Quality of Life After Coronary Stent Implantation in Thai Population

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Abstract

Placement of a stent in the coronary has become common practice in Thailand for treatment of Symptomatic Coronary Artery Disease. We evaluated the impact of such a practice on Life Quality in addition to symptomatic improvement by questionnaire interview using the Sickness Impact Profile format. 34 patients from 3 major cardiac centers †in Bangkok were randomly selected to participate after having successful coronary stenting procedures. Quality of Life and Symptom of Angina improved dramatically after the index procedure and continued to improve at 6 weeks and 12 weeks evaluation time. We conclude that dilatation with stent implantation of coronary stenosis is beneficial in the Thai Population both in symptoms as well as Life Quality improvement.

Key word : Quality of Life, Coronary Stent Implantation, Thai Population

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Transcatheter enlargement of the coronary artery lumen in patients who have atherosclerotic stenosis, with balloon dilatation and stent implantation has become the standard therapy for alleviating myocardial ischemia and angina pectoris. The practice has gained momentum in Asia-Pacific region especially in Thailand. The number has risen, at least in Thailand, exponentially since the initial 18 cases done as introduction in 1989[1]. It was estimated that more than 600 coronary stent procedures were done in 1998. Although the clinical impact of stent implantation is huge because the

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practice has produced a decrease in the need for emergency surgery, the incidence of acute myocardial infarction and death[2] despite unfavorable clinical and anatomical conditions treated[3]. However quality of life, considered difficult to measure objectively, was hardly mentioned in the literature. As coronary stenting has become more fashionable at the present time we undertook this study to evaluate subjectively and objectively the benefit of this modality of therapy in patients who had symptomatic coronary artery disease. Our hypothesis was that people who underwent luminal enlargement of their coronary artery with coronary stenting would enjoy a better life quality afterwards.

MATERIAL AND METHOD

Subjects:

Patients who would undergo coronary dilatation & stent implantation from 3 major cardiac centers in Bangkok (Ramathibodi Hospital, Chulalongkorn Hospital and Phramongkutkloa Hospital) were randomly approached to participate in the study.

Coronary intervention

Coronary dilatation and stent implantation were carried out in the usual standard fashion. These were done mostly from the femoral route but trans-radial approach was allowed. All patients received intravenous heparin and aspirin prior to coronary dilatation. Decision of technique and equipment used was up to the practicing cardiologist. The indication in stent implantation after balloon dilatation was mainly due to inadequate angiography pictures following balloon dilatation. The patient was observed in the coronary care unit where the introducer sheath was removed usually 6 hours after the procedure. The patient was allowed to ambulate the day after sheath removal. All patients received both ASA & Ticlopidine (2-4 weeks) after the procedure. Some of them received an additional short course of heparin either subcutaneous or intravenous afterwards. Patients were discharged home after they were able to ambulate and were without chest discomfort or entry site complication.

Evaluation of life Quality

The Sickness Impact Profile is a behavior-based measure of health status composed of 136 statements about health-related dysfunction. Dysfunction is defined as the "modification or impairment in degree or manner of carrying on an activity, cessation of an activity, or initiation of a new activity that interferes with or substitutes for a usual activity"[4]. Each of the SIP statements describes a behavior. The subjects endorse each statement if it describes them currently and is related to their state of health. Each item has attached to it a value proportional to the amount of dysfunction. The total per cent dysfunction is calculated by summing the values for the endorsed items, dividing by the sum of the values for all items and multiplying by 100. The items are grouped into twelve categories i.e. sleep and rest, emotional behavior, body care and movement, home management, mobility, social interaction, ambulation, alertness behavior, communication, recreation and pastimes, eating, and work. These 12 categories are re-grouped in 3 areas of living i.e. physical ability, psychosocial activity and general health status. In addition to the total score, per cent dysfunction in each category can be calculated by summing the values of the endorsed items within the area and dividing by the sum of the values of all items within the area. Higher scores mean disability and discontent with life. All patients were interviewed face to face and were asked to answer these questionnaires prior to the index coronary stenting procedure. The process was repeated at 2, 6 and 12 weeks at the clinic. Patients were also asked about their sexual activity at the same time frame.

Evaluation of chest pain

Canadian Classification of Angina Pectoris and the number of nitroglycerin pills were used as the marker of symptomatic impairment or improvement before and after the index procedure. They were measured at the same time frame as evaluation of life quality.

Analysis of Data

Information of life quality was compared using Friedman test due to the nature of continuous variables. Discrete number of Angina class and number of NTG use were analyzed using Wilcoxon signed rank test. The comparisons were done as before and after index coronary stenting and as different timeframes to the one before. The analysis was facilitated by using SPSS software.

