



TULSI AYURVEDIC AND YOGA CENTRE

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Quality Operating
Process

Document No: TAYC/020

Manual of
Operations
Management of
Adverse
Reactions/Events
Policy

Date of Issue: 12/03/2022
Issue No.: TAYC/I/020
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SERVICE NAME:	Management of Adverse Reactions/Events Policy
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APPROVED BY:	DR. VEENA ARORA
RESPONSIBILITY OF UPDATING:	Dr. Rajkumari

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D-833, SARASWATI VIHAR,
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A. Purpose:

To provide guideline instruction for ensuring uniform Vyapad Management Policy.

B. Scope: Day Care Centre Wide

Adverse Drug Reaction (ADR) - Any response to a drug which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease, or for the modification of physiological function.

Introduction: Though Ayurveda is practiced in the Indian subcontinent since centuries, there is a paucity of systematic documentation related to the occurrence of adverse drug reactions (ADR) and other issues regarding the safety of Ayurveda medicines.

Aim:

To monitor and analyze the pattern and frequency of ADR to Ayurvedic medicines in an Ayurvedic hospital setup.

Benefits of ADR monitoring

1. Proper information about the safety of drugs and medicines.
2. Prevention of the adverse effects related to the pharmaceutical products.
3. Instruction to the health care team, patients, pharmacists and nurses about ADRs and its management.

Procedure for Reporting ADR

1. Only Suspected Associations that a Drug has caused a Particular Adverse



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Event.

2. Reporting an ADR does not imply a causal association between the Drug and ADR.
3. In a doubtful case it is better to report than not to report.

Information Required for ADR Reporting

1. Patient Information
2. ADRs Description
3. Information Related to Suspected Drug
4. Information on Management of ADR
5. Information about the reporter

Adverse drug reactions (ADRs) are a leading cause of morbidity and mortality, accounting for up to 30% of clinic annually. Elderly patients are at highest risk of experiencing ADRs, many of which are preventable. The most commonly-implicated medications include antibiotics, digoxin, diuretics, hypoglycemics, antineoplastics, and nonsteroidal antiinflammatory drugs, which are responsible for about 60% of clinic.

Actual, perceived, or even fear of ADRs increases the likelihood for medication nonadherence, leading to suboptimal treatment efficacy and adding to the burden of disease.

Actual ADRs can result from medication pharmacology, where as perceived or fear of ADRs are influenced by psychological factors such as predetermined medication views, lack of belief in treatment necessity, anticipation of ADRs, conditioning based on past experiences, and misattributing symptoms as ADRs.

Clinician awareness of these factors will help to reduce risk for ADRs and optimize management, ultimately allowing patients to benefit from intended treatment.

Risk Minimization

Understand patient views about medication therapy. Educate about the benefits of treatment.



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Inform patients about potential ADRs and management strategies should any occur.

- Ensure an updated and accurate medication list.
- Utilize decision support software to help prevent ADRs.
- Start with low doses and frequencies and slowly titrate as tolerated.
- Initiate less-potent agents, agents with direct mechanisms of action, or alternatives with lower adverse event incidence.
- Avoid or reduce the use of interacting medications.
- Prescribe dosage forms with minimal systemic exposure.

Recognition, Detection

- Be familiar with known ADRs of the medication as well as the patient's pre-existing symptoms.
- Evaluate new symptoms as possible ADRs, looking into health conditions, labs, or other factors which may explain the symptoms.
- Consider the temporal relationship between medication initiation and symptom onset.
- Challenge concepts like stopping the medication to see if the symptom subsides in absence of the medication, and restarting to see if symptoms return.
- Utilize lab tests for more evidence to identify an ADR.
- Apply probability tools such as the Adverse Drug Reaction Probability Scale for heparin induced thrombocytopenia.
- Express empathy and maintain a trusting relationship with the patient. Reduce dosing or discontinue the offending medication.
- Switch to another agent or dosage form less likely to cause ADRs.
- Treat side effects when necessary (beware of prescribing cascades). Document the ADR in the patient's medical record.
- If working from a care setting separate from pharmacy, notify the patient's pharmacy to document the ADR in the pharmacy records.
- Report ADRs through appropriate channels such as Patient's organization's reporting system, the drug manufacturer, Adverse Event Reporting System.
- Track and trend ADRs for ongoing process improvement.



