<td>0.1</td>
<td>4(3.3)</td>
<td>0.3</td>
</tr>
<tr>
<td>HDL &lt; 1.16mmol/L</td>
<td>59(47)</td>
<td>0.3</td>
<td>86(90)</td>
<td>0.5</td>
<td>2(1.6)</td>
<td>0.2</td>
<td>7(5.6)</td>
<td>0.3</td>
</tr>
<tr>
<td>Non-HDL ≥2.85mmol/L</td>
<td>54(50)</td>
<td>0.07</td>
<td>100(93)</td>
<td>0.8</td>
<td>5(4.7)</td>
<td>0.1</td>
<td>2(2)</td>
<td>0.00</td>
</tr>
<tr>
<td>Apo B ≥1.2g/L</td>
<td>68(54)</td>
<td>0.001</td>
<td>114(91)</td>
<td>0.9</td>
<td>3(2.4)</td>
<td>0.7</td>
<td>5(4)</td>
<td>0.07</td>
</tr>
<tr>
<td>HTN</td>
<td>31(47)</td>
<td>0.6</td>
<td>61(92)</td>
<td>0.8</td>
<td>2(3)</td>
<td>0.6</td>
<td>4(6)</td>
<td>0.4</td>
</tr>
</tbody>
</table>

TC: total cholesterol, DM: diabetes mellitus, HTN: hypertension, LDL: low density lipoprotein, HDL: high density lipoprotein

Table 3. Odd ratio of ApoB for cardiovascular morbidity and mortality events

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Odd ratio</th>
<th>P-value</th>
<th>(95%) CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Morbidity events</td>
<td>2.67</td>
<td>0.0001</td>
<td>1.53-4.66</td>
</tr>
<tr>
<td>Mortality events</td>
<td>0.76</td>
<td>0.46</td>
<td>0.22-2.72</td>
</tr>
</tbody>
</table>

Discussion

Lipid profile constituents include high total cholesterol, high LDL-C, high Apo B levels and high Apo B/Apo A-I ratio representing cardiovascular risk factors in the general population. Based on the results regarding finding an appropriate marker(s) in lipid profile, it was observed that the serum apolipoproteins are probably better markers of the balance between preatherogenic and atherogenic lipoproteins and predictors of cardiovascular risk. On the other hand, very low-density lipoprotein (VLDL) particles, intermediate-density lipoprotein (IDL), and LDL particles covered by apolipoprotein B (Apo B) molecule, can give us more information regarding their atherogenicity; serum concentrations of Apo B contain a number of atherogenic particles. Different studies have emphasized on a positive correlation between Apo B levels, specially ApoB/ApoA-I ratios, and cardiovascular morbidity.

Haidari et al. showed that Apo B was the best predictor of CAD in a subgroup of very young patients (age≤40, n=77, OR 8.6, P < 0.009). They showed that the severity of atherosclerosis correlated significantly with the serum Apo B concentration in the normolipidemic subgroup (r=0.22, P < 0.008). In another study in Iran, Azizi and his co-workers showed that the concentration of Apo B was a better marker than the traditional lipids in discriminating between patients with cardiovascular disease and patients without CVD in non-diabetic patients with premature coronary artery disease. Kirmizis et al. in a correlation analysis showed that apolipoproteins and their ratio correlated with cardiovascular morbidity in hemodialysis patients, i.e. ApoA-I negatively and Apo B and ApoB/ApoA-I ratio positively (r = −0.6, P < 0.05; r = 0.659, P < 0.01; and r = 0.614, P < 0.01, respectively). In this study, it was found that there is a relationship between Apo B and major cardiovascular events including CABG and PCI in patients after their myocardial infarction. The odds ratio of Apo B for morbidity and mortality events are represented in Table 3.

Wallenfeldt et al. demonstrated that the ApoB/ApoA-I ratio was associated with metabolic syndrome and with the change in carotid artery IMT (intima-media thickness) during 3 years of follow-up. Yoshida et al. in a prospective study showed that during follow-up period (mean 334 days), 30 (19%) coronary events (including 5% revascularization for target lesions and 14% for new lesions) were observed. They also reported that coronary events significantly increased in patients with higher ApoB/ApoA-I ratio (>75th percentile) compared to those with a lower ratio (P = 0.001). In addition, LRP (Lipid-rich plaque) was significantly higher in patients with higher ApoB/ApoA-I ratio in comparison with their counterparts (P = 0.001).

In a multivariate logistic model, after adjusting confounding and coronary risk factors, higher ApoB/ApoA-I ratio was significantly associated with LRP (OR 4.36, 95% CI = 1.81–9.48, P = 0.001). They concluded that elevated ApoB/ApoA-I ratio would predict higher coronary events, and is also significantly associated with LRP measured by IB-IVUS (integrated backscatter intravascular ultrasound). These results may explain the contribution of ApoB/ApoA-I ratio to the increased risk of coronary events after percutaneous coronary intervention.

Corsetti et al. demonstrated that the 4G/5G polymorphism in the promoter region of the PAI-1 (Plasminogen Activator Inhibitor-1) gene is associated with the risk for recurrent coronary events in a subgroup of normolipidemic postinfarction patients. Consequently, because of the importance of genetic variations, we suggest that it is better to study the variations of cardiovascular markers, such as PAI-1, Paraoxonase-1 (PON-1) and adipokines (such as adiponectin, leptin, e.g.) that can affect cardiovascular system in normolipemic and hyperlipemic participants.
with or without CVD. As mentioned, we also carried out a study on the relationship between PON-1 gene polymorphisms and high ApoB/ApoA-I ratios in normolipemic participants. A positive relation was found between L55M polymorphism of PON-1 and high ApoB/ApoA-I ratios (P = 0.016). The limitations of our study would be small sample size and rather short follow up period of patients. Therefore, studies focusing on the measurements of cardiac risk markers like Apo B and longer follow up periods are suggested. In conclusion, this study revealed that Apo B appears to be an appropriate marker for evaluating cardiovascular events in patients after MI. Evaluation of the other cardiovascular lipid markers such as Apo A-I and Lp(a) (in addition to Apo B) in such patients is also recommended to follow the patients’ morbidities.

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Conflict of interests: The authors declare no conflicts of interest.

References
Multimodal Preincisional Premedication to Prevent Acute Pain After Cholecystectomy

Dawood Aghamohammadi¹, Hamzeh Hosseinzadeh¹, Mahmood Eidy¹, Zahra Mohammadzadeh Vizhe², Mohammad Bassir Abolghasemi Fakhri³, Reza Movassaghi³, Kamyar Ghabili⁴, Samad EJ Golzari⁵,6*

¹Department of Anesthesiology, Tabriz University of Medical Sciences, Tabriz, Iran
²Faculty of Medicine, Tabriz University of Medical Sciences, Tabriz, Iran
³Department of Surgery, Tabriz University of Medical Sciences, Tabriz, Iran
⁴Physical Medicine and Rehabilitation Research Center, Tabriz University of Medical Sciences, Tabriz, Iran
⁵Medical Philosophy and History Research center, Tabriz University of Medical Sciences, Tabriz, Iran
⁶Students Research Committee, Tabriz University of Medical Sciences, Tabriz, Iran

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ABSTRACT

Introduction: Postoperative pain as an important medical concern is usually treated by opioids which also are of various inevitable side effects. The aim of this study was to assess the efficacy of multimodal preincisional premedication on preventing post-cholecystectomy acute pain. Methods: In a randomized clinical trial, sixty patients undergoing open cholecystectomy were randomized into two groups. Before anesthesia induction, Diclofenac suppository (100 mg) and oral Clonidine (0.2 mg) were administered in the first group. Immediately before operation, patients received Ketamine (1 mg/kg IV) while the control group received placebo. The site of incision was infiltrated by the surgeon with 20 mL Bupivacaine 0.25% in both groups. Anesthesia induction and maintenance were similar in both groups. The severity of pain was recorded 2, 4, 6, 12, 24 and 48 hours after operation according to Visual Analogue Scale. Results: The severity of pain at two defined stages (6 and 12 hours later) was significantly less in the intervention group than the control group (P<0.005). The average pain severity score was less than the control group (P<0.005). Conclusion: In our study, the administration of Clonidine, Diclofenac and Ketamine and bupivacaine infiltration to the site of incision, altogether was associated with a significant decrease in pain score and opioid requirement after cholecystectomy in comparison to bupivacaine infiltration to the site of incision.

