

## Percutaneous Coronary Intervention (PCI) of Chronic Total Occlusion (CTO) lesion in Bangladeshi patient population: a single center experience- In hospital and 90 days outcome

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### Abstract

#### Objectives

Aim of the study was to evaluate the primary in-hospital success and 90 days outcome of PCI in patients with CTO lesions, using either Bare-metal stents (BMS) or Drug Eluting Stent (DES) like Sirolimus-eluting or Paclitaxel-eluting stent.

#### Methods

Total 71 patients were included in this non-randomized prospective cohort as per the definition of CTO, from a total of 875 patients who had PCI at our center in the quantifying period. Total 92 stents were deployed in 71 patients. After the guide wire crossing and the balloon dilation, measurement of the culprit lesion were done by using Siemens QCA measuring system. Among the patients, Male: 59 and Female: 12. Mean age were for Male: 53yrs, for Female: 65yrs. Associated CAD risk factors were Dyslipidemia, High Blood pressure, Diabetes Mellitus, Positive FH for CAD and Smoking (all male).

#### Results

Our study shows 71 patients (8.1%) had CTO lesion out of total 875 PCI procedures. Among the study group; 56 (79%) were Dyslipidemic, 50 (70%) were hypertensive: 40 (56%) patients were Diabetic, 25 (42%) were all male smoker. Female patients were more obese (BMI M 26: F 27) and developed CAD in advance age. We found that the incidences of CTO lesions

were more in LAD territory 27 (38%) followed by RCA 26 (37%) and LCX 18 (25%). Average length and diameter of stented vessel was greater in RCA than LAD and LCX. Stents used: BMS 34 (36.9%), Sirolimus 25 (27.2%), Paclitaxel 18 (19.6%), Biolimus 10 (10.8%) and Everolimus 5 (5.4%). Post procedural, in-hospital and 90 days out come was 100% in our present study.

#### Conclusion

Our study has revealed that PCI in patients with CTO lesion has shown good success rate in our hospital with no procedural complication both in-hospital and 90 days after, either treated with BMS or DES.

**Key words:** PCI, CTO Lesion, DES, BMS.

#### Introduction

Chronic total occlusion (CTO) are common, and found in approximately one-third of patients with significant coronary disease who undergo angiography.<sup>1,2</sup> Percutaneous coronary intervention (PCI) of CTOs accounts for 10-15% of all angioplasties; however, after successful recanalization, there is an increased rate of subsequent restenosis and reocclusion compared with nonocclusive stenosis.<sup>3,4</sup> Although several randomized trials demonstrated the efficacy of stents implantation over balloon angioplasty, even with the stents there remains a significant rate of restenosis (32-55%) and reocclusion (8-12%).<sup>5-10</sup>

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Several studies have shown increase in procedural success and survival outcome with the reduction of MACE and late luminal loss and restenosis by Sirolimus eluting stent than bare metal stent.<sup>9,11-13</sup> Vessel size, specially small vessel with increase in tortuosity, diabetes with complex lesion, lengthy plaque are major contributory factors in stent restenosis. In the Drug stents era, successful PCI in CTO lesions is really a great challenge for interventionist. In this present study, we have evaluated primary end point of 90 days survival outcome after successful PCI in patients with CTO lesion.

### **Methods**

Chronic Total Occlusion (CTO) lesion was defined as an angiographically, no antegrade filling of distal vessel other than via collaterals. All patients included had a native vessel occlusion estimated to be of at least one month's duration<sup>14</sup> based on either a history of sudden chest pain or a previous myocardial infarction in the same target territory, the evidence of ischemia related to target vessel (signs of ischemia during an abnormal TMT (ST depression >1.0mm horizontal or down sloping or up sloping ST depression >2.0mm or signs of ongoing angina with the ECG changes on the target territory). However, temporal criteria to define CTO lesion was ranging from >2weeks to >3months. In general lesion with >3 months was considered as chronic according to the AHA/ACC lesion classification. The estimated length of the occlusion was measured from the point of the total occlusion to the most proximal part of the distal vessel which was visualized by collaterals filled by contrast.<sup>5, 8</sup> Consents were taken from all these patients.

### **Patient Population**

Patients were selected from all the PCI procedures at our centers as per definition of CTO lesions were included in this study. In patients, whom guide wire failed to cross the lesions were excluded from the study.