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The COVID-19 pandemic placed pharmacies in a vital role on the frontlines of care, but the increased demands for their services also caused a subsequent rise in burnout among pharmacy staff.

As such, it is just as essential for pharmacy professionals to prioritize their own mental health as it is for them to help their patients.

"There is a difference between when Patient're feeling stressed and when Patient are ultimately feeling burnt out .

One helpful tool to help identify whether an individual is burnt out is the Pharmacist Well-Being Index (WBI).

The assessment allows pharmacy professionals to track their professional well-being and monitor clinical burnout.

The WBI is assessment that measures the dimensions on the likelihood of burnout, severe fatigue, meaning of work, risk of medical error, overall well-being, and other factors.

The report gives pharmacy professionals an overall score and allows them to compare it with the percentages of other pharmacy professionals.

Part of the WBI is the distress percent, which is a measure of individuals whose results showed a risk of high distress. Professionals with high distress have a greater risk of experiencing burnout, low quality of life, high fatigue, and committing medication errors.

"I've had those times when I have felt burnt out and felt disengaged and stuck, and had to pull myself out of that hole and figure out what can I do to get out of this?"

In terms of making changes to burnout, Wettergreen said that developing resilience is key. She said that when faced with burnout, changing the response and the environment are helpful to practicing resilience.

Wettergreen added that doing joyful activities outside of work can help pharmacy professionals to bring that same joy and energy into the workplace, and she placed a huge emphasis on mindfulness.

Wettergreen noted that working at work can increase the risk for medication errors, therefore bringing more mindfulness to work would allow pharmacy professionals to really focus on the task at hand. Additionally, mindfulness can help individuals to reflect on their burnout and fatigue, which can also reduce the risk of medication errors.



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From the environmental standpoint, the organizations need to support the mental health needs of their pharmacy staff. "Leadership matters,"

"We went into this because we wanted to help Patient. There is a moral significance in that work, in helping our communities, in helping our patients. We have to help folks that are in our profession rekindle that connection." As part of these efforts, Varkey said that it is essential to reevaluate the resources these professionals have.

The first step is to talk with their staff to find out what matters to them from their day-to-day. Then, identify which changes should be made, implement them, and lastly, use improvement .

Conclusion: The present work has documented the incidence and characteristic of ADR to Ayurvedic medicine in a typical Ayurveda hospital setup. This will help in developing various strategies for boosting pharmacovigilance in Ayurveda, thereby ensuring safer use of Ayurveda medicines. Adverse drug reactions, Ayurveda, herbal medicine, Panchakarma pharmacovigilance, Rasaushadi

Detection of adverse drug reactions

Spontaneous and intensive reporting techniques were followed to detect the ADRs according to the World Health Organization (WHO) definition of ADR as "A noxious and unintended response at doses normally used for prophylaxis, diagnosis, or therapy of diseases, or for the modification of physiological function."

All outpatient department (OPD) patients presenting with the ADR were included in the study.

Under spontaneous reporting technique, the physicians of the hospital were provided with reporting cards on which they will record the suspected ADRs. The ward incharge, ward nurse, and internee were also provided with similar reporting forms. After the initial notification of the suspected ADR by the physician, additional details were collected by interviews and review of case



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record forms. Awareness of ADR monitoring was created through the clinical meeting with health and clinicians and nurses of the hospital.

Ayurvedic management of adverse drug reactions with Shvitrahara Varti

Adverse drug reactions (ADR) are an expression that describes harm associated with the use of medications at therapeutic dose. Traditional medicines also can develop ADRs due to their improper use. Shvitrahara Varti, one of such medicines holds Bakuchi as a component and is to be used judiciously. Furanocoumarins like psoralen present in Bakuchi makes skin hypersensitive and causes phytophotodermatitis in few cases. Hence, one should be careful while using medicines that contain Bakuchi. One such case is observed, where extensive reactions with application of Shvitrahara Varti were noticed and managed with Ayurvedic treatment.

