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Assessment and Monitoring of Adverse Effect of Metoprolol

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Abstract

Pharmacovigilance plays a key role in the health system through the evaluation, monitoring and detection of drug interactions and their impact on humans. . Therefore, drug safety requires monitoring of adverse reactions for each drug throughout its life cycle, during drug development, e.g. Pharmacovigilance deals with the detection, evaluation, understanding and prevention of adverse effects Metoprolol Observational studies suggest that beta-blockers may lower the risk of exacerbations and death in patients with moderate or severe chronic obstructive pulmonary disease (COPD), but randomized trials have not yet verified these findings. We can see Metoprolol's MOA and ADR in all of their forms.

Keywords: Pharmacovigilance; Metoprolol; ADR

Introduction

1. To provide persons involved in the manufacture of complementary medicines with the practical.
2. Aspects and knowledge to be able to ensure that their company complies with the current requirement for Good Manufacturing Practice. 3) To meet the requirement that only Good Manufacturing Practices P trained personnel may manufacture the medicinal product.
3. Understanding where regulations come from, who has the power to enforce them, and why they need to be adhered to
4. Demonstrate and understand the components of good manufacturing practice and their role in the production of quality medicines.
5. demonstrated and understood the contribution of quality control and quality assurance to good manufacturing practices;

Concept of Pharmacovigilance

Pharmacovigilance has been outlined by the planet Health Organization as "The and activities with reference to the detection, assessment, understanding and hindrance of adverse effects or the other attainable drug-related drawback Objective

Objective

1. Improvement of patient care and safety in relevance the utilization of medicines with medical and paramedical interventions remains to be a crucial parameter.
2. the most objectives of pharmacovigilance involve exhibiting the efficaciousness of medication by watching their adverse impact profile for several years from the laboratory to the pharmacy; trailing any forceful effects of medication rising public health and safety in relevance the utilization of medicines; encouraging the safe.
3. Rational and efficient use of drugs; promoting understanding, education and clinical coaching in pharmacovigilance; and effective communication to the generic public
4. In addition, providing info to shoppers, practitioners, and regulators on the effective use of medication alongside planning programs
5. Procedures for aggregation and analyzing reports from patients and clinicians conclude to the objectives of pharmacovigilance studies.

Selection of Drug Class

Class: Antihypertensive β blocker

Mechanism of action

Metoprolol is an inhibitor of the beta-1-adrenergic receptor that only works on cardiac cells and has no effect on the beta-2 receptors. Without exhibiting activity toward membrane stabilization or intrinsic sympathomimetics, this inhibition reduces cardiac output through negative chronotropic and inotropic effects.

Pharmacological Effect

1. Pharmacokinetic Factor
2. Pharmacodynamics Factor
3. Absorption
4. Volume of distribution
5. Metabolism
6. Half-life
7. Route of elimination

Indications

Metoprolol is indicated for treatment of Angina

1. Atrial fibrillation, atrial flutter
2. Hypertension
3. Tachycardia
4. Thyroid storm.
5. Cardiovascular diseases
6. Heart failure
7. myocardial infarction

Adverse effect

Adverse effects, especially with higher doses, include

1. Dizziness, 5.Unusual dreams,
2. Drowsiness, 6.Trouble sleeping,
3. Fatigue, 7.Depression,
4. Diarrhea, 8. Vision problems[15]

Precautions

Metoprolol might also additionally get worse the signs and symptoms of heart failure in a few patients, who might also additionally experience chest pain or discomfort, dilated neck veins, extreme fatigue, abnormal breathing, an abnormal heartbeat, shortness of breath, swelling of the face, fingers, feet, or decrease legs, weight gain, or wheezing

Pregnancy and breastfeeding

Risk for the fetus has now no longer been dominated out, per being rated pregnancy class C in the United States .Metoprolol is class C in Australia, meaning that it is able to be suspected of causing dangerous consequences at the human fetus (however normal formations) [6]. It appears to besafein breastfeeding

Drug Interaction

Interactions between Two Drugs
1. Metoprolol + Aminophylline -
2. Metoprolol + Atropine

Contraindications

Metoprolol crosses the placenta

Any beta-adrenergic blocker, including metoprolol, can cause myocardial ischemia and other complications if stopped suddenly.

1. myocardial edema
2. ventricular irregularities
3. 4.Hyperthyroidism
4. Thyroid condition, 6. thyroiditis
5. Because the medication can conceal tachycardia, metoprolol should be administered cautiously in individuals with hyperthyroidism or thyrotoxicosis.
6. Metoprolol cross the placental barrier in pregnancy. The placenta is crossed by metoprolol!