A total 71 patient out of 875 patients admitted for PCI, were selected as CTO lesion. PCI were done either with BMS or DES. DES included Cypher (Cordis, USA) and TAXUS (Boston Scientific, USA). The BMS included Multilink-Vision, Zeta (Guidant, USA) and Micro-Driver (Medtronic, USA) and Genous (Orbus, Netherlands). Coronary angioplasty was performed according to standard rules. Neither ablative techniques (rotablator, directional atherectomy) nor cutting balloon were used. Predilatation was optional before stent implantation with a shorter balloon to avoid geographic miss. A successful procedure was defined as TIMI-3 antegrade flow, and <20% residual stenosis in two orthogonal views. Post-deployment dilation was performed at high inflation pressure in all patients.

### **Drug Therapy**

All the patients received Aspirin 300 mg/day and Clopidogrol as a loading dose 300 mg prior to PCI and continued for 3-6 months and received atorvastatin along with standard Medical management for CAD. During the procedure, an intravenous heparin bolus (100IU/kg) and GP IIb/IIIa receptor blocker Integrilin were administered as required. The use of GP IIb/IIIa Receptor blocker was recommended as per protocol. Quantitative angiographic measurements of the target lesion were obtained in order to deploy correct size stents. In the event of chest pain, post-procedural ECG and CPK were measured and compared with the baseline. Check angio were taken, whenever indicated.

### **Primary End Points**

Primary end-points were considered to be acute or sub-acute stent thrombosis, death, Q-wave myocardial infarction, urgent CABG or repeat PCI within the 90 days of the original procedures.

**Statistical analysis**

All data were expressed as mean ± SD (Quantitative variables) and percentile of distribution (categorical). Body Mass Index (BMI) was calculated as body weight in kg divided by height in sq meter (kg/m<sup>2</sup>).

**Results:**

PCI were performed in total 71 patients (Male 59, Female 12) with CTO lesion.

Table 1. Showing the profile and clinical data of studied population. Female are older than male (Male 52.5 ± 9.1 vs Female: 65.3 ± 10.4) and more obese (BMI in male: male 26.3 ± 3.9 vs 27.3 ± 2.9). Both Systolic and Diastolic BP were higher in female than male (for SBP-Male: Female 135 ± 16 vs 155.3± 33.7 and for DBP-Male: Female 77.3±11.7 vs 86.3 ±12.5). Average number of CAD risk factors was higher in male than female (2.25 ± 0.5: 2.17 ± 0.7).

**Table 1. Demographic Profile of patient**

	Male		Female				
Number	59		12				
Age (yrs)	52.5	±	9.1	65.3	±	10.4	
BMI(kg/m <sup>2</sup> )	26.3	±	3.9	27.3	±	2.9	
SBP(mmHg)	135	±	16	155.3	±	33.7	
DBP(mmHg)	77.3	±	11.7	86.3	±	12.5	
No.of Risk Factor	2.25	±	0.5	2.17	±	0.7	

Data were presented as Mean ± SD

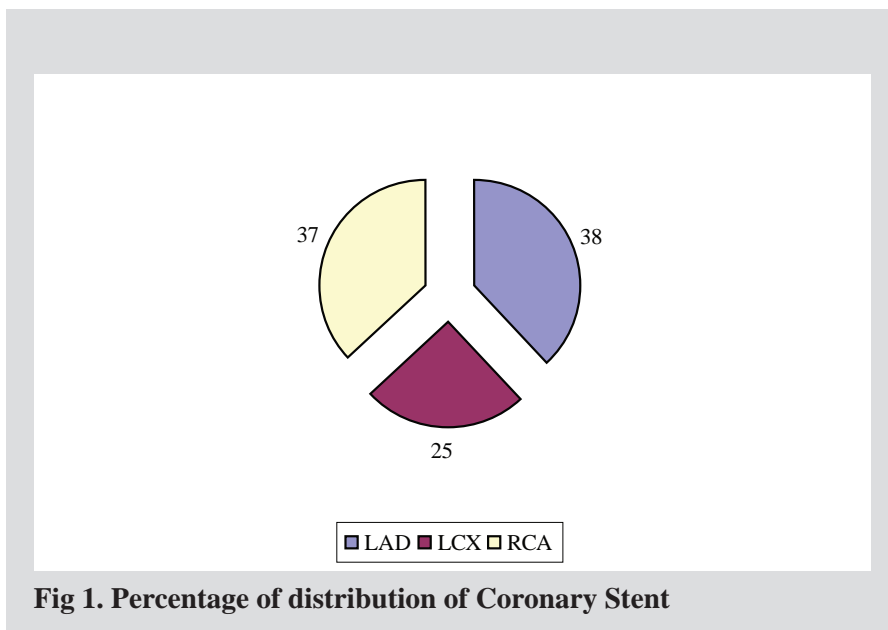
Table 2, showing the average length of the stents (in LAD: 24.2 ± 5.5; LCX: 20.2 ± 6.7; RCA 25.9 ± 6.6) and diameter (LAD 2.9 ± 0.3; LCX 2.9 ± 0.5; RCA: 3.1 ± 0.4).