Introduction

Post-operative pain can be derived from the anesthesia techniques used for the surgery, for instances the back pain caused following spinal anesthesia or the surgical process solely.¹,² Surgical procedures are associated with tissue injury and its consequent release of inflammatory mediators i.e. histamine etc. which in turn activates peripheral nociceptors transmitting stimuli to the central nervous system (CNS). Peripheral functional nociceptors are sensitized by the continuous release of inflammatory mediators which is associated with a decreased activation threshold and increased rates of activation and basal (spontaneous) discharge.³ Poorly-controlled postoperative pain would result in undesirable acute and chronic effects including delayed long-term recovery and chronic pain. Furthermore, uncontrolled postoperative pain activates the sympathetic nervous system; hence contributing to increased morbidity and mortality rates.³,⁴ Central sensitization has been suggested to be prevented by preemptive analgesia reducing acute and chronic pain. However, very few studies support the efficacy of preemptive analgesia.³,⁵ The term “preemptive analgesia” is considered as a controversial one, being questioned for its clinical relevance.³,⁶ Multimodal analgesic regimens, i.e. administration of non-opioid analgesics for minimizing the postoperative opioid requirement, would allow more prompt post-operative recovery and therefore retaining normal daily activities.³,⁴ Due to the existing ambiguity in terms of the preemptive analgesia value, we decided to evaluate the effect of quadruple premedication for preemptive analgesia in open cholecystectomy operation. Our suggested quadruple premedication regimen for reducing the postoperative pain of the patients undergoing open cholecystectomy consisted of a single dose of diclofenac (100 mg suppository),

*Corresponding author: Samad EJ Golzari, E-mail: dr.golzari@hotmail.com
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clonidine 0.2 mg PO, Ketamine 1 mg/kg IV, and a local anesthetic wound infiltration using Bupivacaine.

Materials and methods

The present study has been approved by Local Ethics Committee of Tabriz University of Medical Sciences with the approval number of 87/1-2/10 published in the letter number 5/4/174 in 12/30/2008. All medications used in this study are FDA approved. Written informed consents were obtained from all patients before entering the study. Our research is a randomized placebo-controlled clinical parallel trial in which 60 patients over 18 years old participated from 2009-2010. The patients were hospitalized in Imam Reza hospital, Tabriz, East Azerbaijan, Iran and scheduled to undergo open cholecystectomy via Kocher incision. Inclusion criteria were as follows: Age over 18, filling out the informed consent form, being operated by open Cholecystectomy via Kocher incision. Exclusion criteria were as follows: Patient’s refusal for participation, uncontrolled and complicated underlying disease, addiction to opiates or alcohol, ingestion and usage of antipsychotic drugs, history of drug reactions and addiction, having coagulopathies and analgesic consumption. Patients were divided into two 30 unit groups, based on their order of entrance to the operating room (experiment group receiving premedication and the control group receiving placebo). This selection was done by casual transposition and the programs on http://www.randomization.com/ website. The first anesthesiologist who was unaware of the rest of the trial performed this randomization. A 2 sheet paper form was allocated for collecting data. The first sheet included the information of patient such as name, surname, age, gender, and operation date and type (emergent or elective). File number of admission was coded as form number. The second sheet was coded as the same number in the operating room and inserted to patients file by the second anesthesiologist who at the meantime conducted the anesthesia. The 2nd sheet contained the pain scoring and analgesic use tables and the code number which was fulfilled in the ward by a colleague who was unaware of patients order and evaluated the patient with a code number. Thirty minutes before the operation, case group was given one Clonidine tablet (0.2 mg) & one Diclofenac suppository (100 mg). For anesthesia induction, Atracurium 0.5 mg/kg -1, Ketamine IV (1 mg kg-1), Remifentanil 1µg/kg-1 and Propofol (1-2.5 mg kg-1) were administered. Total Intra Venus Anesthesia (TIVA) was administered for maintenance of anesthesia using Propofol 50-150µg/kg/h and Remifentanil 1µg/kg/min. The site of incision was infiltrated by the surgeon with 20 mL Bupivacaine 0.25% before starting operation. At the end of operation, the muscle relaxation was reversed by 2.5 mg Neostigmine and 1.5 mg Atropine. In the ward, the pain score of patients were measured using Visual Analogue Scale & Numeral Verbal Rating Score in 2nd, 4th, 6th, 12th, 24th and 48th hours post-operation. For control group, no premedication was administered and instead of Clonidine, Diclofenac and Ketamine, the patients received placebo. Similarly, we administered Total Intra Venus Anesthesia and surgery site infiltration by Bupivacaine for the control patients. Scaling pain score was also the same as treatment group and all patients in both groups received analgesics (Pethidine Intra Muscular 25 mg injection immediately for post operative pain and Diclofenac suppository 100 mg after 24 hours PRN) in the ward if the pain intensity exceeded 4 VAS scores. In the ward each patient received analgesics including Diclofenac suppository 100 mg or Pethidine Intra Muscular injection 25 mg if needed. Patients, the nurses caring for them, the colleague who recorded all the data and the surgeon were blinded so the conduct of anesthesia and to minimize any possible bias, analgesia was controlled based on a protocol.

Statistical methods

The obtained data were analyzed by the statistical program SPSS 16 (SPSS Inc., Chicago, IL, USA). Quantitative data were explained as median and standard deviation. Qualitative data also were presented by frequencies. For comparison of quantitative and qualitative data (with normal distribution) Chi-squared test and t-test were used. Significant level for P value was estimated to be less than 0.05.

Results

The mean age of the patients was 58.98 ±16.39 years with the range of 19 to 85 years. In treatment group (23 females, 7 males), the mean age was 58.55 ±16.27 years old. In control group (25 females, 5 males), the mean age was 50.4 ±16.77 years old. Chi-squared test showed there was no significant difference in sex distribution in both groups. ($P=0.748$, $df=1$, $x^2=0.418$). T-test revealed that there was no significant difference between mean ages of 2 groups. ($P=0.845$, $t(0,197)=57$). Among 60 patients, 6 (10%) were operated emergently while the rest (90%) were operated electively. 3 of the emergently operated patients were female (50%) and 3 were male (50%). 45 of the elective patients were female (83.33%) and 9 were male (16.66%). Chi-squared test revealed no significant relation of sex distribution in electively or emergently operated patients. ($P=0.088$, $df=1$, $x^2=3.750$). In all 60 patients, the most severe pain was experienced within 6th and 12th hour post-operation. Table 1 demonstrates the difference in pain expressing in 2 groups of patients. The mean overall score of pain in treatment and control groups was 3.6±0.88 and 5.07±0.92 respectively. Analysis performed by t-test showed significant difference both groups and the treatment group expressed less pain than the control group ($P<0.005$). The need for Pethidine increased until the 12th hour (highest score was in 6th and 12th hours) then decreased by 24th and 48th hour. Comparison of the mean pain score in patients of
intervention and control group by t-test revealed that there was a significant difference between the pain score of these 2 groups. Consequently, the patients in treatment group having received premedication of quadruplet drugs (Ketamine, Clonidine, Diclofenac and Bupivacaine infiltration) complained from less pain than the control group. Analysis performed by chi-squared test shows that among all post operation hours, the pain score of the treatment group was more significantly less than the control group in 6th and 12th hours after operation. Therefore, the required dosage of Pethidine in these 2 hours (6 and 12) was significantly less in treatment group than the control group. In conclusion, our study demonstrated that quadruple therapy with Diclofenac suppository 100 mg, Clonidine 0.2 mg per oral before operation, Ketamine 1 mg/kg IV during induction, and a local anesthetic field block with Bupivacaine 0.25% 20 mL, administered before open Cholecystectomy is associated with reduced pain scores and Pethidine use in the first 6th and 12th hours after surgery. The usage of postoperative NSAID (Diclofenac) however was not significantly influenced. Need for Pethidine in different hours post operation is shown in Table 2. Need for Diclofenac in different hours post operation is shown in Table 3. No complication or adverse reactions to the administered medications were observed.

