

# Percutaneous Balloon Mitral Valvuloplasty : Proposed Protocol for Patients Health Needs Management

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**Abstract:** Patient undergoing procedure of percutaneous balloon mitral valvuloplasty (PBMV) have many needs that should be assessed to improve both the quality and value of care. **Aim:** This study aimed to propose a protocol for patients` health needs management during percutaneous balloon mitral valvuloplasty (PBMV) procedure. **Subjects and Method:** A descriptive design was utilized in this study, that was conducted in the Cardiology Departments and Out Patients` Clinics at Madinah Cardiac Center. A purposive sample of (60) adult patients from both genders undergoing percutaneous balloon mitral valvuloplasty procedure were recruited from the above mentioned settings. The study tools were: 1) Patients` health needs assessment sheet (pre/post procedure) that included physical, psychological, social, spiritual and educational needs. 2) Anxiety Rating Scale (pre/post procedure) to assess anxiety level. 3) Numerical pain scale (pre/post procedure) to assess pain severity level. **Results:** More than half of the studied patients were working, with age above 35 years, male and married. In addition, they had health needs pre procedure. **Conclusion:** The present study concluded that patients under the study had higher needs: physical, psychological, social, spiritual and educational pre percutaneous balloon mitral valvuloplasty (PBMV) procedure compared to post procedure. In addition, the highest needs pre procedure were physical followed by educational, spiritual, psychological and then later social. **Recommendations:** Further studies should be carried out on a large number of such group of patients with evidence of results and generalization.

**Keywords:** Percutaneous Balloon Mitral Valvuloplasty - Patients`Health Needs Management - Proposed Protocol.

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## I. INTRODUCTION

In recent years percutaneous balloon mitral valvuloplasty (PBMV) is one of preferred treatment in heart disease intervention therapy. Patients who have been diagnosed with mitral valve stenosis, high-risk aortic stenosis or certain blockages of the plumonic valve may benefit from balloon valvuloplasty. These valvular obstructions are relieved using highly specialized balloon catheters (Dowling et al., 2023 & Brown et al., 2017). A balloon is threaded into the heart through the vein (femoral) in the groin and temporarily expanded across the narrowed valve. The goal of this procedure is to enhance blood flow across the mitral valve. Mitral regurgitation is a potential complication thus PBMV is contraindicated if moderate or severe level is present. It is a procedure that performed in the cardiac catheterization laboratory by cardiologist and

specialized team of nurses and technicians under local anesthesia for 1 hour. The preparation and recovery time add to overall time (Parikh et al., 2022 and Azarbal & LeWinter, 2018).

Prevalence of rheumatic heart disease (RHD) was observed in Oceania, South Asia and central sub-Saharan Africa also. It is estimated that in 2015 there were 29.7 to 43.1 million cases and 9.6 to 11.5 million disability-adjusted life-years. There is a high incidence of advanced mitral stenosis in adult life. A genetic predisposition to develop RHD appears to be important in certain countries (Bykowski et al. 2023 & Watkins et al., 2017).

The recently recommended balloon/annulus ratio is 1.2 to 1.25. Following the procedure, the dramatic reduction of pressure gradient, the rise of cardiac output have been noted, whereas complications may occur but are unusual and minimal. In conclusion, the procedure is equally successful in patients, while worldwide recognized studies prove the safety, feasibility, and effectiveness. However, for early detection of any complication, life-long clinical follow-up is mandatory (Parikh et al., 2022 & Talukder et al., 2020).

Patient undergoing Percutaneous Balloon Mitral Valvuloplasty procedure (PBMV) have many needs that should be assessed to improve both the quality and value of care. These needs include: physical dimension such as activities of daily living, physical preparation, general assessment, interventional technique, investigations and treatment, post-procedural pain management, control of nausea and vomiting, postoperative diet, complications` management, procedural access site care and self-care post discharge (LeMone et al., 2015). Psychological dimension such as: reducing anxiety from pain and complications and information about emotional health lifestyle ....etc. Social dimension such as: patient's social activities, work, driving and social support. Spiritual dimension such as sight for the future, motivation ....etc. Nurses plays a vital role to increase awareness for such group of patients based on their needs, treatment options and discharge instructions (Ford et al., 2018 and Harb & Griffin, 2017).