**Table 2. Average size of Stent used with inflation pressure**

	Length (mm)			Diameter(mm)			Inflation Pressure(ATM)		
LAD	24.2	±	5.5	2.9	±	0.3	14.1	±	5.5
LCX	20.2	±	6.7	2.9	±	0.5	13.2	±	1.8
RCA	25.9	±	6.6	3.1	±	0.4	14.9	±	1.8

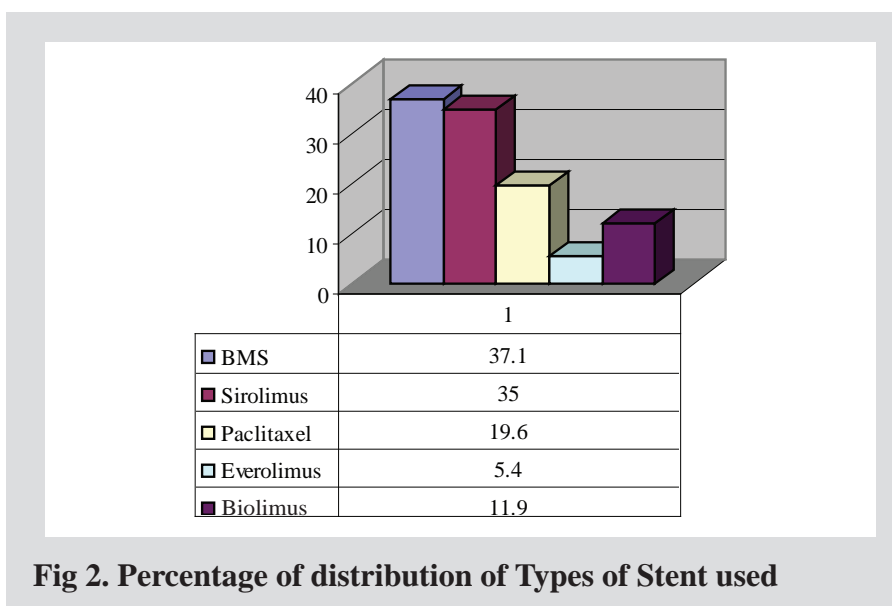
Data were presented as Mean ± SD

Fig. I Pie graph showing the percentage wise distribution of PCI in CTO lesions as to, LAD in 27 patients (38%), PCI to RCA in 26 patients (37%) and PCI to LCX in 18 patients (25%) were done.



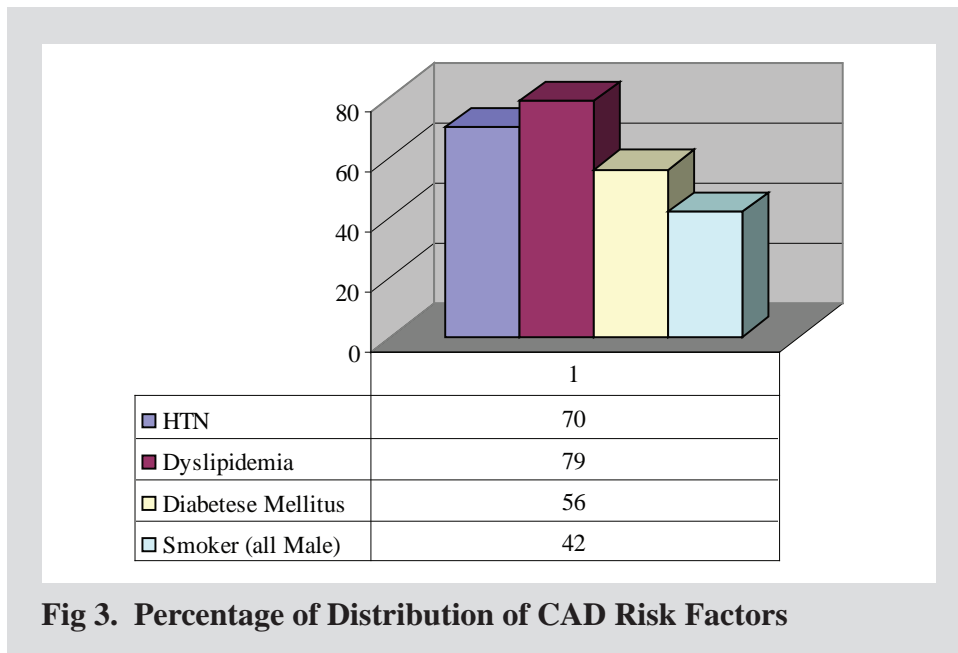
**Fig 1. Percentage of distribution of Coronary Stent**

