CH Lee 李志恒
WH Chow 周榮興
OH Kwok 郭安慶

Percutaneous balloon mitral valvuloplasty during pregnancy: long-term follow-up of infant growth and development

懷孕期間經皮氣囊二尖瓣瓣膜成形術：嬰兒發育成長的長期跟進

We have studied the long-term growth and development of seven infants who had been exposed during the foetal stage to ionising radiation associated with percutaneous balloon mitral valvuloplasty between 1 April 1991 and 30 November 1993. We found that infants of mothers who underwent this procedure during the second and third trimester of pregnancy had normal long-term growth and development. This finding supports the argument that percutaneous balloon mitral valvuloplasty using the Inoue balloon technique should be the procedure of choice for pregnant women who have severe mitral stenosis refractory to medical therapy.

我們研究了1991年4月1日至1993年11月30日之間，在胎兒階段曾暴露於經皮氣囊二尖瓣瓣膜成形術相關聯的電離放射中7名嬰兒的長期發育成長情況。我們發現，母親在懷孕的第二及第三個妊娠期間進行這種放射所產生的嬰兒有正常的長期發育成長。這發現支持下述論點：使用Inoue氣囊技術的經皮氣囊二尖瓣瓣膜成形術，應該是患有嚴重二尖瓣狹窄而難醫治的孕婦的選擇。

Key words:
Balloon dilatation;
Fetus/radiation effects;
Mitral valve stenosis;
Radiation protection/instrumentation

關鍵詞：
氣囊擴張術；
胎兒／放射影響；
二尖瓣狹窄；
放射保護／測試設備

HKMJ 2001;7:85-8

Cardiac Medical Unit, Grantham Hospital, 125 Wong Chuk Hang Road, Hong Kong
CH Lee, MB, BS, MRCP
WH Chow, FHKCP, FHKAM (Medicine)
OH Kwok, FHKCP, FHKAM (Medicine)

Correspondence to: Dr CH Lee

Introduction

Since its first introduction in 1984, percutaneous balloon mitral valvuloplasty (PBMV) using the Inoue balloon technique, has become the accepted treatment for patients with severe symptomatic mitral stenosis. This technique is less invasive than mitral valve replacement because thoracotomy and the risks of general anaesthesia are avoided. Thus, procedural and hospitalisation times are much shortened. Furthermore, unlike after mitral valve replacement, anticoagulation is not necessary after PBMV, except for selected patients who have atrial fibrillation.

Pregnant women with severe symptomatic mitral stenosis represent a highly selected patient subgroup. The narrowed mitral valve orifice causes a decrease in cardiac output and an increase in pulmonary artery pressure and capillary wedge pressure, which can result in pulmonary oedema. Haemodynamic changes that are associated with pregnancy expose these patients to cardiovascular decompensation. The general management involves limitation of activity, sodium restriction, antibiotic prophylaxis, and administration of β-blockers, digoxin, and diuretic therapy. Alternative

therapies need to be considered for those patients who respond unsatisfactorily to drug treatment.

Percutaneous balloon mitral valvuloplasty provides palliation for pregnant women with mitral stenosis, and the reported success rate is nearly 100%.[1-4] There are concerns, however, about the radiation exposure to the foetus that occurs during the procedure. Previous reports of the use of PBMV in pregnant women have mainly focused on symptomatic and haemodynamic improvements.[5] There are relatively few reports that describe the infant's development and short-term growth outcomes.[6] Long-term follow-up data of infants who have been exposed to ionising radiation during their foetal stage are lacking and the long-term outcome of these children remains unknown. This study aimed to investigate the long-term growth and development of children who were exposed to radiation associated with the PBMV procedure before they were born.

Methods

From 1 April 1991 to 30 November 1993, a total of eight consecutive pregnant women underwent PBMV at the Grantham Hospital. All patients had severe mitral stenosis with symptoms that included exertional dyspnoea and palpitation. Six of the women were classified as New York Heart Association functional class II and two were classified as functional class III. Their mean (standard deviation [SD]) age at the time of the procedure was 31.3 (4.4) years (range, 27.0-37.0 years). All patients were primigravidas. The mean (SD) gestational age at the time of the procedure was 24.0 (4.2) weeks (range, 21.0-30.0 weeks) [Table].