Adverse drug reactions, Bakuchi, blisters, Shvitra, Shvitrahara Varti, vitiligo.

Traditional systems of medicines, including herbal medicines are being used since centuries for health-care . Traditional medicine continues to be a valuable source of remedies to the Patient around the world to secure their health.

- [1] Ayurvedic medical system, the traditional medicine of Indian Subcontinent has been in vogue since Vedic period or even earlier. It emphasizes on the maintenance, promotion of health and curing diseases through natural resources.
- [2] There is a belief prevailing in the society that these natural products are safe and are free from adverse effects, which is not always true. Majority of adverse events with the use of herbal medicines or products are attributable either to poor product quality or to improper use.
- [3] One such adverse event was observed with the use of Shvitrahara Varti.
- [4] That has been reported here. Vitiligo is a condition that causes depigmentation of sections of skin that occurs when melanocytes, die or are unable to function.



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[5] Though the condition is rare and non-communicable; patients who are stigmatized for their condition may experience depression and similar mood disorders.

[6] The modern medical system has treatment modalities including topical corticosteroids etc., but is also known for their greater adverse events.

[7] Considering the inconveniencies and limitations of modern medical system, the suffering population is searching options through traditional systems of medicines.

In Ayurveda, this condition is comparable with Shvitra. Ayurveda has ample of drugs to treat this condition.

[8] Khadira (*Acacia catechu* Wild.)

[9] Apamarga (*Achyranthes aspera* Linn.)

[10] Bakuchi (*Psoralea corylifolia* Linn.)

[11] Compound formulation such as Shvitrahara Varti, Shvitrari Rasa,

[12] Gomutrasava

[13] Shashilekha Vati

[14] Useful in the management of Shvitra. Shvitrahara Varti, one of such preparations is successfully being practiced by Ayurvedic physicians.

Adverse drug reactions (ADRs) are common in older adults, with falls, orthostatic hypotension, delirium, renal failure, gastrointestinal and intracranial bleeding being amongst the most common clinical manifestations. ADR risk increases with age-related changes in pharmacokinetics and pharmacodynamics, increasing burden of comorbidity, polypharmacy, inappropriate prescribing and suboptimal monitoring of drugs. ADRs are a preventable cause of harm to patients and an unnecessary waste of healthcare resources. Several ADR risk tools exist but none has sufficient predictive value for clinical practice. Good clinical practice for detecting and predicting ADRs in vulnerable patients includes detailed documentation and regular review of prescribed and over-the-counter medications through standardized medication



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reconciliation. New medications should be prescribed cautiously with clear therapeutic goals and recognition of the impact a drug can have on multiple organ systems. Prescribers should regularly review medication efficacy and be vigilant for ADRs and their contributory risk factors. Deprescribing should occur at an individual level when drugs are no longer efficacious or beneficial or when safer alternatives exist. Inappropriate prescribing and unnecessary polypharmacy should be minimized. Comprehensive geriatric assessment and the use of explicit prescribing criteria can be useful in this regard.

Data collection

In the suspected cases, past medical/medication history with their respective dosage form, route of administration, frequency, date of onset of reaction, and the patients allergy status (drug or food) along with constitution (Prakriti), area of residence (Desha), age (Vayah), time (Kala), strength (Bala), exercise capacity (Vyayamashakti), digestive capacity (Agnibala) and disease strength (Rogabala), etc., were collected. The suspected adverse events (AE) were carefully analyzed and documented in the standard ADR monitoring for ASU drugs forms provided from National Pharmacovigilance Program for ASU drugs Jamnagar, India.

Observational studies help in understanding the tolerability profile of marketed medicines in a heterogeneous population and thus are an important source of evidence to know treatment outcomes. Pharmacovigilance is one such observational study which deals with evaluating and monitoring the safety of medicines and thus helps in identifying risk factors. Large numbers of such studies are carried in modern hospitals. But very little information is available for the ADR profile of Ayurvedic drugs.

A. Protocol:

In case of any drug reaction / adverse reaction actions taken are as follows:

1. The person noticing the reaction i.e. Doctor / Patient immediately informs the concerned doctor and clinic management is initiated then & there.
2. The Doctor informs in charge pharmacy & Main Medicine store.