Discussion

The results of the present study show that quadruple therapy with diclofenac 100 mg Trans-rectal, Clonidine 0.2 mg oral, Ketamine 1 mg/kg Intravenous for induction, and a local anesthetic wound infiltration with bupivacaine administered before open cholecystectomy reduces pain scores and analgesic use in the first 6th and 12th h after surgery. Postoperative pain is proven to be reduced by each of the four afore-mentioned treatment modalities through different mechanisms.\(^5\)\(^,\)\(^12\) Therefore, we hypothesized that combining all four modality would be associated with the maximum benefit through different mechanisms for preemptive analgesia.

The advantages of local anesthetic field block prior to hernia surgery have been previously been studied in two different studies by Beausset et al., and also by Lowenstein et al. for abdominal hysterectomy. Local infiltration of anesthetics blocks C-fiber input to the dorsal horn of the spine which in turn inhibits central sensitization via blocking nociceptive impulses from reaching the CNS and suppressing the sustained state of hyper excitability responsible for intense postoperative pain. This, seemingly inadequate for pain control, is preferred by most surgeons.\(^5\)\(^,\)\(^6\)

Preemptive administration of Levobupivacaine in Gurbet et al. research showed that administration of Levobupivacaine in the early postoperative period is significantly associated with less pain experience compared with patients who received no local anesthetics.\(^7\) Persec et al. showed that post incisional treatment with α2-adrenoreceptor agonist Clonidine is associated with reduced analgesic requirements.\(^8\) Flacke and colleagues proposed that narcotic requirement reduced following the usage of Clonidine in patients undergoing coronary surgery which was in line with the findings of Mikawa et al. study carried out on children by oral premedication with Clonidine.\(^9\)\(^,\)\(^10\) Based on the results obtained from above mentioned studies we added Clonidine to our regimen as one of the elements of our premedication.

In two similar studies, the role of single dose Diclofenac suppository in reduction of post cesarean section pain was emphasized\(^11\) in which patients used a single Diclofenac suppository preoperatively; however the need for Diclofenac was not significantly different postoperatively which could have been due to Pethidine usage difference. In a study similar to ours, without the usage of clonidine, Pavlin et al. introduced a tri-modal premedication consisting of Rofecoxib, preincisional Ketamine, and local anesthetic infiltration (Lidocaine and Bupivacaine) with longer follow up period of a week that ultimately resulted in reduced pain scores and analgesic requirement just in the first 24 hours after surgery, with no significant effect on later hours.\(^1\)\(^,\)\(^12\) Patients in our study however were followed up until 48 hours post operation. And pain significantly reduced as previously described.

Conclusion

Administration of multimodal preincisional premedication consisting of Clonidine, Diclofenac, Ketamine and bupivacaine infiltration to the site of incision, could lead to
bupivacaine infiltration to the site of incision, could lead to a significant decrease in pain score and opioid requirement after cholecystectomy in comparison to bupivacaine infiltration to the site of incision.

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References


Inferior Vena Cava Index in Edematous Patients

Shamsi Ghaffari¹, Majid Malaki², Mohammad Reza Ghaffari³, Kamran Asiaie²

¹Department of Pediatric Cardiology, Tabriz University of Medical Sciences, Tabriz, Iran
²Pediatric Health Research Center, Tabriz University of Medical Sciences, Tabriz, Iran
³Department of Tuberculosis and Pulmonary Diseases Research Center, Tabriz University of Medical Sciences, Tabriz, Iran

Introduction

Identification of volume overload as the cause of a patient’s respiratory distress can be difficult particularly in patients with co-morbid condition such as chronic obstructive pulmonary disease (COPD). In this conditions physical examination is unreliable in addition there are no imaging or laboratory test for this purpose specially.¹ Ultrasonographic measurement of respiratory variations of inferior vena cava (IVC) diameter have been shown that can be correlated with volume depletion in patients with septic shock,² the necessary to find a non invasive, low cost and accessible method for evaluation of body fluid status is an obligatory reason for us to evaluate IVCi in edematous state as a condition with extracellular fluid overload although the affectivity of this method has been tried for intravascular fluid estimating of adults group earlier.³

Materials and methods

Fifty-four children admitted to pediatric ward of Madani heart center below age 7 years were enrolled into the study including of non edema 30 cases, mild to moderate edema 13 cases and significant edema 11 cases. In the ultrasound examination, we concentrate on assessment of IVC diameters. The measurements were performed twice, initially The IVC index was introduced into clinical practice with inferior vena cava diameter (IVCd) measurement in maximum and minimum values at diaphragm level by using standard formula [(IVCmax-IVCmin)/IVCmax] × 100. Delta ratio of IVC diameter were also measured both during inspiration (maximum) and during expiration (minimum) delta ratio was difference of IVC maximum and IVC minimum in millimeter unit. We define edema as clinical practice in assessment to assign a positive number for the severity of pitting edema in the lower extremities as follows: +1 = a normal foot and leg contour with a barely perceptible pit; +2 = fairly normal lower extremity contours with a moderately deep pit; +3 = obvious foot and leg swelling with a deep pit; +4 = severe foot and leg swelling that distorts the normal contours with a deep pit.

Grade +1 consider as normal Grade +2 and +3 as non significant and +4 was considered as significant edema. Exclusion criteria were: shock state and congenital vascular malformations.

All ultrasound examinations were taken with GE Logiq 500 (GE Medical Systems, Waukesha, WI, USA) with a 3.5-to 5-MHz convex probe. For statistical analysis, the formula for differences for mann whitney test and regression tests were used for relation of edema and IVCi in SPSS 16 software, P less than 0.05 consider significant. An informed written consent was obtained from all volunteers and the procedures followed were in accord with the ethical standards of our institution’s committee on human experimentation. The ultrasound examination was taken with the subject in a supine position with the transducer placed underneath the xiphoid process in a longitudinal direction. The IVC diameter was measured beneath the confluence with
Results
54 patients include 18 female and 38 male entered to this study their means ±SD age were 27±20 months from 54 patients who entered to this study 30 patients had no clinical edema , 13 patients had mild edema and 11 other cases had severe edema . Means ±SD (minimum, maximum) of IVC diameters values in children were 4.5mm ±1.7 (minimum 2mm, maximum 8mm) in non edema group it was 4.36 ±1.8 mm ,mild to moderate edema group, 5.2±1.7 mm, severe form 3.6±0.5 mm maximum diameter of IVC in non edema group was 7.5±2mm in mild to moderate edema 8.2±1.8 and in severe edema it was 7.3±2 mm. 

Means±SD of IVCi in patients without considering of edema was 44%±16 and delta ratio was 3.7±1.6 (Table 1). IVC in patients without clinical edema was higher compared to patients with mild (46%±16 vs. 42%±16) and significant edema (46%±16 vs. 38%±17). In spite of decreasing of IVCi with severity of edema scale these measures were not different significantly between groups (Table1).

These IVCi measures were compared between no edema condition with both mild edema and significant edema which showed there is a reverse relation between edema presence and IVCi but these differences were not significant, there is not any differences between no edema condition with mild edema (P=0.3) and significant edema (P =0.9 ) . Delta ratio decreased with significant edematous state 2.6 mm in compared to mild 3.7mm and no edema 3.8 mm in average but this relation was not significant (P=0.05) among three groups of non edema , mild to moderate edema and severe edema (Table1).