RESULTS

Thirty-four patients (25 males) with symptoms of angina pectoris and significant stenosis of

their coronary artery amenable to transcatheter dilatation, participated in the questionnaire study. Their mean age was 60.8 with the range of 38-74. Three (8.8%) did not have any formal education and the questionnaire had to be read to them with the answer checked by the research nurse. The majority (85.3%) had a stable picture of angina prior to the procedure, 61.8 per cent of which were having class 2 angina pectoris by Canadian Classification. 67.6 per cent of patients required sublingual nitroglycerin on a usual basis. Risk factors for atherosclerosis in this population were hypercholesterolemia (>200 mg/dl) in 70.8 per cent, personality type A in 70.6 per cent smoking in 55.8 per cent, hypertension in 44.1 per cent physical inactivity in 38.2 per cent, and diabetes in 20.6 per cent. Angiographically 52.9 per cent had double vessel disease, 29.4 per cent had single vessel disease.

All 34 patients had had successful stent implantation in at least one of their coronary arteries i.e. the most culprit and the most significant artery. 67.6 per cent of patients received 1 stent. 72.5 per cent had no residual stenosis after coronary balloon intervention where 27.5 per cent had average residual stenosis of 22.3 per cent. There was no emergency bypass graft required and there was no major cardiac or access site complication. The average length of hospital stay was 3.32 days.

At 2 weeks, 82.4 per cent of patients were not having any chest pain or angina pectoris, while 2.9 per cent were in Canadian Class 1, 11.8 per cent were in Canadian Class 2, and 2.9 per cent were in Canadian Class 3 respectively. Compared to prior to coronary intervention all 34 patients were having angina with 5.9 in class 1, 61.8 per cent in class 2, 11.8 per cent in class 3 and 5.9 per cent in class 4. At 6 weeks 85.3 per cent of patients were free of angina while 14.7 per cent were in class 2 respectively. At 12 weeks the number looked less attractive partly due to restenosis with 88.2 per cent of patients being asymptomatic, 11.8 per cent were in class 2. The frequency of chest pain and the number of sublingual nitroglycerin used per week were significantly less at 2 weeks and continued to be significantly less at 6 weeks and at 12 weeks. (Fig. 4). Of interest >40 per cent were reported to have normal sexual activity after the procedure compared to 8.8 per cent prior to the index stent implantation.

Quality of Life evaluated by Bergner questionnaire is displayed in Fig. 1. Scoring in each of the 12 categories was significantly better after coronary intervention. Scoring in each of the 3 areas of living was also better, translating into a better scoring of overall Sickness Impact Profile of patients in this study as a whole. The difference was statistically significant at each time frame comparison. The improvement of life quality paralleled the reduction in the amount of nitroglycerin used as seen in Fig. 2.

DISCUSSION

Enlargement of coronary luminal diameter with balloon dilatation has proved to result in symptomatic and life quality improvement. The procedure has been faced and challenged with as high as a 5 per cent chance of acute closure and 30 per cent chance of restenosis. Intra-luminal placement of prosthesis, so called stenting, has attenuated such complications. In BENESTENT & STRESS trials placement of metal prosthesis in the coronary artery of stable elective type of patients demonstrated an absolute 10 per cent reduction of the rate

Example of sickness impact profile questionnaire related to sleep and rest.
Please respond to (check) only those statements that you are sure describe you today and are related to your state of health.
1. I spend much of the day lying down in order to rest_____
2. I sit during much of the day_____
3. I sleep or doze most of the time_____
etc.

Example of sickness impact profile questionnaire related to body movement
Please respond to (check) only those statements that your are sure describe you today and are related to your state of health.
1. I make difficult moves with help e.g. getting into or out of cars, bathtubs_____
2. I do not move into or out of bed or chair by myself but am moved by a person or mechanical aid_____
3. I stand only for short periods of time_____
etc.

Fig. 1. Examples of some of the questionnaire used in the study.

of restenosis. However, the rate of subacute stent thrombosis and access site (mainly the groin) bleeding were usually high because of warfarin therapy post-stent placement.

