

Case Study

A CASE OF LACUNAR INFARCTION OF BRAIN AND HYPERTENSION ASSOCIATED WITH PROLONGED USE OF "SUKHI"

K. P. PATTNAIK, A. TARAI, R. SAMAL, M. R. SINGHA

Department of Pharmacology, S.C.B. Medical College, Cuttack, Odisha.
Email: drkaliprasad@yahoo.co.in

Received: 20 Jun 2014 Revised and Accepted: 24 Jul 2014

ABSTRACT

This article highlights the case of a young lady who has been treated for a prolonged period with Anti-hypertensive medications for hypertension and other symptomatic medicines for vertigo and scalp pain etc. Ultimately this case was found to be a case of Hypertension with lacunar infarction of brain associated with prolonged self medication with SUKHI (an Oral contraceptive pill of Bangladesh) and reemphasizes the importance of proper history taking by the treating doctor, disadvantages of self-medication, improper availability of medicines and importance of language on the medicine strips.

Keywords: Adverse drug reaction, OCPs, Brain infarction, Self-medications, Sukhi

INTRODUCTION

Adverse drug reactions are considered as leading cause of morbidity and mortality. In recent decades it has been demonstrated as one of the top ten leading cause of mortality globally. It is estimated that ADRs are 4th to 6th leading cause of mortality in USA and in Europe [1]. It is estimated that 197,000 deaths per year are due to ADRs [2]. ADRs result in the death of several thousands of patients each year, and many more suffer. The percentage of hospital admissions due to adverse drug reactions in some countries is about or more than 10% [3]. Self-medication is also a very important health concern globally. Self-medication has been reported as being on the rise in recent years globally [4, 5]. The World Health Organization has emphasized that self-medication must be correctly taught and controlled [4].

The association between Oral contraceptives and stroke is been much debated. The analysis of literature revealed the association between use of oral contraceptives and occurrence of cerebral thrombosis [6, 7]. At the same time there are also studies which advocates that the low-dose (<50 µg of ethinyl estradiol) OCPs were not associated with stroke [8].

Here we are presenting a case of young married lady who visited to our hospital with, Hypertension for last 4 years & had complain of scalp pain, head reeling & vertigo for 3 years and was treated with antihypertensive, multi-vitamins, Betahistine, without much benefit for her symptoms. Ultimately the case was found to be a case of Hypertension & lacunar infarct, which was possibly due to long term, irrational, self medication of "SUKHI".

Case report

35 years young married lady with 2 children (last child birth 14 years back) came to our hospital in September 2011 with complain of repeated attacks of scalp pain, reeling of head & vertigo.

The history revealed, she was detected as Hypertensive in the year 2007 & was on Amlodipine (5 mg) with Atenolol (50 mg) once daily for last 4 years, although she had no Hypertension earlier during her pregnancy checkups. There was no history of vomiting, fever, loss of consciousness, convulsions or head injury. She was not a known diabetic, neither a smoker nor an alcoholic.

Treatment history for hypertension and reeling of head revealed that she had consulted in local hospitals repeatedly and was being treated with Amlodipine & Atenolol along with analgesics, betahistine and multivitamins without significant benefits for vertigo, head reeling & scalp pain etc. She had not mentioned

regarding intake of any other medicines during routine history taking.

With this back ground, the patient was thoroughly worked out by the authors in collaboration with the neurologists to find out possible cause of her complains. On clinical examination BP was 140/90 mm of Hg On 23.11.2011 & 150/90 on 29.11.2011. Pulse rate was 80/min regular with good volume. There was no focal neurological deficit with plantar bilateral flexure. Fundoscopy was done but did not reveal any abnormality. Respiratory & Cardiovascular evaluation revealed no abnormality. Baseline haematology investigations (i.e. DC, TLC, Hb %, ESR) & biochemical (i.e. Fasting & post prandial blood glucose, serum urea, creatinine, Na⁺ and K⁺) within normal limits.

In view of recurrent scalp pain, vertigo and reeling of head without being relieved by symptomatic treatment with Betahistine, Cinnarizine, Prochlorperazine etc. & medications for hypertension, a CT scan of brain was done as advised by the neurologist On 23.11.2013. The CT brain showed a left paraventricular lacunar infarction.

So, this patient was ultimately diagnosed as a case of young hypertensive with young stroke. Again a detailed history of any other medications was repeatedly asked to the patient and then only she revealed regarding self-medication of "Sukhi" tablet for contraceptive purposes for last 14 years, after her second childbirth. She also expressed that she had not informed regarding this medication to any of her previous treating doctors because, she was being given the information by the sellers of this medicines, that this is a very safe traditional medicine for contraception.