Table 1. Inferior vena cava index (IVCi) and delta ratio in patients with different edematous conditions

<table>
<thead>
<tr>
<th>Indices</th>
<th>Edema(n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>[Mean±SD(Min,Max)]</td>
<td>No(3)</td>
</tr>
<tr>
<td>IVCi(44±16 (0,71)]</td>
<td>46±16(0,71)</td>
</tr>
<tr>
<td>DELTA[ 3.7±1.6 (0,8)]</td>
<td>3.7±1.6(0,8)</td>
</tr>
</tbody>
</table>

Discussion
The accuracy of body fluid status assessment plays a vital role in the diagnostic and therapeutic processes of acute and chronic disorders, influencing on their further treatment and final recovery. There are different methods of evaluating body hydration status, but none of them is optimal and all of them have some limitations.1 The benefits of IVC indices are so diverse it has been used in dehydrated patients or shocked condition with respect that ultrasound is easy to perform, quick and precise. There are many optimistic reports pointing to the usefulness of sono graphic IVC diameter assessment in monitoring body water condition in patients undergoing hemodialysis6-7 or patients with nephrotic syndrome.8 Cheriex et al. proposed the optimal values of IVC diameter ranging between 8 and 11.5 mm per square meter of BSA on the basis of measurements from the examined group of adult patients under hemodialysis.9 According to Chang et al., there is a significant reduction of cardiovascular, gastrointestinal, and neu rologic complications if the body dry weight of hemodialysis patients if it was determined and monitored with the sonographic method by measuring vessels diameters like as IVC.10 Simultaneously, some indicates to serious problems as limitations for the usefulness of IVC diameter assessment. It seems that both the equipment quality and appropriately trained staff can play role although lack of IVC diameter reference values for the pediatric group because of measurement of IVC diameter is difficult to measure in pediatric group is another problem in children has not been considered seriously.

In this study we try to find these measures as standard reference in pediatric group beside to measure these parameters in edematous conditions for the first time in Tabriz Madani heart center. It seems that estimation of edema evaluated by physical examination as objective finding may be misleading in mild or moderate form with respect to routine standards which used clinically lead to false results especially if we have not the baseline weight of patients or there is not baseline information about patient history . Although in other studies IVCi less than 40% indicate to overhydration11 our study show that in children with clinically severe edema this value was 38% and in mild or moderate group it was 42 % this data show limitation of this method for detecting subclinical ,mild or moderate edema in children because of there is narrow differences of IVCi from mild to severe edema (42% vs. 38%).

In this study, which performed in patients under age 6 years our results, showed that IVC diameters solely both in inspiration or expiration phases will not different with age significantly and we should try for other standards like as IVC diameter to body surface area in other studies. This study shows although IVCi is a convenient parameter for evaluation of IVC diameter changes in contrast to measuring IVC diameter solely but it is not a sensitive technique in volume overload condition in spite of decreasing of IVCi and delta ratio in edematous conditions this means that in edematous condition IVCi or delta ratio cannot be helpful for edema severity discrimination in pediatric population significantly. Researcher should try to find another more standard measure instead of IVC values in pediatric group for volume estimation.
Conclusion

IVC diameters are not change with increasing age significantly and IVCi is a rough means for estimating of edema severity in pediatric population although IVCi less than 42% is suggestive for edema but there are a large overlap findings of IVCi among mild,moderate and severe edema that make difficult using this measure.

References


Modified Cricothyroidotomy in Skill Laboratory

Hassan Soleimanpour1*, Samad Shams Vahdati2, Ata Mahmoodpoor2, Jafar Rahimi Panahi2, Mohamad Reza Afhami3, Mahboub Pouraghaei3, Samad EJ Golzari3,4

1Department of Emergency Medicine, Tabriz University of Medical Sciences, Tabriz, Iran
2Department of Anesthesiology, Tabriz University of Medical Sciences, Tabriz, Iran
3Physical Medicine and Rehabilitation Research Center, Tabriz University of Medical Sciences, Tabriz, Iran
4Students’ Research Committee, Tabriz University of Medical Sciences, Tabriz, Iran

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ABSTRACT

Introduction: Unsuccessful tracheal intubation is considered the most common cause of anesthesia death or brain damage. This study delineates our experience recommending modifications in the cricothyroidotomy technique. Methods: Thirty emergency medicine residents of participated in a study performed on the human simulator moulage in Skill Laboratory of Tabriz University of Medical Science. The cricothyroid membrane was punctured using a 16-gauge cannula. Later, J guide wire was advanced into trachea and standard 16-gauge intravenous cannula with a removable needle stylet withdrawn after the puncture being dilated by a dilator. Consequently, a cuffed tracheal tube (ID= 6) was introduced from the foramen. Results: From 30 residents, 18 residents performed cricothyroidotomy within 1 minute, 7 residents in 2 minutes and 5 residents failed to fulfill the procedure. Conclusion: Several studies using cadavers and human simulators have demonstrated the pre-hospital feasibility of this technique. However, descriptions of clinical pre-hospital experience with percutaneous cricothyroidotomy are limited. This study shows that skill lab may help residents to acquire techniques required in management of difficult airway.

Introduction

From the point of view of medical directors, adequate training in the use of efficient and available alternate airways is essential.1-3 Maintenance of alternate airway skills is of great importance due to their clinical use occurring under urgent conditions.3,4 Both simulated and practical experiences are required for training these skills.5-7 Training on live patients in controlled settings seems quite desirable; however, for most alternate airways in emergency conditions, this may not be practical. For instance, elective cricothyroidotomy rarely occurs on the operating room patients.7 Although, no clinical indications for alternate airway use have been defined, it is practically recommended for the alternate airways to be used following failed endotracheal intubation (ETI) attempts or in situations where endotracheal intubation attempts seem to be difficult or impossible. “Difficult Airway” is defined as conditions involving difficult airway anatomy, severe airway trauma, or inadequate operator skill. This could be identified before or after initial intubations attempts. In situations where airway management difficulty is obviously beyond the skill of the operator, it is recommended to consider alternate airway management.8,9 Difficult airway guidelines recommend only three intubation attempts (insertion of blade) and any further endotracheal intubation efforts should be discontinued.8,9 Alternate airway use should be monitored by a comprehensive quality assurance and quality improvement programs involving emergent medical directors in continuous quality improvement (CQI) activities. All usage of alternate and salvage airways should be documented based on “Recommended Guidelines for Uniform Reporting of Data from Pre-hospital Airway Management”.10 It is highly recommended to maintain patient follow-up including linkage to in-hospital course as the only indicators of pre-hospital difficult airway management complications. Percutaneous cricothyroidotomy, first described as an in-hospital alternate airway by Fischer, has been proposed in the anesthesia literature for difficult airway management.7 Problems with tracheal intubation in spite of being infrequent are the most common cause of anesthesia death or brain damage. We hypothesized that percutaneous dilatational cricothyroidotomy might be performed in the failed or difficult airway as an alternative as it seems to be simpler than other alternatives.

*Corresponding author: Hassan Soleimanpour, E-mail: soleimanpourh@tbzmed.ac.ir
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Materials and methods

Study Design

This study was a randomized controlled cross-over design on human simulator moulage which was performed for the first time in Tabriz University of Medical Science, Iran.

Study Setting

This study was held in skill lab of educational development center (EDC) of Tabriz Medical University. Residents of emergency medicine participated in this study.

Methodology of Study

The disposable percutaneous introducer kit consists of a standard 16-gauge intravenous cannula with a removable needle stylet (No-16 blade), a translucent syringe, a J-tipped 0.052 inch coated stainless steel guide wire, an introducing dilator and lubricating gel.

STEP 1 (Localization and perforation): Skin perforation was performed at the lower edge of the thyroid cartilage in cricothyroid cartilage. The trachea was punctured using a standard 16-gauge intravenous cannula with a removable needle stylet; as the needle was advanced into the tracheal lumen air was aspirated with the syringe.

STEP 2 (Insertion of J wire): The needle was pulled back and the J tipped guide wire advanced into the tracheal lumen.