The rate of sub-acute thrombosis i.e. recurrent myocardial infarction usually ST elevation type after stent implantation, was reported to be as high as 7 per cent in STRESS[5] and BENES-

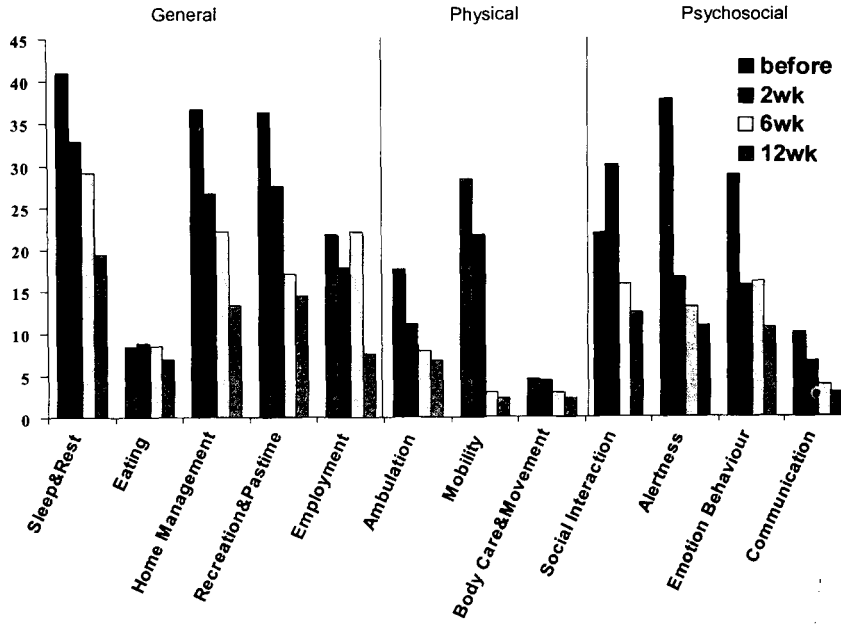

Fig. 2. Score of each 12 sub-categories of life quality by sickness impact profile evaluation.

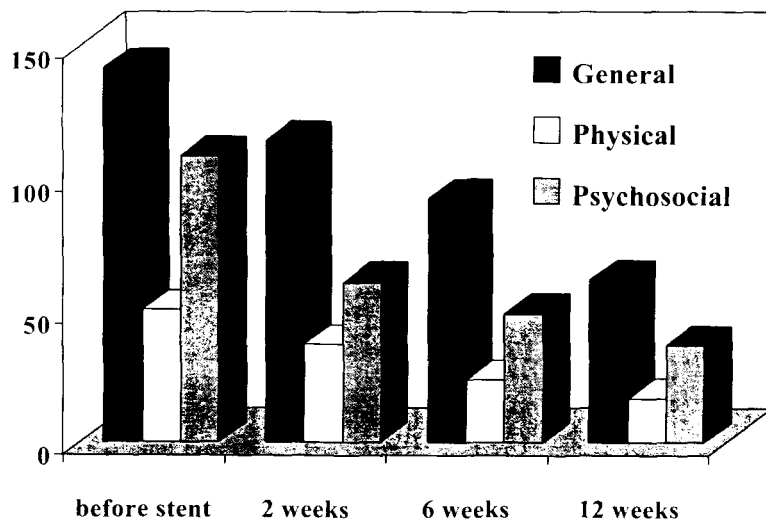

Fig. 3. Score of sickness impact profile in different time frames of coronary stenting. A higher score means discontent with life. The graphs demonstrate the improvement of different dimensions of life quality. The difference is statistically significant in each and every interval compared ($p<0.05$).

TENT[6] trials. The causes of this malignant complication are the use of 1st generation stiff stent with inadequate stent expansion technique using too low a dilatation force and due to inadequate suppression of platelet adhesion and aggregation process. The access site, mostly groin, bleeding and hematoma also had an exceedingly high incidence. The use of Warfarin as the aggressive anticoagulation has probably contributed to this high rate of bleeding. Sub-acute thrombosis and the access site complication with early era of stent implantation may not result in improvement of overall life quality. Most patients in this study received a 2nd generation stent and the high-pressure dilatation technique was used in every case. In addition, every patient received Ticlopidine and Aspirin as the standard antiplatelet regimen. This combination has been proved to provide the lowest rate of sub-acute stent thrombosis[7,8]. No one in this study received warfarin and there was no report of access site complication or sub-acute thrombosis. This may explain our findings of short hospital stay and improvement of life quality as early as 2 weeks.

Sickness Impact Profile, as introduced by Bergner in 1978, has been used with and without adjustment in evaluation of life quality in many disease states including COPD[9], Head Injury[10] and Post Cardiac Arrest[11]. There was a substantial correlation between physician assessments of health status and patients ' SIP scores[12]. The items included in the questionnaire were standardized and structured in a way that subjects were asked to respond positively to those items, which they were sure of, described them and were related to their health. Body Care and movement and Social Interaction provide approximately 35 per cent of the SIP score.