All patients were admitted 1 day before the procedure. Transoesophageal echocardiography was performed before the procedure to ensure favourable valvular anatomy and the absence of a left atrial thrombus. Only those patients with a Wilkins score of <8 were recruited. The Wilkins score is based on valvular mobility, calcification, and thickening, as well as subvalvular thickening as seen on an echocardiogram. The possible scores range from 4 to 16. The lower the score, the more favourable is the valvular anatomy for those undergoing PBMV. All patients were asked to give written consent before the procedure, and antibiotic prophylaxis with intravenous ampicillin and gentamicin were given preoperatively. All procedures were performed under local anaesthesia and with the abdomen protected from the fluoroscope with a lead shield. Following transeptal puncture, an Inoue balloon was positioned in the mitral orifice. The balloon was inflated in a stepwise manner until the indentation in the balloon created by the stenotic valve was no longer visible. A post-dilatation left ventriculogram was performed to detect mitral regurgitation. The transmitral valve pressure gradient was measured before and after the procedure.

The subsequent course of the pregnancy was regularly assessed in the out-patient clinic after each patient's discharge. After birth, the infant and mother were followed up in the specialty out-patient clinic at 1, 3, and 6 months, then at 1 year, and yearly thereafter. The infant's developmental milestones and physical and mental development were assessed and recorded during each follow-up visit. Each child's academic performance at school was also assessed.

Results

Seven of the eight patients had successful PBMV performed, giving a success rate of approximately 88%. The mean (SD) follow-up time was 7.4 (0.8) years. The mean (SD) procedure and fluoroscopy times were 42.0 (11.0) minutes and 10.2 (4.4) minutes, respectively. The mean (SD) mitral valve area increased from 0.9 (0.4) cm^2 to 1.9 (0.7) cm^2. The mean (SD) mitral valve gradient decreased from 18 (6) mm Hg to 6 (2) mm Hg. The mean (SD) Inoue balloon size was 25.2 (1.0) mm (range, 24.0-26.5 mm). For the patients who had a successful procedure performed, all

Table. Patient and infant characteristics

Patient No.	Age (months)	Height (cm)	Weight (kg)	Body surface area (m^2)	Gestational age (weeks)	Wilkins score
1	29	155	53	1.50	20	6
2	27	161	66	1.68	25	4
3	28	171	70	1.80	30	8
4	37	152	53	1.47	29	6
5	29	156	39	1.33	20	8
6	31	152	50	1.45	22	6
7	33	146	42	1.30	26	6
8	36	153	48	1.42	20	8

experienced a reduction of drug treatment, improvement in exercise capacity, and a normal course during the pregnancy, followed by full-term delivery. Three had a spontaneous vaginal delivery, two had a forceps delivery, one required vacuum extraction, and one had a caesarean section. The mean (SD) birthweight of the babies was 2.8 (0.4) kg.

At the latest follow-up visit, the mean (SD) age of the seven children was 7.0 (0.8) years (range, 6.0-8.0 years). The mean (SD) height and weight were 118.8 (1.8) cm and 21.8 (0.9) kg, respectively. These values are around the 50th percentile values on the paediatric growth chart for the local population. All but one of the children were in excellent health with regards to physical and mental growth and development. The son of the seventh patient was found to have asthma, which required regular salbutamol inhaler therapy, and an inguinal hernia. These conditions are probably unrelated to the radiation exposure received during the foetal stage; thus, this was considered a successful case. All these children are now studying in primary school and show satisfactory performance.

One patient was in the 20th gestational week of pregnancy when referred to the Grantham Hospital because of severe mitral stenosis. The echocardiogram showed a mitral valve area of 0.6 cm^2, a pliable valve, and no mitral regurgitation. The PBMV procedure was performed in the 21st gestational week. However, the procedure was complicated by severe mitral regurgitation and acute pulmonary oedema, which required emergency mitral valve replacement. The patient had a spontaneous incomplete abortion 1 day after the surgery and was transferred to the obstetric unit for evacuation of the uterus. She eventually recovered after a prolonged hospital stay.

Discussion

The ionising radiation exposure that occurs during interventional cardiology procedures has always been a great concern.[7] This issue is particularly sensitive for pregnant women undergoing these procedures due to the potential teratogenic risk. The exposure of an embryo or foetus to ionising radiation produces effects that differ in their nature and severity according to the gestational age at which the exposure occurs.[7,8] Detrimental effects include severe mental retardation, organ malformation, and malignancy, especially leukaemia.[7,8]

Numerous measures have been suggested during PBMV for pregnant women to minimise radiation exposure. These include shielding the abdomen and pelvis, avoidance of left ventriculography, performance of the procedure after the 20th week of gestation (when organogenesis has been completed), and using a transthoracic or transoesophageal echocardiogram as a guide during the transeptal puncture of the heart. Despite these precautions, unwanted effects on the foetus is still a great and real concern for pregnant women.