STEP 3 (Incision and Dilation): Cricothyroid membrane was incised minimally and vertically in both sides of J wire insertion for the purpose of dilator insertion facility. The dilator was mounted on the guide wire.

STEP 4 (Cuffed tracheal tube (ID= 6)): In this step, the dilator was withdrawn and cuffed tracheal tube was inserted (ID= 6) through the foramen; later J guide wire was extracted. Finally, tracheal tube was fixed in place with tape.

STEP 5 (Confirmation): Tracheal tube position was checked by symmetrical chest rising and auscultation.

Data

The number of the attempts were recorded at the end of first minute, second minute and if failed after 2 minutes. The obtained data were compared between these residents.

Data analysis

The data were analyzed in SPSS 15.0 statistical package and descriptive analysis was performed for all data.

Results

Thirty emergency medicine residents worked on the same kind of human simulator moulage and the start and the finishing times of the procedure were documented for all of them. Eighteen residents finished the procedure within the first minute, 7 residents in second minute and 5 residents failed to perform the procedure (Figure 1). The mean time of procedure completion was 84.8±52.6 seconds (Median=59 seconds and Mode=58 seconds; Figure 2).

Primary outcome was defined as successful cannulation; 3 of the participants failed this step requiring more time for fulfilling the procedure. Secondary outcome included needle insertion which was performed successfully by all of the participants. Final proportion was successful intratracheal insertion and subjective ease of insertion. Two of participants failed and could not perform the procedure properly.

Discussion

Being used for over 45 years, open cricothyroidotomy is a safe and rapid procedure; however, it does require appropriate training. Cricothyroidotomy has been studied in the hospital and emergency department settings as both a primary and alternate airways for management of difficult airway. Several trials have described cricothyroidotomy use in the pre-hospital settings. In spite of being widely taught, the pre-hospital application of cricothyroidotomy has been reported to be rare and blamed for having significant complications and poor outcomes. Some of the indications for cricothyroidotomy include oral and maxillofacial trauma, suspected cervical spine injury, and inability to perform endotracheal intubation because of oral hemorrhage, emesis, or anatomy that obscures visualization of the vocal cords. Cricothyroidotomy seems to be relatively easy (relative to a tracheotomy) to perform.
for non-physicians or non-surgeons in the emergency surgical airway access while minimal training is required. Laryngeal pathology remains the solely most important contraindication for cricothyroidotomy. Conditions causing inflammation are its contraindications including trauma, infection, and translaryngeal intubation.\textsuperscript{22} Percutaneous cricothyroidotomy uses a modified Seldinger (guide wire) technique to facilitate location and insertion of a tracheal tube through the cricothyroid membrane. Commercially packaged kits contain the equipment necessary to perform the procedure.\textsuperscript{23-29,33} Being first described as an in-hospital alternate airway by Fischer\textsuperscript{34}, percutaneous cricothyroidotomy technique is believed to have fewer complications than open cricothyroidotomy.\textsuperscript{30,32} Percutaneous cricothyroidotomy has been described in the anesthesia literature for difficult airway management.\textsuperscript{34,35} It was not until 1992 that the use of percutaneous cricothyroidotomy was first described in the emergency department.\textsuperscript{36} The pre-hospital use of percutaneous cricothyroidotomy was proposed over a decade ago.\textsuperscript{36} Several studies using cadavers and human simulators have demonstrated the pre-hospital feasibility of this technique.\textsuperscript{30,31,37} However, very limited descriptions of clinical pre-hospital experience with percutaneous cricothyroidotomy could be found. Schumann \textit{et al.} believed that it is important to train residents with different methods of cricothyroidotomy in cadavers in addition to training in mannequins to achieve a higher level of efficacy in real-life situations.\textsuperscript{33} Metterlein \textit{et al.} showed that wire-guided method is a more reliable technique, being associated with fewer complications. However, the direct puncture was faster to perform. Whenever placed accurately, both devices would provide sufficient ventilation.\textsuperscript{38} Aneeshkumar \textit{et al.} reported that with adequate prior training, it is a quick, simple and safe procedure, resulting in no significant cardio-respiratory complications and providing efficient ventilation in emergency situations.\textsuperscript{39} In our study, we observed that this procedure could be performed in emergency states so easily and quickly. Ciaglia \textit{et al.} showed that percutaneous dilatational method can be used with safety and speed.\textsuperscript{57}

\textbf{Conclusion}

In summary, several studies using cadavers and human simulators have demonstrated the pre-hospital feasibility of this technique. Descriptions of clinical pre-hospital experience with percutaneous cricothyroidotomy are limited, however this study shows that this method might be considered as a new and simple way to overcome difficult airway in emergent situations.

\textbf{Ethical issues:} The local ethics committee of Tabriz University of Medical Sciences approved the study and all patients signed informed consent. \textbf{Conflict of interests:} The authors declare no conflicts of interest.

\textbf{References}


Introduction

Depression is one of the most frequent mental disorders which can be compared with common cold. About 20 percent of adults in every society may show one or several symptoms of depression.1 It has been confirmed that coronary heart disease is the main cause of death in almost all over the world.2 In cognitive approach, it is accepted that high dependence on an established belief can increase the degree of depression in his life. Based on this fact, a research was carried out at Tehran psychological Institute of Shahid Rajaee Heart center hypothesizing that, compared to the other patients; CAD patients are more neurotic, extrovert; yet less empiricist and less concordant.3 Accordingly, Yazdandumst et al. conducted a research on coronary patients focusing on not only the frequency of depression but also severe coronary disease.3 Depression is the most common psychological and mental disorder among CAD patients having numerous direct and indirect risk factors.4 In a research conducted by Cincinnati Medical College on CAD patients, it was indicated that depression plays an important role as a risk factor in CAD.5 Furthermore, as reported by American psycho-somatic society, the patients denying their disease suffer less concordance and stay more in hospital as well.6 A report, by Iran university of Medical sciences showed that, when patients with myocardial infarction (MI) compared to normal individuals regarding depression and unhealthily attitudes, depression severity and unhealthy attitudes were significantly higher in MI patients in comparison with normal cases (P≤0.05).7 Modabber’s research in Kurdistan, Iran on the frequency and severity of depression in coronary and cataract patients demonstrated that almost 70% of the studied samples in the coronary patients had depression (P=.0001). Significantly, the highest percentage of depression was seen among females (P=.003).8 In a research conducted by Colombia university, it was figured out that among 314 patients affected by severe coronary syndrome, 166 cases had no symptom of depression in BDI test, while 91 cases had scores between 10 to 16 of BDI and 57 cases were diagnosed with average to severe depression with BDI >16 grades .9 A research by Isfahan cardiovascular research center pointed out that after participating in a mental health program, patients’ depression decreased significantly (P<0.0001).10 In a research conducted by Brazilian Metropolitan University, it has been emphasized that physical diseases would lead to psychobiological alterations throughout one’s life.11 Also a research by Liverpool University in Canada emphasized on the mental and psychological supports being able to reduce the anxiety and signs of the depression.12 Based on a study carried out by Tabriz Cardiovascular Research Center using MMPI test, 14 percent of the patients scheduled to undergo cardiac surgery experienced anxiety and depression during their hospitalization.13 Considering the high frequency and prevalence of MI, a study being conducted on the relation of MI and depression seemed quite necessary.
Materials and methods
In this study, 128 patients with coronary disease hospitalized in Shahid Madani hospital were allocated. Unhealthy attitudes, degree of depression and the severity of CAD of the patients were studied. All data were analyzed using statistical methods.

Results
About 7% of the females had no symptoms of depression, while 34.9%, 22.2% and 9.5% of them had symptoms of mild, moderate and severe depression respectively. About 77.6% of the males had no symptoms of depression, while 11.9%, 6% and 4.5% of them had symptoms of mild, moderate and severe depression respectively. A statistically significant relation was detected between depression and gender. Additionally, a significant association was discovered between depression and sex of the patients with unhealthy attitudes based on literacy. Furthermore, a significant relation was observed between the types of unhealthy attitudes and BDI scores as follows: The means of the unhealthy attitudes in patients with mild, moderate and severe BDI scores were 179.89±20.56, 169.72±26.43, and 182.62±32.08 respectively. Therefore, unhealthy attitudes are more common in patients with severe BDI scores. A significant relation between unhealthy attitudes and literacy was discovered. In addition, among those with BSc degree, the existence of unhealthy attitudes was severe.