Patients should receive consistent information and effective discharge instructions to be prepared for transition of care from hospital to home. An effective practical discharge advice will increase patients` confidence, improve health status and make them feel safe and comfortable. It is vital to provide certain guidelines about their analgesic regimen, wound care, returning to daily activities and dietary advice (Wang et al., 2016 & Chen et al., 2015). Therefore, this study aimed to propose a protocol for patients` health needs management during Percutaneous Balloon Mitral Valvuloplasty procedure to improve both the quality and value of patients care.

## II. BODY OF ARTICLE

### Aim of the study:

This study aims to propose a protocol for patients` health needs management during Percutaneous Balloon Mitral Valvuloplasty procedure. This aim was achieved through the following:

- Identifying pre/post procedure patients` health needs (physical, psychological, social, spiritual and educational) of the patients having percutaneous balloon mitral valvuloplasty.
- Assessing anxiety and pain levels among the study patients.
- Propose a protocol for health needs management among patients undergoing Percutaneous Balloon Mitral Valvuloplasty.

### Research Questions:

- What are the health needs among study patients pre/post percutaneous balloon mitral valvuloplasty procedure ?
- What are the anxiety and pain levels among the study patients pre/post percutaneous balloon mitral valvuloplasty procedure ?
- Is there a relation between studied patients` health needs and the proposed protocol?

### Operational Definitions:

- **Health needs:** means physical, psychological, social, spiritual and educational needs.

- **During** : means pre-/post-procedure
- **Protocol**: is a set of instructions which describe a process or method to be followed to meet the health needs of patient having percutaneous balloon mitral valvuloplasty.

#### Methods:

- **Design**: a descriptive explorative design was utilized in this study.
- **Setting**: the study was conducted at the Cardiology Departments and Out Patients` Clinics at Madinah Cardiac Center.
- **Subjects**: a purposive sample of (60) adult patients undergoing percutaneous balloon mitral valvuloplasty procedure within six months was involved in this study from the above-mentioned setting.
- *Inclusion criteria*: adult patients with mitral stenosis undergoing percutaneous balloon mitral valvuloplasty, with no other co-morbidities (e.g. renal failure, cancer, cerebrovascular stroke...etc.)

#### ● Tools:

**I. Patients' interviewing questionnaire** (pre/post procedure): it was designed by the researchers in light of the relevant and related literatures review then translated to a simple Arabic language. It will included the following :

❖ **Characteristics of the study patients** such as: age, gender, level of education, marital status, occupation, income and residence.

❖ **Patients' medical records** to identify past, present medical history, diagnosis, investigations and treatment.

❖ **Patients` health needs assessment sheet** was included :

- *Physical needs*, such as resuming activities of daily living, follow prescribed diet, perform exercises, maintain hygienic measures, sufficient sleeping hours, and relive fatigue.
- *Psychological needs*, such as relieve anxiety, sense of safety, coping, fear of complications, and fear of loneliness.
- *Social needs*, such as social support, recreation activities, sexual change, work adjustment, need for assistance, financial burden and feeling of usefulness.
- *Educational needs*, such as definition/causes of mitral stenosis, manifestations, treatment, advantages of the procedure, health education and discharge instructions, e.g, wound care, infection control, diet, follow up, drugs, investigations, and daily activities.
- *Spiritual needs*, such as satisfaction improvement, inner peace sensation, future positive vision and increase spiritual practices.

**II. Anxiety Rating Scale** (pre/post procedure): It was developed by Hamilton (1959), to assess anxiety level among study patients and consisted of thirteen variables. Reliability of the scale items using alpha cronbach test = 0.83.

#### Scoring System:

Patients` responses were (0-3) scores and total score ranged from 0-39. They categorized anxiety level as follows: no (zero) , mild (0 - less than 23) , moderate (23 - less than 29) and sever (29 - 39).