Considering young Hypertensive & young stroke investigations were done to exclude any other cause for brain infarction in women of this young age group before stamping it as a case of drug (Sukhi) induced Hypertension and lacunar infarction.

- Anti-Nuclear Antibody (ANA): Negative (0.17)
- Anti Phospholipid Antibody (APLA) Ig G: Negative (1.01)
- Anti Phospholipid Antibody (APLA) Ig M: Negative (1.12)
- Fasting Plasma Glucose: 84 mg/dl
- Lipid Profile: Within normal limits

Serum (LDLc = 91, HDLc = 45,

Triglycerides = 72, Total Cholesterol = 166)

- Serum Homocysteine: 1252 (Normal)
- Sickling Test: Negative

- ESR: 09 mm

The above investigations exclude the possibilities of common causes of young stroke i.e. SLE (Systemic Lupus Erythematosus), Anti-Phospholipid Antibody Syndrome, Diabetes, Dyslipidemia, Hyperhomocysteinemia or Sickle cell disease in this patient.

In view of above clinical and investigational findings "SUKHI" tablet was considered as a possible cause of hypertension and cerebral infarction, it was withdrawn on 29.11.2011 & the patient was treated with Clopidogrel tablet 75 mg once daily, Aspirin 150 mg once daily, Rosuvastatin 10 mg once daily and Gabapentin 75 mg once daily on the advice of neurologist and the patient was advised to continue Amlodipine and Atenolol. Patient was followed up for a month with all medications. At the end of a month of her treatment, in her next check up on 7.1.2012 the patient had improved symptoms. After 2 months she had no complaint of any scalp pain or vertigo and her BP was also reduced to 120/80 mm of Hg. Then the dose of Atenolol and Amlodipine was reduced to half i.e. Amlodipine to 2.5 mg & Atenolol to 25 mg. After 2 months on 15.3.2012 the patient had again come for check up. Her BP was found to be 110/76 mm Hg & the anti-hypertensives were stopped all together. In next check up after 2 months her BP was 114/80 which was within normal limits.

DISCUSSION

So to summarize this case, This 35 years young married lady who was taking Sukhi tablets (self-medications) for last 14 years after birth of her second child. She was detected as hypertensive after 10 years of use of Sukhi and was on Amlodipine and Atenolol in November 2011- She had presented with vertigo, reeling of head, scalp pain which was found to be associated with left brain infarction. All common possible causes of young stroke i.e. APLA, SLE, Hyperhomocysteinemia, dyslipidemia etc were ruled out. After discontinuation of Sukhi tablets, her BP came to normal & the symptoms of scalp pain, reeling of head, vertigo were relieved.

So, there is a causal relationship between use of Sukhi tablets and with hypertension & brain infarct.

Causality Assessment

Regarding lacunar infarction -

This 35 year young lady was taking SUKHI for last 14 years. She developed hypertension for last 4 years and developed scalp pain & vertigo for last 3 years. Later found to have Left paraventricular lacunar Infarction. All investigations for finding the cause of stroke in young patient did not revealed any abnormality. Except she was taking SUKHI for last 14 years. Though SUKHI strips are labeled in Bengali language without any mentioned composition but search in the internet, revealed in IPPF (International Planned Parenthood Federation) Directory of Hormonal Contraceptives that SUKHI contains - Lysterol 2.5 mg + Ethinyl estradiol 50 mcg, combined pill manufactured in Bangladesh.

Hence SUKHI may be the possible cause of Lacunar infarction in this patient.

Regarding hypertension

Her BP was 150/90 on 29.11.2011 during SUKHI use even with Amlodipine: 5 mg + Atenolol: 50 mg. Sukhi was withdrawn on 29.11.2011 & Amlodipine: 5 mg + Atenolol: 50 mg was continued. After one month of withdrawal of SUKHI on 07.01.2012 her BP was 120/80 and Amlodipine dose was reduced to 2.5 mg and Atenolol to 25 mg. Again after one month she had a BP of 116/78 mm of Hg & even after antihypertensive drugs were withdrawn her BP remained within normal level after withdrawal of SUKHI tablets.

Hence SUKHI may be the PROBABLE cause of Hypertension in this patient.