Discussion
Throughout the research it was revealed that 22% of the individuals seem to show signs of mild to severe depression with more dominance in females. The mentioned findings are in line with the previous researches conducted by Tehran University (30%), Kurdistan University (70%), Iran University, Hayward, Colombia and Tabriz universities of medical sciences. As previously discussed, depression plays a fundamental role in the appearance of coronary disease. Different mechanisms have been considered to be responsible for depression such as arrhythmia, changes in sympathetic and parasympathetic tones, heart rate changes, Ischemic Heart disease, decrease in serotonin levels and increase in cortisol levels. On the other hand, the relation between unhealthy attitudes and depression intensity has been identified. These findings are in accordance with the report of the Kurdistan University of Medical Sciences. Generally, the probability of depression in vulnerable cases according to DAS test is 7 times higher than the others. The findings also appeared to be equated with the findings of Iran University of Medical Sciences. According to the study, patients with myocardial infarction are more vulnerable than normal people to suffer from depression. The average number of unhealthy attitudes is also significantly different. As a result, the study suggests pharmacotherapy or psychotherapy for patients before or after their recovery from myocardial infarctions at discharge from the hospital. Based on the data obtained from the variance analysis, the means of the unhealthy attitudes in the illiterate, undergraduate, diploma, postgraduate and BSc. people were 160.66±14.35, 171.38±21.95, 176.55±22.2, 195±21.18, 202.60±25.25 respectively. Considering F=6.28 and P=0.0001, it could be concluded that there is a significant relation between unhealthy attitudes and level of literacy and unhealthy attitudes tend to be more common in people with BSc degree. The degree of depression in women is more significant. Therefore, considering the role of women in family, it can be suggested that before their discharge from the hospital, they should be visited by a psychiatrist. This study completely confirms the findings of Kurdistan University of Medical Sciences, Tehran, Liverpool, Mashhad, and Finland universities. It is recommended that in addition to treatment by psychiatrists, psychological interventions are performed.

Acknowledgments
The authors are grateful to the patients and colleagues who cooperated with us throughout this research. Ethical issues: The local ethics committee of Tabriz University of Medical Sciences approved the study and all patients signed informed consent. Conflict of interests: The authors declare no conflicts of interest.

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Depression in CAD

OPTIMA Tacrolimus-eluting Stent: A Twelve-month Clinical Follow-up with Two Different Periods of Dual Antiplatelet Therapy; 2-month vs. 6-month Approach

Nasser Aslanabadi, Ahmad Separham, Reza Beheshhti, Samad Ghaffari, Bahram Sohrabi
Cardiovascular Research Center, Tabriz University of Medical Sciences, Tabriz, Iran

ABSTRACT

Introduction: There are limited data comparing long-term efficacy and safety of OPTIMA tacrolimus-eluting stent (TES) with Dual Antiplatelet Therapy (DAT) in daily practice. Therefore, we evaluated the safety and performance of OPTIMA TES with 2 or 6-month dual antiplatelet therapy in a 12-month follow up period. Methods: In a prospective, non-randomized single center registry in which 106 patients that underwent percutaneous coronary intervention with the OPTIMA TES between January 2010 and February 2011 were enrolled. After stenting, 62 patients received DAT for 2 months and the remainder for 6 months. Major Adverse Cardiac Events (MACE), stent thrombosis rate and target lesion revascularization (TLR) were evaluated in a 12-month follow-up period for 2-and 6-month DAT groups. Results: No cases with death, MI or stent thrombosis were observed within the 12-month follow-up period in either of the groups. TLR and MACE rates were higher in 6-month DAT group compared to 2-month group (6.8% vs. 3.2% respectively, P=0.001) which may be due to this group having more diffuse disease (23.60±5.69 vs. 20.88±5.14, P=0.018). Conclusions: OPTIMA tacrolimus-eluting stent is safe and efficient with short term DAT period. A randomized trial is needed for better evaluations of OPTIMA TES in daily clinical practice.

Introduction

Drug-eluting stents (DESs) have reduced restenosis and target lesion revascularization (TLR) compared to bare-metal stents (BMS). However, long term safety of first and second generation DESs is still controversial due to concerns about late and very late stent thrombosis. Durable polymers have been associated with local inflammatory and hypersensitivity reaction and subsequent delayed vascular healing and impaired reendothelialization leading to stent thrombosis. To eliminate short or long-term effects of polymers on arterial healing, polymer-free DESs have been developed.

On the other hand, first and second generation DESs require a prolonged dual antiplatelet therapy period up to 1 year to reduce late stent thrombosis risk. In this respect, DES use may have limitations in some patients including patients with Contraindications to long-term DAT, patients who are taking oral anticoagulants because of increased bleeding risk, patients requiring major surgery within 1 year after DES implantation, and patients with no adherence to DAT due to socioeconomic issues.

The OPTIMA tacrolimus-eluting stent (TES; SORIN, Italy) is a recently-introduced polymer-free DES. OPTIMA, possessing a proprietary drug-release system while having reservoirs on the stent outer surface, ensures a highly targeted release only focusing on the vessel wall; it also has an integral carbofilm coating providing early endothelialization.

Tacrolimus, an antiproliferative agent used in the OPTIMA stent is a macrolide immunosuppressive agent that binds to cytosolic FK-506 binding protein-12; it is through this complex that it demonstrates its inhibitory effect on the T-lymphocyte signal transduction and IL-2 transcription. This agent’s antiproliferative effects is less than sirolimus, but in combination with its anti-inflammatory effects it represents a favorable compound reducing stent restenosis and stent thrombosis.

Little is known about the OPTIMA stent use with short DAT in daily clinical practice. Therefore, we conducted a prospective single-center registry investigating safety and efficacy of OPTIMA TES, in a 12-month follow-up period, in real-world patients undergoing Percutaneous Coronary Intervention (PCI), followed by a DAT period of 2-6 months at our hospital.

Materials and methods

Patient population

Between January 2010 and February 2011, 106 patients with documented ischemia, or acute coronary syndrome (ACS) including acute myocardial infarction (AMI) were enrolled in this prospective, non-randomized single center study.
Inclusion criteria were as follow: Patients ≥18 years, at least one angiographic coronary stenosis more than 70% with a target vessel diameter ≥ 2.5 mm, < 4 mm, and lesion length less than 31 mm, with up to 5 lesions suitable for PCI. Exclusion criteria were as follow: intolerance or allergy to aspirin or clopidogrel, pregnant women, bleeding diathesis or contraindication to antiplatelet or anticoagulation therapy.

Written informed consent was obtained from all patients, and the study protocol was approved by the local ethical committee.

**Percutaneous coronary Intervention (PCI) procedure**

All patients were given a loading dose of 300 mg clopidogrel and aspirin 100 mg before procedure. During the procedure, all patients received an IV bolus dose of unfractionated heparin (100 u/kg) and the use of glycoprotein IIb/IIIa inhibitor was left to the discretion of the operator. Coronary angioplasty and stenting were performed based on the standard methods. After stenting, all patients received Aspirin 100mg daily indefinitely. After PCI, 62 patients received clopidogrel 75mg/d for 2 months and 42 patients for 6 months. Duration of DAT period was based at the discretion of the cardiologist treating the patient.

**Follow-up**

Clinical follow-up was performed by telephone contact or office visits in the following 1, 6 and 12 months. Coronary angiography was performed when there were recurrent ischemic symptoms or readmission due to unstable Angina.