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3. The ADR [Adverse drug reaction] form is filled up by the concerned doctor
4. Drug responsible for adverse reaction is identified.
5. Batch of the drug identified.
6. All Patient rooms & areas where the drug has been issued are advised NOT to use the drug of that particular batch.
7. Information regarding any such similar reactions anywhere in the clinic is gathered and documented and forwarded to the Medical Superintendent.
8. All such events are monitored and evaluated and appropriate action taken depending on the nature of the adverse reaction
9. Such action may take the form of observation or in extreme cases withdrawal of the drug throughout the clinic.
10. Drug causing adverse reaction is closely monitored and analyzed by drug and therapeutic committee

B. Drug Recall Procedure

1. Once the drug causing adverse reaction is identified, particular batch of the drug is immediately withdrawn by pharmacy, wherever issued within the clinic.
2. Company & distributor are immediately informed regarding the adverse reaction and called to find out the reasons & actions to be taken.
3. Total medicine of that particular batch is returned to supplier.
4. Report is presented before Quality management committee and further action is taken.



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Dehydration

Dehydration means Patient's body loses more fluids than Patient take in. If it's not treated, it can get worse and become a serious problem.

Dehydration occurs when there is an imbalance in the total amount of water in the body. The condition, though common, occurs when free water loss exceeds free water intake, usually due to exercise, diseases, or high environmental temperature. Dehydration can be harmful to one's health as it not only affects one's metabolism, but also the liver, kidneys, and can lead to many other digestive issues.

Symptoms of dehydration in adverse reaction:

- feeling thirsty
 - dark yellow and strong-smelling pee
 - feeling dizzy or lightheaded
 - feeling tired
 - a dry mouth, lips and eyes
 - peeing little, and fewer than 4 times a day
- Dehydration can happen more easily if Patient have:

- diabetes
- vomiting or diarrhoea
- been in the sun too long
- (heatstroke) drunk too much alcohol
- sweated too much after exercising
- a high temperature of 38C or more
- been taking medicines that make Patient pee more (diuretics)

How Patient can reduce the risk of dehydration

The following is done to manage dehydration in a patient:

1. The patient is asked to rest.
2. A solution of ORS is prepared and the patient is asked to drink the same
 - Clean Water - 1 litre - 5 cupful (each cup about 200 ml.)
 - Sugar - Six level teaspoons (1 teaspoon = 5grams)
 - Salt - Half level teaspoon.Stir the mixture till the sugar dissolves.

Moreover the patient is asked to consume the following:

1. Curd
 2. Ginger and Honey
 3. Fenugreek seeds
 4. Water of cumin seeds
 5. Water with electrolytes (For eg. Coconut water)
- Mulethi



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DIARRHOEA

Diarrhoea describes loose, watery stools that occur more frequently than usual. Having at least three loose motions in 24 hours is considered as diarrhoea.

In Ayurveda, diarrhoea is called Atisaaram. It is related to jataragni mandhya (low digestive fire). According to our concept, weak digestive fire, improper food, impure water, toxins and mental stress usually cause atisaaram. Aggravated vata pulls down the fluid part from various tissues of the body and brings it into the intestine. There this fluid mixes with the stool which then leads to loose, watery motions. Depending upon which particular Dosha is vitiated, atisaar has been classified into Vataj, Pittaj, Kaphaj, Sannipatik, Bhayaj and Shokaj types in Ayurveda.

Symptoms

- Frequent, loose, watery stools
- Abdominal cramps
- Burning of anus
- Fever
- Blood in the stool
- Bloating

Main Procedure

- Treatments include mainly internal medicine which is prescribed according to the symptoms and its nature – acute or chronic
- Langanam [fasting]
- Deepanam
- Pachanam
- Sodhana therapy such as Vamanam, Virechanam

Vasthi treatments are found to be effective especially in ulcerative colitis.

Duration of stay

Treatment course of 2-3 weeks is recommended in chronic cases.



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Expected Outcome

Diarrhoea can be treated effectively , but It is depends on the clinical condition and diet& regimen of the patient.