Fig. 1 Pie graph showing the percentage wise distribution of PCI in CTO lesions as to, LAD in 27 patients (38%), PCI to RCA in 26 patients (37%) and PCI to LCX in 18 patients (25%) were done.



**Fig 2. Percentage of distribution of Types of Stent used**

Fig 2. Showing percentage distribution of the type of stent used, BMS 34 (37%) followed by Sirolimus-eluting stent 25 (27.2%) and Paclitaxel-eluting stent 18 (19.6%), Biolimus in 10 patients (11%) and Everolimus in 5 patients (5.4%). Among the Coronary artery diseases (CAD) risk factors,



**Fig 3. Percentage of Distribution of CAD Risk Factors**

Fig 3. Showing that Dyslipidemia is the predominant risk factors in 56 (79%) patients followed by HTN in 50 (70%), DM in 40 (56%), and smoker in 25 (42%) patients (all male).

**Discussion**

We have carried out this non-randomized prospective cohort study to see the 90 days post procedural outcome in PCI of CTO lesion in Bangladeshi patient perspective. As we know CTO lesion PCI is one of the challenging procedures among all PCI cases.

By definition, a CTO lesion is a lesion of more than 3 months duration with thrombolysis in myocardial infarction (TIMI) grade 0 or I- distal flow.<sup>15</sup> In the absence of serial angiogram, clinical timing of Acute MI or angina with ECG changes consistent with the location of occlusion is helpful to estimate the duration of occlusion.

Intervention in CTO lesion is a major challenge for the cardiologist practicing PCI. Success rates of PCI in CTOs have steadily increased over the last 15 yrs because of greater operator experiences, improvements in equipments and procedural techniques.<sup>9,16</sup> Length of occlusion, duration of occlusion, presence of

tapered entry configuration, bridging collaterals and calcification are also important predictors of procedural success.<sup>17-18</sup> New concept for CTO recanalization using controlled Antegrade and Retrograde Subintimal Tracking (CART) is a favorable strategy for invasive cardiologist. This has shown a feasible, safe and higher success rate,<sup>19</sup> although, procedural success of PCI of patients with CTO lesion was (55-90%).<sup>20</sup> Most interventional cardiologist has their own set standard within the already framed guidelines by ACC/AHA/ESC. Stone et al<sup>19</sup> has recommended that in general, when CTO represented by significant lesion in the coronary tree, PCI is warranted in 3 condition: 1) Occluded vessel is responsible for the clinical symptoms, 2) Myocardial territory supplied by the occluded vessel, and 3) the likelihood of success is moderate to high (>60%) with anticipated major complications like death to be <1% and myocardial infarction to be <5%.

Importance of revascularization of CTOs, with the improvement in anginal symptoms, exercise capacity, and left ventricular function has been well established.<sup>8,16</sup> In addition successful recanalization reduces the subsequent need for bypass surgery and importantly, long term evaluation has shown a survival of 10 yr in 73.5% after successful PCI than compared to 65.1% with unsuccessful PCI.<sup>9</sup> Attempts at CTO revascularization represents 8-15% of all PCI.<sup>21</sup> It improves anginal symptoms, exercise tolerance and LV function.<sup>22</sup> In addition, it lessens the incidences of MACE including cardiac mortality.<sup>15, 23</sup> The most common mode for PCI failure in CTOs, is the inability of successful passage of a guide wire into the true lumen of the distal vessel.<sup>24-25</sup> Kinoshita et al has demonstrated that failure to cross guide wire (63%), long intimal dissection with creation of false lumen (24%) , dye extravasations, failure to cross the lesion with balloon or dilate adequately (2%) and thrombosis (1.2%) are the common problems encountered in CTO intervention.