**III. Numerical pain scale** (pre/post procedure): it was used to measure pain severity among patients under study. It was based on Jacques (2011) to measure severity of pain. It was composed of a line divided by numbered points from (0-10).

#### Scoring system:

Patients' answers were categorized pain level as follows: No (zero), mild (0 - less than 4), moderate (4-less than 7) and severe (7 - 10).

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**IV - Patients` satisfaction assessment sheet (post procedure).** It was based on **Kleefstra et al. (2012)** to assess patient ` satisfaction for general day care . It was consisted of: Admission procedure (3 items), nursing care (2 items), medical care (2 items) , information (4 items), autonomy (3 items) and discharge and aftercare (3 items) .

It contain 17 questions . Answers were sorted as follows (1 = unsatisfied, 2 = somewhat satisfied, 3 = rather satisfied, 4 = quite satisfied and 5 = very satisfied) .

### Scoring system:

Total score was calculated as follows : 17 questions × 5 point = 85

High satisfaction ( 51 - 85 ) and Low satisfaction ( Less than 51 ) .

### **Content validity:**

It was ascertained by a group of experts from Medical and Nursing Department . Their opinions were elicited regarding to the tools format layout, consistency and scoring system . Contents of the tools were tested regarding to the knowledge accuracy, relevance and competence .

### **Pilot study:**

A pilot trial was carried out on 10% of the total study sample to test the clarity and practicability of the tools, in addition to subjects and settings. Pilot subjects were later included in the study as there were no radical modifications in the study tools .

### **Field Work:**

- Sampling was started and expected to be completed within six months.
- Purpose of the study was simply explained to patients who agree to participate in the study prior to any data collection.
- The researchers were collect data from patients pre/post procedure.
- Data collection was done 2 days/week by the researchers in the morning and afternoon shifts.
- The proposed protocol content was consistent with the related literatures and based on patients` health needs .
- The protocol was presented as follows :
  - Pre procedure preparations
  - During procedure management
  - Post procedure management
  - Discharge Instructions

### **Administrative design:**

- An official permission was obtained from Director of the Madinah Cardiac Center in which the study was conducted .

### • **Statistical design:**

Data were organized, tabulated and analyzed using number, percentage, mean and standard deviation .

### **Ethical considerations:**

In the planning stage approval was obtained from directors of the above mentioned setting. All patients were informed about the study and their rights according to medical research ethics that they were free to decide whether or not they would participate in the study. Then a written informed consent was obtained from each patient who agreed to participate in the study .

III. RESULTS

Table (1) Characteristics of the Studied Patients (n=60)

Items	Studied Patients	
	(No )	%
Age / yrs : ≤ 35 yrs	18	30.0
>35 yrs	42	70.0
Gender : Male	34	56.7
Female	26	43.3
Marital status Single	20	33.3
Married	40	66.7
BMI (weight )		
Under (<18.5kg)	30	50.0
Normal (18.5 – 25 kg)	13	21.7
Over (>25)	17	28.3
Education : Illiterate / Primary	15	25.0
Secondary	30	50.0
University	15	25.0
Job : Not Working	17	28.3
Working	43	71.7

Table (1) : Shows studied patients’ characteristics . Results indicated that more than half of them were working , with age above 35 years , male and married (71.7 , 70.0 , 56.7, 68.7&66.7 respectively).As regards education and BMI , half of them were under weight with secondary level of education .

Table (1) Percentage Distribution of the Studied Patients As Regards Their Complaints

Items of Complaints	Studied Patients	
	(No)	(%)
Palpitation	60	100 .0
Shortening of breath	60	100 .0
Orthopnea	52	86.7
Cough	54	90 .0
Lower limb edema	60	100.0
Chest pain	55	91.7
Fatigue	57	95.0

Table (2): Shows studied patients according to their complaints. Results revealed that all of study subjects (100.0) had palpitation, shortening of breath and lower limb edema. In addition, the majority had fatigue and chest pain (95.0 & 91.7) respectively.

