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Traditional Medicine in Iraq, is it still a source of serious adverse events?

A documentation of serious adverse events of Sagwa among infants in Iraqi Paediatric Hospitals

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ABSTRACT

Traditional medicine is an old practise adopted by people since centuries. Based on using some organic and inorganic substances, and believes and spiritual thoughts by some lay people to exert " a beneficial effect on health" as they thought. Despite advances in medicine and technology, many people, especially of low socio-economic, limited literacy, are still believe in these primitive remedies and using them regularly. This practise carries a high risk on the health and many of these remedies have a lot of adverse events, some of them are lethal.

Sagwa is considered as one of the traditional and self remedies used to treat abdominal discomfort and diarrhoea in children. In the Iraqi pharmacovigilance centre at Ministry of Health we received the notification about these malpractised behaviour. In this report we analysed the data of 43 infants safety reports concerning Sagwa. These reports have been received by the Iraqi pharmacovigilance centre from many Iraqi Paediatric Hospitals. Analysis of Sagwa has shown that it contains many toxic organic and inorganic substances like arsenic, mercury, lead, and animal skin. More than 50 % of the adverse events were gastrointestinal and in about 50 % the presentation was life threatening. So this dangerous practice should be focused on and paid a considerable attention to raise the awareness of vulnerable people about its detrimental consequences.

Key words: Traditional medicine, Sagwa, pharmacovigilance, gastroenteritis.

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INTRODUCTION

Traditional medicine and its healing practices is as old as the written human history and the oldest texts about traditional medicine were found in Asuria, Nenavah in Iraq and sourced back to about 2100 BC.[1] Toxicity related to traditional medicines is becoming more widely recognized as these remedies become popular in the Mediterranean region as well as worldwide.[2]

In Iraq, it is also popular to use traditional and self remedies in different age groups for several indications. Sagwa is considered one of the these remedies in Iraq. It is widely used among limited literacy and the low socioeconomic classes to treat neonates, infants and children with abdominal discomfort and diarrhoea.

By this report, we aimed at showing the pattern of presentation, severity, and potential causality of serious adverse events suspected with the use of Sagwa.

How did we work?

Retrospectively, we reviewed forty-three spontaneous individual case safety reports (ICSRs) submitted to Iraqi Pharmacovigilance Centre at Ministry of Health in Baghdad from three different Paediatric Teaching Hospitals in Baghdad; Eskan Paediatric Hospital in Al-Kharkh Distrit, and Al-Ilwiya and Ibn Al-Baladi Paediatric Hospitals in Al-Rasafa from October 2014 to October 2016.

Iraqi Pharmacovigilance Centre is established in Directorate of Technical Affairs in Ministry of health for collecting, analysing and disseminating information related to safety of medicines, vaccines, and other traditional and herbal remedies. Our Centre receives reports regularly from both public and private health

institutions.

All reports received from the above paediatric hospitals regarding Sagwa poisoning were analysed for characteristics of adverse events (AEs) related to Sagwa. The adverse events were categorized according to WHO-ART, which is a hierarchy system of four levels: System Organ Class (SOC), High level term (HLT), Preferred Term (PT), and Included Term (IT).[3]

Severity of AEs were also studied and the probability of a causal link between the use of the Sagwa and the reported AEs was assessed using the WHO causality assessment model. Which includes the following terms certain, probable/ likely, possible, unlikely, unclassified, and unassesable.[4]

Patient demographics, clinical and Sagwa data, details of the adverse events, time of onset, causal due to remedy details, outcome and severity were extracted from the ICSR. All results were shown in tables as absolute numbers and percentages.

Sagwa components were not known to the majority of the health care professionals (HCPs), Our centre in collaboration with the National Herbal Medicines Selection Board and the department of Herbal Medicines within the Directorate of Technical Affairs and National Centre for Poisoning has made a strenuous efforts to recognize its components. So we can understand the adverse events expected to see and to apply the proper management.

RESULTS

Over the 2 years involved in this report, we found 43 infants documented to have Sagwa poisoning. (**Figure 1**) Documentation was made through direct asking of the mother about the use of Sagwa. Age of the infants ranged from 1 month to 19 months. Twenty-three patients (53%) were female infants and 20 (47%) were males. Duration of AEs ranged from 1 hour to 24 hours. Chief complains on presentation were severe dehydration, vomiting, diarrhoea, and hypotension. These AEs required symptomatic treatment. **Tables 1 and 2** present the characteristics of Sagwa adverse events and their severity respectively.