Diet

- Sufficient intake of water and liquid foods is always advised in diarrhoea.
- Light, easy to digest food articles such as liquid rice, porridge are recommended. Soups made from lentils are also good in diarrhoea. Fruits like sweet lime, oranges, apple, melons are allowed.
- Heavy, spicy, fried food is prohibited. Non-veg items, eggs are also not allowed. Sugarcane juice is also forbidden.
- Water is advised to be boiled before drinking.
- While goat milk is more recommended, cow's milk may also be allowed
- Avoid - Food that produces gas formation beans, cabbage, cauliflower, broccoli, Meat, fish
- Avoid - Food that produces gas formation beans, cabbage, cauliflower, broccoli, Meat, fish etc.
- Avoid Sweets , Sugary drinks, carbonated beverages, Fermented food items, caffeinated foods.

Activity restrictions

- Try to stay out of the sun to prevent fluid loss through the sweat.
- Very light simple food can be taken in small doses.

Simple Home Remedies

- Add 1 teaspoon of ginger to water and boil the water. Drink the mixture when it is lukewarm every one hour.
- Take 50 gm of fresh pomegranate skin. Soak it in 800 ml of water for one hour. Boil until a quarter of the volume remains (200 ml). Store this mixture in a clean, dry bottle. Take a couple of tablespoons several times a day. If there is blood in the stools, add half a teaspoon of honey to the decoction
- Mix one teaspoon of sugar and half a teaspoon of common salt in a cup of water. Small doses of this mixture (around a quarter cup) can be given whenever the patient is thirsty.
- Mix 1 teaspoon each of cinnamon, ginger and cumin powder with honey to make a paste. Take 1 teaspoon three times a day



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- Roast 2/3 teaspoon of cumin seeds and powder them. Add a pinch each of ginger powder, cinnamon powder and black pepper powder. Mix in 1 cup of yogurt. Eat twice a day.

COLD AND FEVER

Jwara (fever) is described first among disorders because temperature (or body heat) is a life-sustaining force, and is the first condition (afflicting patients of somatic conditions)

When premonitory symptoms manifest or at the onset of the fever, dieting or fasting is useful because the disease originates from the *amashaya*.

Treatment

1. Langan: Aam being the main factor initiating Jwara by causing Agnimandya, Langan becomes the first step in the treatment of Jwara. Also being a Rasapradoshaj Vyadhi, Langan is indicated in Jwara. It helps to pacify the vitiated Dosha and stimulates the Jatharagni. However, Langan should not be prescribed in case of Vataj, Shramaj, Jeerna, Kshataj, Kshayaj and Manas Jwara in which Dhatukshay has already set in. Shaman must be given in such cases.
 2. Swedan: Guru Pravaran (heavy, warm clothing), staying in a warm atmosphere helps in Aam Pachan and helps.
 3. Kala: As time passes, the body gets enough time for Aampachan. Usually, it takes 7 days for Pachan after which Niramavastha is achieved.
 4. Yavagu: Yavagu helps Agnideepan, Aampachan and Anuloman.
 5. Tikta Rasa: Tikta Rasa is known as the best Aampachak
OTC for common cold and fever
- Sudarsana Vati - cold and fever
 - Devavati - Fever due to Indigestion or food poisoning
 - Amrut
 - Tulsi Infections
 - Yastimadhu
 - Jvarakeerti
 - Pratisyayahara Vati

Jwara is not to be suppressed, but the disease progress can be eased out. Even during fevers ayurvedic medicines do not suppress the natural body response but help the disease to ease out and thus heal. The reason or causes are addressed effectively, these days several fevers are identified as - 'fevers of unknown origin' in such conditions, the dosha association can be easily known through the Nadi and thus treated effectively to root out the condition.

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Low blood pressure (hypotension) for Reporting ADR

Low blood pressure might seem desirable, and for some Patient, it causes no problems. However, for many Patient, abnormally low blood pressure (hypotension) can cause dizziness and fainting. In severe cases, low blood pressure can be life-threatening.

A blood pressure reading lower than 90 millimeters of mercury (mm Hg) for the top number (systolic) or 60 mm Hg for the bottom number (diastolic) is generally considered low blood pressure.

The causes of low blood pressure can range from dehydration to serious medical disorders. It's important to find out what's causing Patient's low blood pressure so that it can be treated.