Selected Drug Consumption Report (Metoprolol)

Metoprolol is widely used in

1. treat high blood pressure
2. Prevent future heart disease, heart attacks and strokes.
3. Prevent chest pain caused by angina.
4. Prevent migraines.

Adverse Drug Report of Metoprolol

Hospital visit

Name of Doctor: - Dr. Madhuri R. Inamdar
Qualification: - MBBS
How much time you work in this place: - 3 year
Specialist of doctor: - Physician & Consultant, Cardiologist specialist
Name of Doctor: - Dr. Sambhaji Behere
Qualification: - MBBS
How much time you work in this place: - 5 year
Specialist of doctor: - Physician & Consultant, Cardiologist specialist,

Patient interview

Name of patient: - Ms.Paramjeet Kaur Age-40, Sex- Female

1. In which condition you start the treatment?

Ans- High Blood Pressure

2. How long you take this Drug/medicine?

Ans-30 days, MET XL 50

3. You feel any discomfartness/side effect of this drug?

Ans-No

4. Tell me about your medication history?

Ans- She has Hypertension problem last 2 year

5. Did you suggest this treatment for another person which suffer from same condition?

Ans- yes its helpful

6. What other medicine do you take with this medicine?

Ans- NO

Name of patient: - Ms. Pallavi Kadam Age-36 Sex-Female

1. In which condition you start the treatment?

Ans- high Blood Pressure & chest pain

2. How long you take this Drug/medicine?

Ans-from 90days

3. You feel any discomfartness/side effect of this drug?

Ans-No

4. Tell me about your medication history

Ans- he has diabetics, he takes Glycomet 0.5 medicine from 3 year

5. Did you suggest this treatment for another person which suffer from same condition?

Ans- yess it's helpful & feel good

6. What other medicine do you take with this medicine?

Ans- Zincovit tab

Name of patient: - Mr.Vishnu Dadas Age-65, Sex-Male

1. In which condition you start the treatment?

Ans- Heart problem, Angina & chest pain

2. How long you take this Drug/medicine?

Ans-from 2Year

3. You feel any discomfartness/side effect of this drug?

Ans-No

4. Tell me about your medication history

Ans-he has Diabetics

5. Did you suggest this treatment for another person which suffer from same condition?

Ans- yess it's helpful & feel good

6. What other medicine do you take with this medicine?

Ans- Glycomet 0.5 tab

Assesment of ADR

Naranjo scale

The Naranjo Scale was created by Naranjo et al. to assess the chance that an adverse drug reaction (ADR) is caused by the drug itself rather than by other factors. A score is used to categorise probability as certain, probable, possible, or doubtful. Peer reviews frequently use the values from this algorithm to validate the accuracy of an author's conclusions about adverse drug reactions. The Naranjo Scale or Naranjo Score are other names for it.

Metaprolol

Scoring

- ≥ 9 = definite ADR
- 5-8 = probable ADR
- 1-4 = possible ADR
- 0 = doubtful ADR

Due to unstable angina, the patient's BP ranged from 110/70 to 180/90 mm Hg, PR was 84 to 86 bpm, and SPO2 was 98%. After using the aforementioned scales for the observed suspected ADR, the following result was obtained: The patient was given the scales, and the scores were determined by evaluating the ADR. Based on the results obtained utilising various standard scales, causality was confirmed. Re-challenging was skipped because, according to WHO-UMC, it is not necessary for likely medicines. The reaction was strange form (Type-B) with a medium intensity of level 7, according to analysis. Most likely, the reaction can be avoided [1-7] (Figures 1-5).