In spite of the difficulty in obtaining samples of the Sagwa, we succeeded to get one for laboratory investigation. The test results have showed that it contains a high percentage of Lead, in addition to the presence of about 60 different ingredients. Although the composition of Sagwa is known to differ from one place to another, it contains in most of the time the following: Arsenic, mercury, lead, animal skin (mouse), urchin (meat, skin), bentonite, undeclared drugs, animals (stool, urine, blood), latency, coriander, digitalis and many other herbs (**figures 2**).

Table 1: Characteristics of adverse events (AEs) related to Sagwa

Adverse events	Number of AEs *(%)
SOC: Gastrointestinal disorders PT: Gastroenteritis	28 (53)
SOC: Urinary tract disorders HPT: Micturition disorder: polyuria PT: Renal failure acute	2 (4) 4 (8)
SOC: Neurological disorder IT: epilepsy	1 (2)
SOC: Immune disorder and infection IT: Septicaemia	7 (13)
SOC: Metabolic and nutritional disorder HLT: Acidosis	10 (18)
SOC: Psychiatric disorder IT: Lethargy	1 (2)
* Total number of adverse event was 52	

Table 2: Severity of Sagwa related adverse events

Severity of Adverse Events	Number *(%)
Spontaneous improvement	0 (0)
Improvement after symptomatic treatment	3 (7)
Hospitalization with no life threatening risk	13 (31)
Life threatening risk	21 (49)
Death	6
* Total number of adverse event was 43	

The results of causality assessment revealed that 30 cases were probable/likely, 11 were possible, one case was unassessable, and another one was unclassifiable.

DISCUSSION

Traditional and herbal medicines are easily accessible because they are not regulated as medicines, but safety concerns still one of the biggest challenges to health systems around the world. Accordingly it is not unusual to find toxic heavy metals like lead, arsenic or mercury and undeclared drugs in traditional and herbal medicines.[5]

Figure 1: Victims of Sagwa poisoning

Figure 2: Physical shape of Sagwa

For two years we reported 43 cases of Sagwa poisoning referred from different suburbs of Baghdad. This figure represents the tip of iceberg, because it represents only the cases of severe adverse events that enforce the family to seek a medical help. Underneath this tip we expect to find so many unreported cases of ingestion of Sagwa because the patients are either asymptomatic or having mild symptoms.

What add to the complexity of this issue is that the presenting symptoms of Sagwa poisoning are usually nonspecific and similar to a variety of diseases such as gastro-enteritis. Without keeping this option in minds of paediatricians and other health care providers and investigating the mothers about using Sagwa, we will miss so many cases even those who have a severe adverse events.

ACTION AND CONCLUSIONS

This report highlights this unfortunate health problem, its presentation and severity. Majority of infants 63% (28/43) were seriously affected with a fatal outcome in 13% of the reported cases.

Of the challenges facing pharmacovigilance in the field of traditional medicine is communication and education.[6] The Iraqi pharmacovigilance centre has proposed a campaign to increase the awareness among HCPs and consumers regarding the safety hazards of Sagwa. The following activities were initiated and ongoing:

1. The Ministry of health issued an official letter to all HCPs to encourage the immediate notification of such cases to the Iraqi Pharmacovigilance Centre.
2. Through collaboration with the available media channels, the Iraqi Pharmacovigilance Centre has sent messages regarding the risk of Sagwa and encourages stop taking it and early reporting of any safety concerns.
3. The Iraqi Pharmacovigilance Centre in collaboration with the directorate of general health, has prepared educational posters and videos regarding the risk of Sagwa on health to be distributed to all primary health care centres and hospitals as an educational tool for patients' families.
4. The Iraqi Pharmacovigilance Centre in collaboration with extended programme of immunization (EPI) programme to send messages to all beneficiaries regarding risks of Sagwa during regular visits and vaccination campaigns.

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Abbreviation list: Adverse Events (**AEs**), Before Christ (**BC**), extended programme of immunization (**EPI**), Health Care Professionals (**HCPs**), High level term (**HLT**), Included Term (**IT**), Individual case safety reports (**ICSRs**), Preferred Term (**PT**), System Organ Classification (**SOC**), World Health Organization (**WHO**).

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