Table 1. The pattern of chest pain according to Canadiam classification of angina pectoris in the study population at different intervals. The improvement of pain was seen as early as 2 weeks and parallel to the improvement of life quality as a whole.

	Before (%)	2 weeks (%)	6 weeks (%)	12 weeks (%)
No angina	14.7	82.4	85.3	88.2
Canadian	85.3	17.6	14.7	11.8
Class I	5.9	2.9	0	0
Class II	61.8	11.8	14.7	11.8
Class III	11.8	0	0	0
Class IV	5.9	2.9	0	0

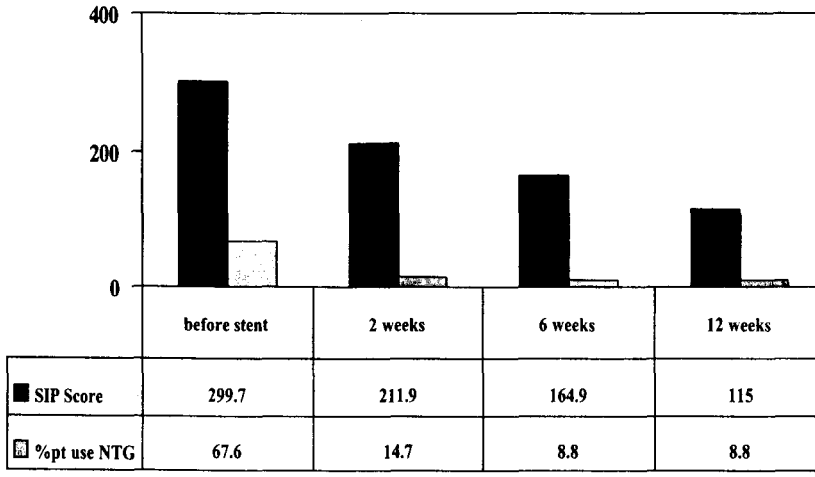

Fig. 4. The relationship between the overall SIP scores and the number of patients requiring NTG.

The questionnaire looked into quality from most angles of life. The improvement occurred early after stent implantation and continued to improve. The improvement of life quality determined this way was due to several possibilities. The early ambulation without any further aggressive anticoagulation contributed most to the early discharge. The perception of pain was also different at different time frames of the disease. Another explanation is the way patients perceived the result of the procedure. The result of the coronary stenting angiographically was shown almost immediately upon completion of the procedure. The impact of this perception of almost having a new artery may alter the perception of chest pain and reassure them of returning to normal earlier than expected.

Different methods have been used to evaluate the effect of stent implantation on life quality. The stent Restenosis study[13] used a mailing survey that included 36 short-form health questions, Canadian Cardiovascular Society Classification and the Duke Activity Status Index. 80 per cent of patients responded. 47 per cent reported a very good or excellent health status after stent implantation. RITA trial[14] used the Nottingham Health Profile as the reference of life quality study in 1011 patients after coronary revascularization (either PTCA or CABG). Both interventions produced marked improvement in all quality-of-life dimensions (energy, pain, emotional reactions, sleep, social isolation, and mobility). Of interest, the RITA Trial also demonstrated a close link between angina grade and quality of life i.e. patients with angina at 2 years had more quality of life impairment than angina-free patients, whose perceived health was similar to population norms.

Since the procedure of placing such a prosthesis in the coronary artery has gained momentum in Thailand, we need to evaluate the justification of such a practice. This study may not give the whole picture of the cost-effectiveness version of the procedure but it does provide some platform for quality assessment. In our country, a future healthcare reimbursement selection process may need to incorporate such evidence of benefit from a local study.

Limitation of the study. The small sample size is probably the major limitation. In any event, the difference in life quality was large and proved statistically significant. We did not, however, measure the number at 6 months since this is the period that one may be faced with the process of restenosis in the stent. Bias is usually an issue when subjective expression is being evaluated objectively.

Summary. Stent implantation of stenotic coronary artery resulting in symptomatic improvement as well as in better life quality in the Thai population.