Implications of this report

This case report highlights various important aspects

1. Problem & extent of self medications: This lady has self medicated Sukhi tablets for such a long duration of 14 years. By obtaining the

tablets from local quacks, not even consulting qualified doctors from any authorized field of medicine i.e. Allopathic, Ayurvedic, Homeopathic etc and had ended up in Hypertension & brain infarct.

2. This report re-emphasizes the importance of detailed history taking (especially drug history by doctors): This lady has visited various doctors for Hypertension and vertigo, head reeling & scalp pain over a period of 4 years. However doctors have given Anti-hypertensives, symptomatic treatment for vertigo, scalp pain but none of the doctor has successfully explored the long duration of Sukhi self-medication by the patient, even though patient has not informed about the Sukhi intake with a false perception that Sukhi is a very safe traditional medicine. Had the drug history been successfully taken during the treatment of hypertension, Brain infarction might have been prevented in this patient.

3. Unauthorized availability of Sukhi: SUKHI is an oral contraceptive meant for free distribution in Bangladesh being available in India. It is collected from Bangladesh and available in coastal areas of across the Indian-Bangladesh border. This has been reported in many national and local newspapers many times[9]. So there is an obvious need for stringent regulations to control such improper availability of drugs, which is a serious concern.

4. Importance of Language: Finally, the users of "SUKHI" believe it to be an Ayurvedic or Homeopathic preparation and are free from the adverse effects associated with other contraceptive preparations available in the market. The reason behind such wrong impression that the information about the composition of the drug and other information are printed in Bengali language. So many consumers using it even the doctors are not able to read the composition and interpret the information correctly and this increases the irrational use of these drugs.

So ultimately this case report shows that irrational prolonged self medications with Sukhi (an low dose OCP) has resulted in Hypertension (probable) & brain infarction (Possible) in this young lady. This case reemphasizes the importance of obtaining detailed drug history in a patients by the doctor before treating the patient, disadvantages of self-medication and also highlights regarding improper availability of medicines and importance of language for information on the product.

ACKNOWLEDGEMENT

We acknowledge the support of Pharmacovigilance programme of India & the Co-ordinating centre, Indian pharmacopoeia commission for their support for collection of adverse drug reaction as a national programme.

We are highly obliged to Prof. Dr. Ashok Mallick, H.O.D. Department of Neurology, S.C.B. Medical College & Hospital.

We are also grateful to Prof. H.O.D. Dept. Of Pharmacology Prof. Dr. S. Mohanty, The Co-ordinator & Mr. S. S. Sahoo, Technical associate, ADR Monitoring Centre, S.C.B. Medical College, Cuttack for their co-operation.

CONFLICT OF INTEREST STATEMENT

There are no conflicts of interest among the authors.

REFERENCES

1. Bruce H, Paul N, A. Jason Lazarou, Pomeranz, Corey. Incidence of Adverse Drug Reactions in Hospitalized Patients;of Prospective Studies. JAMA 1998;279(15):1200-5. doi:10.1001/jama.279.15.1200.
2. Capuano A, Iripino A, Gallo M, Ferrante L, Illiano ML, Rinaldi B, et al. Regional surveillance of emergency-department visits for outpatient adverse drug events. Eur J Clin Pharmacol 2009;65(7):721-8.
3. Min-Hua W, Mariam B, Derek A, R. J. Tai-Yin Alex Paul and Azeem Majeed. Tenyear trends in hospital admissions for adverse drug reactions. England Med J 1 239250 2010;103(6):1999-2009.
4. O. WH. The role of the pharmacist in self-care and self-medication. J World Health Organization 1998.

5. Bradley C, Blenkinsopp A. Over the counter drugs. The future for self medication. *BMJ* 1996;312(7034):835-7.
6. O. WH. Study of Cardiovascular Disease and Steroid Hormone Contraception, Ischaemic stroke and combined oral contraceptives:results of an international, multicentre, case-control study. *J Lancet* 1996:348498-505.
7. Heinemann LA, Lewis MA, Thorogood M, Spitzer WO, Guggenmoos-Holzmann I, Bruppacher R. Case-control study of oral contraceptives and risk of thromboembolic stroke:results from International Study on Oral Contraceptives and Health of Young Women. *BMJ* 1997;315(7121):1502-4.
8. Schwartz SM, Pettini DB, Siscovick DS *et al.* Stroke and use of low-dose oral contraceptives in young women:a pooled analysis of two US studies. *J Stroke* 1998;292277-2284.
9. Now, birth control the Bangladeshi way, published on April 2 , 2007. *THE HINDU*.