Table (2) Distribution of studied patients as regards their health needs pre / post PBMV procedure

Items of Health Needs	Studied Patients	
	Mean No ± SD	
	Pre	Post
Physical	55.0±6.3	37.2 ±8.4
Psychological	42.4 ± 6.4	23.4 ± 7.3
Social	43.3±5.2	24.9±8.4
Spiritual	44.0±4.6	14.0±2.5
Educational	53.4±4.1	38.6±6.2

**Table (3):** Reveals studied patients as regards their health needs pre / post PBMV procedure. A statistically significant difference was observed between the health needs: physical, psychological, social, spiritual and educational in pre/post procedure , whereas more improvement was indicated post procedure .

**Table (4) Distribution of Anxiety and Pain Levels Among Studied Patients Pre/Post Procedure**

Items	Studied Patients (n=60)	
	Pre	Post
	%	%
<b>Pain Level</b>		
Mild	24.7	72.0
Moderate	43.8	22.7
Sever	31.5	5.3
<b>Anxiety Level</b>		
Mild	23.0	79.0
Moderate	47.0	14.0
Sever	30.0	7.0

**Table (4):** Reveals studied patients' anxiety and pain levels pre/post procedure . Concerning pain level , 31.5 of them had severe pain pre procedure , meanwhile , 5.3 post procedure . As regards anxiety level , 30.0 had sever anxiety pre procedure , compared to only 7.0 post procedure .

**Table (5) Distribution of Patients` High Satisfaction Level As Regards PBMV Care Post Procedure**

Items of Satisfaction	Studied Patients (n=60)	
	No	%
Pre-admission visit	42	70.0
Admission	41	68.3
Operative room	45	75.0
Nursing care :	38	63.3
Medical care	49	81.7
Information	39	65.0
Autonomy	30	50.0
Discharge	36	60.0
$\bar{X}$ No $\pm$ SD	40.0 $\pm$ 5.7	
% of Mean	66.7%	

**Table (5):** Shows studied patients` satisfaction level as regards PBMV care post procedure . As noticed more than three fifths of them were satisfied for the following : Pre-admission visit , admission , operative room , nursing / medical care , information and discharge .

#### IV. DISCUSSION

Balloon valvuloplasty is an alternative to valve replacement in patients with critical stenosis to enlarges the orifice of a heart valve that has been narrowed by a congenital defect, calcification, rheumatic fever, or aging (Parikh et al. , 2022 & Talukder et al., 2020 ) . It is a procedure that may relieve many of the symptoms of valve disease . Some patients may continue to need medications, even after a successful procedure. Lifestyle factors that can worsen valve disease may also need to be changed. An exercise program may be prescribed to improve health after the procedure (Munusamy & Kannan , 2019) . This study aimed to propose a protocol for patients` health needs management during Percutaneous Balloon Mitral Valvuloplasty procedure .

In the present study, findings regarding to patients' characteristics revealed that, more than two thirds of the studied patients were with 35 yrs and more . This finding was supported by Khashaba et al. (2009) who found that, the mean age of patients undergoing percutaneous balloon mitral valvotomy was 39  $\pm$  38 years.

In relation to studied patients' complaints. Study findings revealed that all of them had palpitation and breath shortness. Moreover, the majority had cough and chest pain. **Bykowski et al. (2023) & Pomerantzeff et al. (2020)** reported that common symptoms of the study subjects were palpitation, shortening of breath and fatigue and two thirds of them had orthopnea and cough. Moreover, depending on patients' own comments after one week from procedure they still have palpitation attacks, dyspnea or cough.

As regards studied patients health needs pre / post PBMV procedure. A statistically significant difference was observed between the health needs: physical, psychological, social, spiritual and educational in pre/post procedure, whereas more improvement was indicated post procedure. According to Abraham Maslow's hierarchy of needs, a physical need is something critical to the survival of the human body. Maslow lists the basic physical needs as water, air, food, warmth, sex, sleep and the disposal of bodily waste. There are four levels of needs: safety, social belonging and support, self-esteem and self-awareness or actualization. Until the basic physical needs of the human body are met, Maslow emphasizes that all other needs become moot (**LeMone et al., 2015**).