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REFERENCES

1. Boonbaichaiyapruck S, Mahanondha N, Sritara P, Chakorn T, Chaithiraphan S. Bangkok Cardiac Intervention Registry. Ramathibodi Medical Journal 1995; 18: 15-8.
2. Hong MK, Wong CW, Kent KM, et al. An aggressive stent strategy improves procedural success and reduces major in-hospital ischemic complication. Circulation 1995:I-535.
3. Malosky S, Hirchfeld J, Hermann H. Comparison of results of intracoronary stenting in patients with unstable angina vs stable angina. Cathet Cardiovasc Diagn 1994; 31:95-101.
4. Bergner M, Bobbitt RA, Kressel S, Pollard W, Gilson BS, Morris JR. The Sickness Impact Profile: Conceptual formulation and methodology for the development of a health status measure. Int J Health Serviece 1976; 6: 393-415.
5. Fischman DL, Leon MB, Baim D, et al. A randomized comparison of coronary stent placement and balloon angioplasty in the treatment of coronary artery disease. N Engl J Med 1994;331: 496-501.
6. Serruys PW, de Jacgerre PPT, Kiemeneij F, et al. A comparison of balloon expandable stent implantation with balloon angioplasty in patients with coronary artery disease. N Engl J Med 1994;331: 489-95.
7. Schomig A, Neumann FJ, Kastrati A, et al. A randomized comparison of antiplatelet and anticogulant therapy after the placement of coronary artery stents. N Engl J Med 1996;334:1084-9.
8. Colombo A, Hall P, Nakamura P, et al. Intracoronary stenting without anticogulation accomplished

with intravascular ultrasound guidance. Circulation 1995;91:1676-88.
9. McSweeny AJ, Grant I, Heaton RK, Adams KM, Timms RM. Life Quality of Patients with Chronic Obstructive Pulmonary Disease. Arch Intrn Med 1982;142:473-8.
10. Temkin N, McLean A, Dikmen S, Gale J, Bergner M, Almes MJ. Development and Evaluation of Modifications to the Sickness Impact Profile for Head Injury 1988;41:47-57.
11. Bergner L, Bergner M, Hallstrom A, Eisenberg M, Cobb L. Health Status of Survivors of Out-of-Hospital Cardiac Arrest Six Months Later. AJPH 1984;74:508-10.
12. Martin D, Gilson B, Bergner M, et al. The Sickness Impact Profile: Potential Use of a Health Status Instrument for Physician Training. J Med Educ 1976;51:942-4.
13. Krumholz HM, Cohen DJ, Williams C, et al. Health after coronary stenting or balloon angioplasty: results from the stent Restenosis Study. Am Heart J 1997;134(3)L337-44.
14. Pocock SJ, Henderson RA, Seed P, Treasure T, Hampton JR. Quality of life, employment status, and anginal symptoms after coronary angioplasty or bypass surgery. 3 year follow-up in the Randomized Intervention Treatment of Angina (RITA) Trial. Circulation 1996;94:135-42.

คุณภาพชีวิตหลังการขยายหลอดเลือดหัวใจที่มีการใช้ตะแกรงลวดค้ำยันในผู้ป่วยไทย

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การขยายหลอดเลือดหัวใจที่มีการใช้ตะแกรงลวดค้ำยันเป็นหัตถการของการรักษาโรคหลอดเลือดหัวใจตีบตันที่ทำกันมากขึ้นในประเทศไทย งานวิจัยนี้ได้ทำการศึกษาผลของการรักษาด้วยวิธีนี้ที่มีต่อคุณภาพชีวิตของผู้ป่วยโรคหลอดเลือดหัวใจตีบตัน โดยคัดเลือกผู้ป่วย 34 คนจากศูนย์หัวใจในกรุงเทพมหานคร 3 แห่ง† และทำการวัดผลของการรักษาต่อคุณภาพชีวิตหลังจากที่ได้รับการรักษาด้วยการขยายหลอดเลือดหัวใจที่มีการใช้ตะแกรงลวดค้ำยันร่วมด้วย เป็นเรียบร้อยแล้วในแบบ Sickness Impact Profile (SIP) ซึ่งเป็นเครื่องมือและแบบฟอร์มที่ใช้วัดคุณภาพชีวิตร่วมไปกับอาการเจ็บหน้าอก พบว่าคุณภาพของชีวิตผู้ป่วยและอาการเจ็บหน้าอกของผู้ป่วยเหล่านี้ดีขึ้นมากจากการวัดที่ 2, 6 และ 12 สัปดาห์หลังจากที่ได้รับการรักษา ทางผู้วิจัยสรุปว่าการรักษาภาวะโรคหลอดเลือดหัวใจตีบตันด้วยการขยายหลอดเลือดที่มีการใช้ตะแกรงลวดค้ำยันเป็นการรักษาที่ทำให้คุณภาพของชีวิตผู้ป่วยดีขึ้น

คำสำคัญ : คุณภาพชีวิต, การขยายหลอดเลือดหัวใจที่มีการใช้ตะแกรงลวดค้ำยัน, ผู้ป่วยไทย

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