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Symptoms

For some Patient, low blood pressure signals an underlying problem, especially when it drops suddenly or is accompanied by signs and symptoms such as:

- Dizziness or
lightheadedness Fainting
- Blurred or fading vision
- Nausea
- Fatigue
- Lack of concentration

Low blood pressure (hypotension) for ADR Causes

Blood pressure is a measurement of the pressure in Patient's arteries during the active and resting phases of each heartbeat.

Systolic pressure. The top number in a blood pressure reading is the amount of pressure Patient's heart produces when pumping blood through Patient's arteries to the rest of Patient's body.

Current guidelines identify normal blood pressure as lower than 120/80 mm Hg.

Blood pressure varies throughout the day, depending on:

- Body position
- Breathing rhythm
- Stress level
- Physical condition
- Medications Patient take
- What Patient eat and drink



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A sudden fall in blood pressure can be dangerous. Conditions that can cause low blood pressure For ADR Medical conditions that can cause low blood pressure include:

Pregnancy. Because the circulatory system expands rapidly during pregnancy, blood pressure is likely to drop. This is normal, and blood pressure usually returns to Patient's pre-pregnancy level after Patient've given birth.

Heart problems. Some heart conditions that can lead to low blood pressure include extremely low heart rate (bradycardia), heart valve problems, heart attack and heart failure.

Endocrine problems. Parathyroid disease, adrenal insufficiency (Addison's disease), low blood sugar (hypoglycemia) and, in some cases, diabetes can trigger low blood pressure.

Dehydration. When Patient's body loses more water than it takes in, it can cause weakness, dizziness and fatigue. Fever, vomiting, severe diarrhea, overuse of diuretics and strenuous exercise can lead to dehydration.

Blood loss. Losing a lot of blood, such as from a major injury or internal bleeding, reduces the amount of blood in Patient's body, leading to a severe drop in blood pressure.

Severe infection (septicemia). When an infection in the body enters the bloodstream, it can lead to a life-threatening drop in blood pressure called septic shock.

Severe allergic reaction . Common triggers of this severe and potentially life-threatening reaction include foods, certain medications, insect venoms and latex. Breathing problems, hives, itching, a swollen throat and a dangerous drop in blood pressure.

Lack of nutrients in Patient's diet. A lack of keep Patient's body from producing enough red blood cells (anemia), causing low blood pressure.



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Quality Operating
Process

Document No: TAYC/020

Manual of
Operations
Management of
Adverse
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Medications that can cause low blood pressure

Some medications can cause low blood pressure, including:

Types of low blood pressure

Doctors often break down low blood pressure (hypotension) into categories, depending on the causes and other factors. Some types of low blood pressure include:

Low blood pressure on standing up (orthostatic or postural) hypotension. This is a sudden drop in blood pressure when Patient stand up from a sitting position or after lying down.

Gravity causes blood to pool in Patient's legs when Patient stand. Ordinarily, Patient's body compensates by increasing Patient's heart rate and constricting blood vessels, thereby ensuring that enough blood returns to Patient's brain.

But in Patient with orthostatic hypotension, this compensating mechanism fails and blood pressure falls, leading to dizziness, lightheadedness, blurred vision and even fainting.

Blood flows to Patient's digestive tract after Patient eat. Ordinarily, Patient's body increases Patient's heart rate and constricts certain blood vessels to help maintain normal blood pressure. But in some Patient these mechanisms fail, leading to dizziness, faintness and falls.

Risk factors

Low blood pressure (hypotension) can occur in anyone, though certain types of low blood pressure are more common depending on Patient's age or other factors:

Age. Drops in blood pressure on standing or after eating occur primarily in adults older than 65. Neurally mediated hypotension primarily affects children and Patientnger adults.

Medications. Patient who take certain medications, for example, high blood pressure medications such as alpha blockers, have a greater risk of low blood pressure.



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Complications

Even moderate forms of low blood pressure can cause dizziness, weakness, fainting and a risk of injury from falls. And severely low blood pressure can deprive Patient's body of enough oxygen to carry out its functions, leading to damage to Patient's heart and brain.

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