The management focuses on early detection of signs and symptoms, prevention of complications. Gradual activity progression is encouraged as the patient's condition improves. Activity tolerance is monitored and activities modified as needed. Encouraging patients to change their life style to have a regular walk if not walking regularly, diet control and adjustment in right time and healthy components. Strategies to maintain rest and conserve energy become important. **Bykowski et al. (2023) & Alkhouli et al. (2017)** stated that more than half of patients undergoing PBMV expressed that they need to relief fatigue and full recovery of daily physical activity needed less than two weeks. Hygienic measures specially mouth and dental care, avoiding sore throat and upper respiratory tract infection. Daily mouth care, frequent teeth brushing and regular dentist consultation prevent a lot of cumulative oral infections and hidden problems.

**Talukder et al. (2020) mentioned that** teaching patient what to expect pre, during and post procedure is very crucial for cooperation and adherence to the procedure. Patient will be admitted to hospital at least a day before the procedure, assessment and physical preparation could be done. Moreover, balance between fluid intake and diuresis is important, patient should avoid both circulatory overload which causes congestion and dehydration which increases blood viscosity and worsen blood flow through the narrowed valve orifice. Health education can help patients to adapt to illness, prevent complications, carry out prescribed therapy, and solve problems. It can also prevent crisis situations and reduce re-hospitalization.

**Pomerantzeff et al. (2020)** recognized that majority of study subjects had low satisfaction and expectation loss to future concerns, while there was a remarkable improvement after a successful interventional procedure. Moreover, significant number of study patients did not have knowledge on post procedure precautions, hospitalization period, infection and discharge instructions, concluded that in facing this problem, patients should be provided with better instructions pre procedure.

On the light of the present study finding illustrates that the highly affected patients' needs pre procedure were physical followed by educational and social then later psychological and spiritual. Meanwhile post procedure physical and educational needs were found in about two thirds of patients. This was supported by **Alkhouli et al. (2017)** who mentioned that after one week from procedure, patients were not able to return to work and need additional week for convalescence.

Concerning anxiety and pain levels, nearly one third of study patients had severe anxiety and pain pre procedure compared to only little number post procedure. **Bykowski et al.(2023) & Raghav (2018)** stated that, study subjects expressed fear of potential complications pre-procedure and less than half of them reported fear of complications even after a successful procedure, while anxiety was reported in more than two thirds of patients. Reducing pre-procedure anxiety include; pharmacological therapy, information provision, distraction and focusing attention and relaxation procedures. In pre-procedure assessment, the nurse assist patient to identify coping strategies to decrease fear. Patients were benefited from provision of all needed information in verbal and written form in simple sentences and clear terms, explain procedures, active-listening to their concerns, answers honestly and got the expected support from visits **Elkaryoni, et al.(2022)**.

**Dowling et al. (2023) & Howsmon et al. (2020)** stated that moderate stabbing pain was described by majority of patients as recurrent chest pain. As regards pain, assessing as well as, identifying opportunities for pain control is pre-emptive pain management that supports an effective option for post-procedure pain management. In addition, chest discomfort or low

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back or flank pain and discomfort are predictors of complications post-procedure (retroperitoneal hematoma), peripheral pulsation (recording and reporting), monitor for 24 hours manifestations of dyspnea, chest pain, seizure (recording and reporting) and arrange for patients' bed rest for 8 hrs. as in post-coronary car.

### V. CONCLUSION

The present study concluded that patients under the study had physical, psychological, social, spiritual and educational needs pre percutaneous balloon mitral valvuloplasty (PBMV) procedure. In addition, the highest needs pre procedure were physical followed by educational, spiritual, psychological and then later social. Moreover, nearly one third of them had sever level of pain and anxiety pre procedure.

### VI. RECOMMENDATIONS

- The proposed protocol that's evidence – based should be implemented and evaluated.
- An educational training program should be held for patients undergoing percutaneous balloon mitral Valvuloplasty (PBMV).
- Patients are in need to a simplified Arabic booklet about PBMV.
- Continuous health needs assessment for such group of patients
- Further studies should be carried out on a large number of such group of patients with evidence of results and generalization .