**Study endpoints and definitions**

The study endpoint was the 12 month rate of major adverse cardiac events (MACE), defined as the composite of cardiac death, non-fatal myocardial infarction (MI) and TLR. MI was defined either as the development of pathological Q waves in at least 2 contiguous leads with or without elevated cardiac enzymes or troponin I or creatinine kinase-MB enzyme elevation >3 times the upper limit of the normal value. Stent thrombosis (ST) was defined based on the Academic Research consortium (ARC) definitions for definite or probable stent thrombosis and further categorized as acute<1 day; subacute as 1 to 30 days and late>30 days. Restenosis was defined as the diameter stenosis of ≥ 50% of the target lesion.

**Statistical analysis**

Categorical discrete variables were compared by the chi-squared test or the Fisher exact test. Continuous variable were presented as mean ± standard deviation (SD) and were compared with the use of the Student’s t-test. P value < 0.05 was considered statistically significant. Data were analyzed using SPSS 13.

**Results**

Table 1 shows baseline clinical characteristics of the study population. No significant differences were present in the baseline clinical or demographic characteristics between treatment groups with the exception of slightly more Unstable Angina presentation in the 6-month DAT group. (30.6% vs. 45.5%, P=0.057). Table 2 shows baseline angiographic characteristics. A trend toward higher multivessel disease in 6-month DAT group was seen which was statistically insignificant (P=0.006).

<table>
<thead>
<tr>
<th>No. of patients</th>
<th>2 Months DAT</th>
<th>6 Months DAT</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male gender</td>
<td>47/84</td>
<td>84/158</td>
<td>0.45</td>
</tr>
<tr>
<td>Hypertension</td>
<td>31/69</td>
<td>69/138</td>
<td>0.49</td>
</tr>
<tr>
<td>Diabetes</td>
<td>22/46</td>
<td>46/92</td>
<td>0.007</td>
</tr>
<tr>
<td>Smoking</td>
<td>18/36</td>
<td>36/72</td>
<td>0.52</td>
</tr>
<tr>
<td>Obesity</td>
<td>11/22</td>
<td>22/44</td>
<td>1.549</td>
</tr>
<tr>
<td>Male history of CAD</td>
<td>6/12</td>
<td>12/24</td>
<td>1.000</td>
</tr>
<tr>
<td>Clinical status (n=1%):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Stable Angina</td>
<td>23/47</td>
<td>47/94</td>
<td>0.671</td>
</tr>
<tr>
<td>Unstable Angina</td>
<td>19/41</td>
<td>41/82</td>
<td>0.057</td>
</tr>
<tr>
<td>Myocardial infarction ≤24h</td>
<td>20/40</td>
<td>40/80</td>
<td>1.000</td>
</tr>
<tr>
<td>Myocardial infarction &gt;24h</td>
<td>18/36</td>
<td>36/72</td>
<td>0.254</td>
</tr>
<tr>
<td>Mea LVEF</td>
<td>47/91/95/86</td>
<td>91/86/95/86</td>
<td>0.068</td>
</tr>
<tr>
<td>Pathological Eca</td>
<td>46/79/3</td>
<td>79/36/3</td>
<td>0.132</td>
</tr>
<tr>
<td>Previous MI</td>
<td>12/24</td>
<td>24/48</td>
<td>0.143</td>
</tr>
<tr>
<td>Previous PTCa+ Stenting</td>
<td>14/28</td>
<td>28/56</td>
<td>0.431</td>
</tr>
<tr>
<td>CABG</td>
<td>23/46</td>
<td>46/92</td>
<td>0.542</td>
</tr>
</tbody>
</table>

For 2-month and 6-month DAT group, respectively significant differences were reported in terms of lesion length (20.88±5.14 mm versus 23.60±5.69 mm, P=0.018). Other angiographic findings like lesion classification and target vessel location were similar between two groups. Most lesions were located in the left anterior descending artery and were of the B type. All patients underwent successful stent deployment in all cases (Table 3). During 1 year follow-up there was no death, MI or stent thrombosis in either group. TLR was more common in 6-month DAT (6.8% vs. 3.2%, P=0.007; Table 4).

**Discussion**

We demonstrated in this study that, the treatment of coronary artery disease (CAD) using TES OPTIMA stent in real world patients with short DAT is safe and efficacious, with no MI, cardiac death or stent thrombosis report in 1 year follow-up. Previous studies investigating TES efficacy are controversial. The JUPITER I trial showed good safety of Janus TES with no stent thrombosis despite 2-month DAT after stent deployment. Our study device, OPTIMA stent is a new version of Janus TES. In JUPITER II trial, also, there was no stent thrombosis with 6-month DAT. Our study confirms these trials results with respect to safety of OPTIMA stent with no death or stent thrombosis report despite 2 or 6 months DAT and up to 1 year follow-up. However, Total MACE rate in our study was slightly less than JUPITER II trial (6.8% vs. 7.6%) which may be due to better design of OPTIMA stent compared to JANUS stent and small sample size of our study.
**OPTIMA TES: A follow up with DAT**

**Table 2. Baseline angiographic characteristics**

<table>
<thead>
<tr>
<th>Location of Target Lesion(%)</th>
<th>2 Months DAT</th>
<th>6 Months DAT</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>LM</td>
<td>0</td>
<td>0</td>
<td>0.110</td>
</tr>
<tr>
<td>LAD</td>
<td>43(50)</td>
<td>24(49)</td>
<td></td>
</tr>
<tr>
<td>LCX</td>
<td>13(15.1)</td>
<td>14(28.6)</td>
<td></td>
</tr>
<tr>
<td>RCA</td>
<td>30(34.9)</td>
<td>11(22.4)</td>
<td></td>
</tr>
<tr>
<td>Bifurcation lesions(%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>41.3(4.8)</td>
<td>36.8(6.8)</td>
<td>0.230</td>
<td></td>
</tr>
<tr>
<td>Ostial lesions(%)</td>
<td>12.9</td>
<td>12.9</td>
<td>0.799</td>
</tr>
<tr>
<td>CTO lesions(%)</td>
<td>17.7</td>
<td>13.6</td>
<td>0.605</td>
</tr>
<tr>
<td>Thrombotic lesions(%)</td>
<td>21</td>
<td>9.1</td>
<td>0.116</td>
</tr>
<tr>
<td>Heavy calcification(%)</td>
<td>29.5</td>
<td>20.5</td>
<td>0.4</td>
</tr>
<tr>
<td>Severe proximal vessel</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tortuosity</td>
<td>11.3</td>
<td>7</td>
<td>0.5</td>
</tr>
<tr>
<td>Timi Flow ≤1</td>
<td>16.2</td>
<td>23.3</td>
<td>0.78</td>
</tr>
<tr>
<td>Denovo lesions</td>
<td>90.3</td>
<td>83.7</td>
<td>0.37</td>
</tr>
</tbody>
</table>

*RVD= Reference vessel diameter, *MID*= Minimal vimal/d minimal diameter

**Table 3. Procedural characteristics**

<table>
<thead>
<tr>
<th>2 Months DAT</th>
<th>6 Months DAT</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct stenting technique[n(%)]</td>
<td>24(39.3)</td>
<td>14(39.3)</td>
</tr>
<tr>
<td>Stent sizes3mm[n(%)]</td>
<td>57(91.9)</td>
<td>40(95.2)</td>
</tr>
<tr>
<td>Mean stent length (mm)</td>
<td>23.60±5.96</td>
<td>20.88±5.14</td>
</tr>
<tr>
<td>Stent Delivery pressure(atm)</td>
<td>15.11±2.17</td>
<td>15.23±1.6</td>
</tr>
<tr>
<td>Procedural success</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Residual diameter stenosis 20% (by visual estimate) after stenting procedure, Time flow ≥3, No urgent CABG</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Table 4. Clinical outcome according to Dat time duration (cumulative events at 12 months)**

<table>
<thead>
<tr>
<th>No. of patients</th>
<th>2-month DAT</th>
<th>6-month DAT</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>MACE</td>
<td>3.2(2)</td>
<td>6.8(3)</td>
<td>0.001</td>
</tr>
<tr>
<td>Q-Wave</td>
<td>0(0)</td>
<td>0(0)</td>
<td>NA</td>
</tr>
<tr>
<td>Non Q-Wave</td>
<td>0(0)</td>
<td>0(0)</td>
<td>NA</td>
</tr>
<tr>
<td>TLR</td>
<td>3.2(2)</td>
<td>6.8(3)</td>
<td>0.001</td>
</tr>
</tbody>
</table>

* indicates not applicable because of zero value

**Conclusion**

In conclusions, our study confirms safety and efficacy of OPTIMA TES deployment even with short term DAT as short as 2 months. Based on our study results, it seems reasonable to consider OPTIMA TES as an alternative for patients suitable for DES implantation but at high risk for bleeding or with contraindication to long-term DAT. Randomized trials with longer follow-up periods are required to achieve better evaluations of OPTIMA TES in clinical practice.