In our present study, we had limitations of single-centered trial. As most of our patients are not being covered by insurance and noncompliance with follow-up in OPD is difficult. Therefore, we had to limit our study of PCI on these patients up to 90 days after the procedures. Previously, we have published our data on CTO lesion PCI and its 30 days post PCI outcome.<sup>26</sup> In our present study, we found that female are more obese and developed CAD in more advanced age than male patients. Admission BP was higher in female either due to obesity or from non-compliance to their current medication. We also found that average number of CAD risk factors were higher in male than female, although male are having one more exclusive CAD risk factor as being smoker. Among the CAD risk factors dyslipidemia contributed an important role in the development of atherosclerotic CAD followed by HTN, DM and smoking. Incidences of CTO lesion were higher in LAD followed by RCA and LCX of the studied population was

consistent with the results of Holmes et al.<sup>27</sup> Our results are consistent with others studies which showed, that the above mentioned risk factors are the major contributing factor in the development of CAD, specially CTO lesion. In the present study, none of the patient needed repeat procedures or had MACE like MI, Death, Acute Stent thrombosis during in-hospital and 90 days after the procedure.

In the future, we would like to focus on long term survival outcome studies of these patients for up to 6-12 months, if possible angiographically. Effective reduction of in-stent restenosis by 1<sup>st</sup> generation DES like Sirolimus-eluting or Paclitaxel-eluting stents versus bare metal stent as well as 2<sup>nd</sup> generation DES needs to be clarified.

In our present study, none of the patient had procedural complications. We therefore, within limited resources (unavailability of special CTO wires and IVUS), were able to demonstrate that PCI in the CTOs increases procedural success and 90 day survival in our population.

## Conclusion

CTO lesion is one of most the complex and critical type of CAD lesion. This usually carries a lot of procedural risk during or after successful intervention. For this reason, they need to be followed up at regular interval to evaluate and see its success as complications are more common. The procedural complexity of CTO lesion PCI and the lack of familiarity with new equipment and technique innovation specific to CTO intervention often prompt half hearted prematurely aborted attempts at PCI, ensuring high failure rates and physician and patient frustration. Fortunately, the tremendous progress in guide wire, techniques developed in the recent past, coupled with the introduction of dedicated CTO devices, has resulted in success rates of 80-90% by experienced operators in true CTOs.<sup>10</sup>

Our future perspective is to see the long-term survival outcome and restenosis rate of CTO lesion PCI in Bangladeshi patient population, more patient inclusion, multicenter study to be done either by BMS or DES. This needs to be clarified more by retrospective as well as by comparative study in a larger population.