The fact that one patient had a spontaneous abortion after an emergency mitral valve replacement secondary to a failed PBMV procedure suggests that procedural failure may have disastrous consequences for the foetus. The present selection criteria, using a Wilkins score of <8 may need validation for pregnant women. Although most studies have shown that the Wilkins score has a predictive value for the procedural outcome after PBMV, these studies were based on non-pregnant patient data.[9] The predictive power for pregnant women needs to be further studied in a larger series of patients.

This small cohort shows that infants of mothers who underwent PBMV in the second and third trimester of pregnancy have normal long-term growth and development. However, because of the small sample size, the teratogenic effect of the ionising radiation cannot be totally excluded. Furthermore, childhood malignancy is extremely rare and a study of this size

Mitral valve area (cm^2)		Mitral regurgitation	Inoue size (mm)	Pregnancy outcome	Sex of infant	Birthweight (kg)
Pretreatment	Post-treatment					
0.9	1.7	Absent	25.0	Successful	Male	3.2
0.8	2.2	Absent	26.0	Successful	Male	2.3
0.7	1.4	Absent	26.5	Successful	Female	3.3
1.0	1.5	Mild	26.0	Successful	Male	2.4
1.4	3.0	Severe	26.0	Abortion	-	-
1.2	1.8	Absent	24.0	Successful	Female	2.9
1.1	2.5	Absent	24.0	Successful	Male	2.7
0.4	0.7	Absent	24.0	Successful	Male	3.1

cannot address this issue. Given the rarity of childhood malignancy, the benefits of the PBMV probably outweigh the possible increased risk of childhood malignancy. In conclusion, this study supports the argument that PBMV using the Inoue balloon technique should be the procedure of choice for pregnant women who have severe mitral stenosis refractory to medical therapy.

References

1. Farhat MB, Maatouk F, Betbout F, et al. Percutaneous balloon mitral valvuloplasty in eight pregnant women with severe mitral stenosis. Eur Heart J 1992;13:1658-64.
2. Oto MA, Kabukcu M, Ovunc K, et al. Percutaneous balloon valvuloplasty for severe mitral stenosis in pregnancy. Four case reports. Angiology 1997;48:463-7.
3. Ben Farhat M, Gamra H, Betbout F, et al. Percutaneous balloon mitral commissurotomy during pregnancy. Heart 1997;77:564-7.
4. Gupta A, Lokhandwala YY, Satoskar PR, Salvi VS. Balloon mitral valvotomy in pregnancy: maternal and fetal outcomes. J Am Coll Surg 1998;187:409-15.
5. Esteves CA, Ramos AI, Braga SL, Harrison JK, Sousa JE. Effectiveness of percutaneous balloon mitral valvotomy during pregnancy. Am J Cardiol 1991;68:930-4.
6. Mangione JA, Lourenco RM, dos Santos ES, et al. Long-term follow-up of pregnant women after percutaneous mitral valvuloplasty. Catheter Cardiovasc Interv 2000;50:413-7.
7. Balter S. Radiation safety in the cardiac catheterization laboratory: basic principles. Catheter Cardiovasc Interv 1999; 47:229-36.
8. Fattibene P, Mazzei F, Nuccetelli C, Risica S. Prenatal exposure to ionizing radiation: sources, effects and regulatory aspects. Acta Paediatr 1999;88:693-702.
9. Hernandez R, Banuelos C, Alfonso F, et al. Long-term clinical and echocardiographic follow-up after percutaneous mitral valvuloplasty with the Inoue ballon. Circulation 1999; 99:1580-6.

Acknowledgement

Apologies to the following referees of papers in volume 6 of the Journal, whose names were omitted from the 2000 Acknowledgement (HKMJ 2000;6:447-8)

Dr KL Chan
Dr LC Chan
Prof MW Chan
Dr TK Chan
Dr VNY Chan
Dr AR Chang
Dr EMC Chau
Dr EP Chien
Dr D Choy
Dr S Chung
Prof P Cleary
Prof JA Dickinson
Prof WE Fee
Prof TF Fok
Dr DTS Fong
Dr KY Fung
Prof AJ Hedley
Prof PC Ho
Dr G Joynt
Prof A Kleinman
Dr TK Kong
Prof SK Lam
Dr YK Lau
Dr A Lee
Dr L Leong
Prof GM Leung
Dr WKY Leung
Dr PCK Li
Dr CK Lin
Prof SB Lucas
Dr KDK Luk
Dr D Melzer
Prof C Metreweli
Dr A Procter
Dr TC Pun
Dr D Siu
Dr SY So
Dr YT Tai
Dr PKH Tam
Dr L Tang
Dr R Tang
Dr TQ Thach
Dr PPC Tong
Dr WC Wu
Dr JWS Yeung
Dr SK Yip
Dr PM Yuen