**Acknowledgments**

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Conflict of interests: The authors declare no conflicts of interest.

**References**


Cardiopulmonary resuscitation (CPR) is practiced widely since the first practical report on the efficacy of closed chest massage in 1960. Delay in CPR after cardiac arrest could be associated with poor outcome. A hospital CPR discharge rate of 13.14% was reported from the studies in the 1990s, which has been confirmed by the recent Canadian study. Therefore, we decide to study our CPR team which includes emergency residents, nurses, anesthesia technicians and the staff that are involved in resuscitating patients in all hospital wards. Reports of survival after discharge following in-hospital CPR are variable between 7% and 26%. In our research, most of arrests happened in the morning and asystole rhythm was the most common rhythm; a 40 percent survival rate showed that we can improve our CPR team performance. Recent data have recommended that the successful resuscitation efforts could be prevented by insufficient performance of CPR. To increase safety and reduce errors, effective team performance in dynamic and complex environments such as critical care units are required in where decisions are made. There is supporting evidence that suboptimal team performance can have damaging effects. In the context of ACLS training, poor ACLS performance is associated with inefficient leadership and impaired task distribution between the resuscitation team members.

We studied 422 patients in our research from which 59.5% and 40.5% were male and female respectively. The median age of the patients was 68 (SD: 17.284) years old (mode: 73, oldest: 95, youngest: 1). The mean time of CPR performance was 30 minutes with the minimum of 3 minutes and maximum of 60 minutes. We found that most of our patients who arrested (36%) were admitted in pulmonary ward and after that (18.5%) were admitted in gastroenterology ward. Most of patients (51.7%) had arrested in the morning. 44.3% of patients did not have any definitive diagnosis; however, 5.5% of them had ESRD, 5.2% pneumonia, and 4.3% GI Bleeding.

Among patients asystole was the most common pattern (94.3; Figure 1), the other observed patterns are presented in Figure 1. Our CPR team had to intubate 24.4% of the patients while 75.6% were intubated prior to CPR team arrival. Just 40% of the patients could be saved following successful resuscitation.

Therefore, based on the obtained data from the present study, it seems that our CPR team work is effective; however, for being more effective and achieving better results, better organization is essential. By having more experienced and efficient team, and also by paying attention to those wards and times that have the most arrests we can be more prepared and therefore perform resuscitation more successfully than before.


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Apical Hypertrophic Cardiomyopathy in Association with Pulmonary Artery Hypertension

Mehdi Peighambari1, Mozghan Parsaei1, Anita Sadeghpour1, Azin Alizadehasl2

1Rajaie Cardiovascular Medical and Research Center, Tehran University of Medical Sciences, Tehran, Iran
2Cardiovascular Research Center, Tabriz University of Medical Sciences, Tabriz, Iran

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ABSTRACT
Apical Hypertrophic Cardiomyopathy is an uncommon condition constituting 1%-2% of the cases with Hypertrophic Cardiomyopathy (HCM) diagnosis. We interestingly report two patients with apical hypertrophic cardiomyopathy in association with significant pulmonary artery hypertension without any other underlying reason for pulmonary hypertension. The patients were assessed by echocardiography, cardiac catheterization and pulmonary function parameters study.

Introduction
An unusual form of hypertrophic cardiomyopathy (HCM) localized to the left ventricular (LV) apex was first described in 1976. The diagnostic criteria for apical HCM (AHCM) included presence of asymmetric LV hypertrophy, confined predominantly to the LV apex, with an apical wall thickness ≥ 15 mm and a ratio of maximal apical to posterior wall thickness ≥ 1.5, based on an echocardiogram or magnetic resonance imaging. Consisting 1%-2% of the HCM cases, AHCM is distinctly uncommon in other parts of the world. In Japan, this apical variant of HCM constitutes about 25% of patients with HCM.1-3 In this case study, we report two female patients with AHCM in association with significant pulmonary artery hypertension with no explainable reason for pulmonary hypertension. No similar case could be found in the literature review.

Case Report
Two female patients were referred to our center with complaints of dyspnea on exertion and NYHA function class of 1 to 2. Their electrocardiograms (ECG) showed sinus rhythm with giant negative T waves mostly noted in leads V3–V6 measuring 6–12 mm in depth; one of the taken ECGs is presented in Figure 1. Transthoracic echocardiogram revealed a grossly thickened LV apical myocardium with systolic obliteration of the apical portion of the LV cavity (Figure 2). LV apical thickness of 20 and 23 mm was reported in two patients while the diameters in septal and posterobasal thickness were normal. No systolic anterior motion of the anterior mitral leaflet or mitral regurgitation could be seen. On Doppler evaluation of mitral inflow velocities, the ratio between early diastolic flow (E) and atrial systolic flow (A) was less than 1 in both patients. Complete transthoracic echocardiographic examination revealed significant pulmonary artery hypertension (pulmonary artery pressures were equal to 50 and 65 mmHg in two patients). No other abnormal finding was observed in echocardiographic assessment. Furthermore, strain and strain rate studies confirmed muscular hypertrophy and AHCM in our patient which were in differential diagnosis with apical cardiac tumors, LV apical thrombus, and endomyocardial fibrosis (EMF). These patients underwent left and right cardiac catheterization through the left femoral arterial and venous approach. The pulmonary arterial pressure values were 48/18 mmHg and 50/24 mmHg and the mean pulmonary capillary wedge pressure values were 23 mmHg and 20 mmHg. In addition, contrast ventriculography showed a specific LV “spade-like” configuration while coronary angiogram revealed normal coronary arteries in both patients.

Discussion
AHCM is mostly considered of a sporadic nature; however, a few families with autosomal dominant inheritance have been reported.1 Apical HCM could mimic other conditions including apical cardiac tumors, LV apical thrombus, EMF and coronary artery disease. The strain and strain rate echocardiographic studies that we performed differentiated apical HCM from LV apical masses (thrombus or tumor).

*Corresponding author: Azin Alizadehasl, E-mail: alizadeasl@yahoo.com
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LV angiogram showed apical obliteration only during systole phase in our patients, whereas in EMF, apical obliteration occurs in systole and diastole phases; also coronary angiography revealed normal coronary arteries.4,8

Figure 1. Electrocardiogram showing sinus rhythm with giant negative T waves were noted in leads V3–V6

Figure 2. On 2-dimensional echocardiography, an apical 4-chamber view of the left ventricle showing hypertrophy of the apex in an “ace-of-spades” configuration

Echocardiographic assessment constantly shows normal or hyperdynamic LV systolic function in patients with AHCM. However, diastolic function is abnormal with slow early ventricular filling associated with increased dependence on late diastolic filling by atrial contraction. This may lead to left atrial dilatation and pulmonary hypertension.8,9

These patients are however unique in having a moderate to severe form of pulmonary hypertension along with AHCM. In our opinion, the mild diastolic LV dysfunction secondary to AHCM that was seen in our patients may establish mild or maximum mild to moderate pulmonary hypertension; however, we faced unexplained near severe increase in pulmonary artery pressure; all echocardiographic, catheterism and pulmonary function parameters were assessed in both patients. There may be an association between AHCM and pulmonary hypertension. However, we could not find any similar case in the literature review.

References