#### References

1. Stone GW, Rutherford BD, McConahay DR. Procedural outcome of angioplasty for total coronary artery occlusion: an analysis of 971 lesion in 905 patients. *J Am Coll Cardiol.* 1990;15:849-56.
2. Ivanhoe RJ, Weintraub WS, Douglas JS. Percutaneous transluminal coronary angioplasty of chronic total occlusion: primary success, re-stenosis and long-term clinical follow-up. *Circulation.* 1992;85:106-15.
3. Sirens PA, Golf S, Myreng Y. Stenting in chronic coronary occlusion (SICCO): a randomized, controlled trial of adding stent implantation after successful angioplasty. *JACC.* 1996;28:1444-51.
4. Rubartelli P, Nicoli L, Verna E. Stent implantation versus balloon angioplasty in chronic total occlusion: result from the GISSOC trial. *J Am Coll Cardiol.* 1998;32:90-6.
5. Buller CE, Dzavik V, Carere RG. Primary stenting versus balloon angioplasty in occluded coronary arteries. *Circ.* 1999;100:236-42.
6. Serruys PW, Hamburger JN, Koolen JJ. Total occlusion trial with angioplasty by using laser guide wire: the total trial. *Eur Heart J.* 2000;21:1797-805.
7. Hoye A, Tanabe K, Lemos PA. Significant reduction in re-stenosis after the use of sirolimus-eluting stents in the treatment of chronic total occlusion. *JACC.* 2004;43:1954-8.
8. Finci L, Meier B, Favre J. Long-term results of successful and failed angioplasty for chronic total coronary arterial occlusion. *AMJ.* 1990;66:660-2.
9. Suero J, Marso SP, Jones PG. Procedural outcomes and long-term survival among patients undergoing percutaneous coronary intervention of a chronic total occlusion in native coronary arteries. *J Am Coll Cardiol.* 2001;38:409-14.
10. Stone GW, Reifart NJ, Moussa I. Percutaneous recanalization of chronically occluded coronary arteries. *Circ.* 2005;112:2530-37.
11. Suttorp MJ, Laarman GJ, Rahel BM. Primary stenting of totally occluded native coronary arteries II (PRISON II) study: a randomized comparison of bare metal stent implantation with sirolimus-eluting stent implantation for the treatment of total coronary occlusion. *Circulation.* 2006;114:921-928.
12. Moses JW, Leon MB, Pompa JJ. Sirolimus-eluting stents versus standard stents in patients with stenosis in native coronary artery. *N Eng J Med.* 2003;349:1315-1323.
13. Stone GW, Ellis SG, Cox DA. Polymer based paclitaxel-eluting in patients with native coronary artery disease. *N Eng J Med.* 2004;350:221-231.
14. Buller CE, Dzavik V, Carere RG. Primary stenting versus balloon angioplasty in occluded coronary arteries: the total occlusion study of Canada (TOSCA). *Circulation.* 100:236-242.
15. Stone GW, Kandzari DE, Mehran R. Percutaneous recanalization of chronically occluded artery: a consensus document: Part I. *Circulation.* 2005;112:2364-2372.
16. Ramanathan K, Gao M, Nogareda GJ. Successful percutaneous recanalization of a non-acute occluded coronary artery predicts clinical outcomes and survival. *Circulation.* Abstract.2001;1041:II-415.
17. Maiello L, Colombo A, Gianrossi R. Coronary Angioplasty of chronic occlusions: Factors predictive of procedural success. *Am Heart J.* 1992;124:581-584.
18. Noguchi T, Miyazaki S, Morii I. Percutaneous transluminal coronary angioplasty of chronic total occlusions. Determinants of primary success and long-term clinical outcomes. *Catheter Cardiovasc Interv.* 2000;49:258-264.
19. Surmely JF, Tsuchikane E, Katoh O. New concept for CTO recanalization using controlled antegrade and retrograde subintimal tracking (CART) technique. *J Invasive Cardiol.* 2006;18:334-338.
20. Stone GW, Refart NJ, Moussa I. Percutaneous recanalization of chronically occluded coronary arteries: a consensus document: part II. *Circulation.* 2005;112:2530-2537.
21. Kandzari DE. The challenges of chronic total coronary occlusions: an old problem in a new perspective. *J Interv Cardiol.* 2004;17:259-267.
22. Sirens PA, Myreng Y, Molstad P. Improvement in left ventricular ejection fraction and wall motion after successful recanalization of chronic coronary occlusions. *Eur Heart J.* 1998;19:273-281.
23. Olivari Z, Rubartelli P, Piscione F. Immediate results and one year clinical outcomes after percutaneous coronary intervention in chronic total occlusions: data from a multicenter prospective observational study (TOASTGISE). *J Am Coll Cardiol.* 2003;41:1672-1678.
24. Safian RD, McCabe CH, Sipperly ME. Initial success and long-term follow-up of percutaneous

- transluminal coronary angioplasty in chronic total occlusions versus conventional stenosis. *Am J Cardiol.* 1988;61:23G-28G.
25. Kinoshita et al, Katoh O, Nariyama J. Coronary angioplasty of chronic total occlusions with bridging collaterals vessel: immediate and follow-up outcome from a large single-center experience. *J Am Coll Cardiol.* 1995;26:409-415.
  26. AHM Waliul Islam, S Munwar, S Talukder: Percutaneous coronary intervention (PCI) in patients with chronic total occlusion (CTO): a single center experiences. *Cardiovascular J.* 2010;(2):168-174.
  27. Holmes DR Jr, Vlietstra RE, Reeder GS. Angioplasty in total coronary artery stenosis. *J Am Coll Cardiol.* 1984;33:845-9.