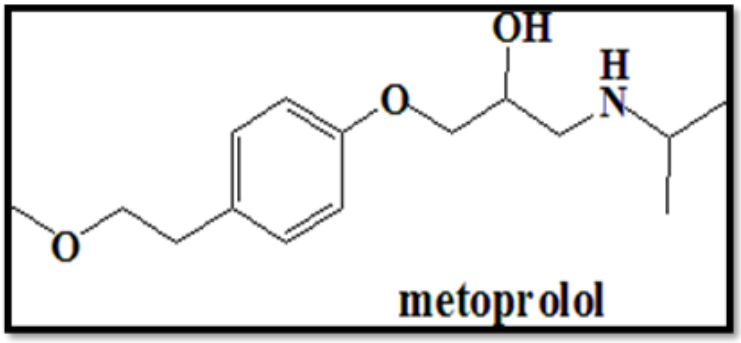


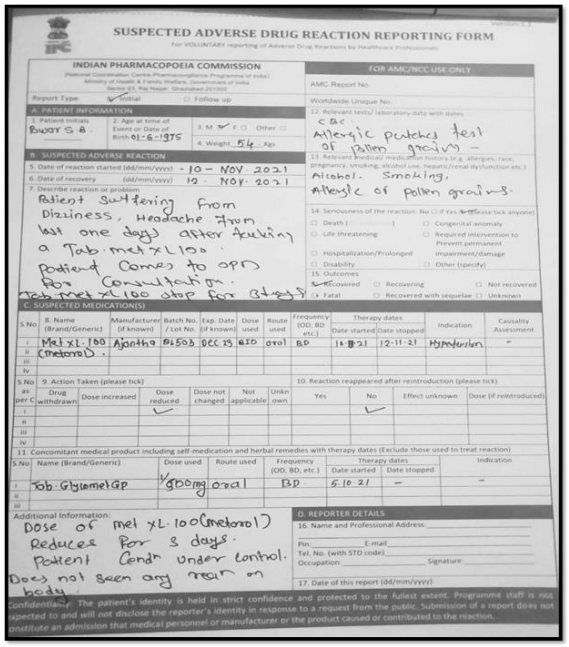
Figure 1: *Structure of Metoprolol.*

JANAHIT MEND GENRAL STORES GHATKOPAR

Print Date 26/11/2021 User-Itemwise Sales from 01/08/21 to 26/11/21 (@ SaleRate) Page No. 1

Code	Item Description	Packing	Qnty	Loose	Value
SUPERUSER					
AMED	55992 MET XL 12.5.	15TAB	12		183.26
AMED	56680 MET XL 25	15TAB	8		257.40
AMED	42943 MET XL 50	15TAB	26		71.37
AMED	42945 MET XL AM 25/5	15TAB	18		342.37
AMED	60692 MET XL AM 50/5	15TAB	2		132.18
AMED	60240 PROLOMET XL 12.5	15TAB	5		812.09
AMED	67837 PROLOMET XL 25	10 TAB	22		1653.00
			User wise subtotal		1798.67
			FINAL TOTAL		4567.00

Figure 2: *Consumption Report of Metoprolol.*



SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

INDIAN PHARMACOPOEIA COMMISSION

FOR AMC/NCC USE ONLY

A. PATIENT INFORMATION

B. SUSPECTED ADVERSE REACTION

Patient suffering from Dizziness, Headache from last one days after taking a Tab. met XL 100. Patient Comes to OPD for Consultation. Tab. met XL 100 stop for 3 days.

C. SUSPECTED MEDICATION(S)

S.No	Name (Brand/Generic)	Manufacturer (if known)	Batch No. / Lot No.	Exp. Date (if known)	Dose used	Route used	Frequency (OD, BD etc.)	Therapy dates Date started	Therapy dates Date stopped	Indication	Causality Assessment
i	Met XL-100 (Metoprolol)	Ajantha	B1503	DEC 23	6TD	oral	BD	16-11-21	12-11-21	Hypertension	-

S.No	Name (Brand/Generic)	Dose used	Route used	Frequency (OD, BD, etc.)	Therapy dates Date started	Therapy dates Date stopped	Indication
i	Tab. Glytomet GP	500mg	oral	BD	5.10.21	-	-

Additional Information: Dose of met XL-100 (Metoprolol) Reduces for 3 days. Patient Condn under control. Does not seen any rash on body

D. REPORTER DETAILS

17. Date of this report (dd/mm/yyyy):

Confidentiality: The patient's identity is held in strict confidence and protected to the fullest extent. Programme staff is not expected to and will not disclose the reporter's identity in response to a request from the public. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction.

Figure 3: *Adverse Drug Reaction From of Metoprolol.*

Figure 4: *Hospital Visit (Friday 24/11/2021).*

Figure 5: *Patient Interview (Friday 24/11/2021).*

Conclusion

Metaprolol is the most widely used selective beta-blocker antagonist. In healthy volunteers, the beta-blocker metoprolol prevents sodium retention caused by negative pressure in the lower body despite low blood pressure. The prevention of sodium retention may be due to weakened neurohormonal responses. These effects of metoprolol on renal responses to LBNP may partially explain the beneficial effects of this drug in patients with heart failure.....

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