**Based on findings of the present study, proposed protocol for patients` health needs management during Percutaneous Balloon Mitral Valvuloplasty procedure (Appendix I).**

#### **Proposed Protocol Contents:**

##### **1-Pre Procedure**

Patient should asked to do the following :

- Sign a consent form
- Ask any questions about the procedure.
- Notify physician if have a reaction to any contrast dye, or allergic to iodine or seafood , medications, latex, tape, or anesthetic agents (local and general).
- Fast for a certain period of time prior to the procedure.
- Notify physician if have any body piercings on chest and/or abdomen.
- Notify physician of all medications (prescription and over-the-counter) and herbal supplements that are taking.
- Notify physician if have a history of bleeding disorders or if taking any anticoagulant (blood-thinning) medications,. It may be necessary to stop some of these medications prior to procedure.
- Notify physician if have a pacemaker.
- Area around the catheter insertion (groin area) may be shaved.
- Receive a sedative prior to the procedure to help relax.

##### **2-During Procedure**

Generally, a valvuloplasty follows this process:

- Remove any jewelry or other objects that may interfere with the procedure.
- Remove clothing and will be given a gown to wear.



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- Empty bladder prior to the procedure.
- An intravenous (IV) line will be started prior to the procedure
- Placed in a supine position on procedure table.
- Connected to an ECG monitor
- Vital signs will be monitored.
- A local anesthetic will be injected into the skin at insertion site.
- Once the local anesthetic has taken effect, a sheath, or introducer, will be inserted into the blood vessel.
- May feel some effects when the contrast dye is injected into the IV line. ( flushing sensation, a salty or metallic taste in mouth, or a brief headache ) last for a few moments.
- if notice any severe discomfort or pain, such as chest pain, neck or jaw pain, back pain, arm pain, shortness of breath, or breathing difficulty, tell physician.
- Remove the sheath, or introducer, from the insertion site four to six hours, to allow effects of blood-thinning medication given during procedure to wear off.
- Lie flat during this time.
- NOTE: If the insertion was in the groin, will not be allowed to bend leg for several hours.
- keep leg straight,

**3-After Procedure**
**In Hospital**

- Patient taken to the recovery room for observation or returned to hospital room.
- Remain flat in bed for several hours after the procedure.
- Monitor vital signs, the insertion site, and circulation/sensation in the affected leg or arm.
- Immediately inform if you feel any chest pain or tightness, or any other pain, as well as any feelings of warmth, bleeding, or pain at the insertion site in your leg or arm.
- Bedrest may vary from two to six hours depending on specific condition.
- If physician placed a closure device, bedrest may be of shorter duration.
- After the sheath is removed, patient may be given a light meal.
- Pain medication for pain or discomfort related to the insertion site or having to lie flat and still for a prolonged period.
- Encouraged to drink water and other fluids to help flush the contrast dye from body.
- Patient may feel the urge to urinate frequently. use a bedpan or urinal while on bedrest so that affected leg or arm will not be bent.
- Resume usual diet after the procedure, unless physician decides otherwise.
- After specified period of bed rest has been completed, The nurse will assist the first time get up, and will check blood pressure while lying in bed, sitting, and standing.
- Patient receive detailed instructions for discharge and recovery period.

**At Home:**

- Monitor the insertion site for any abnormality and notify physician.

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- If physician used a closure device for insertion site, you will be given specific information regarding care of the insertion site.
- There will be a small knot, or lump, under the skin at the injection site gradually disappear over a few weeks. Keep the insertion site clean and dry.
- Specific bathing instructions.
- Not to participate in any strenuous activities.
- When can return to work and resume normal activities.
- Notify physician to report any of the following:
  - Fever and/or chills
  - Increased pain, redness, swelling, or bleeding or other drainage from the insertion site
  - Coolness, numbness and/or tingling, or other changes in the affected extremity
  - Chest pain/pressure, nausea and/or vomiting, profuse sweating, dizziness, and/or fainting

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