Original article

Hospitalizations associated with 2009 influenza A (H1N1) and seasonal influenza in Saurashtra region, India

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Abstract
Introduction: This study investigated the clinico-epidemiological characteristics of patients who were hospitalized with 2009 pandemic H1N1 influenza virus infection and seasonal influenza in the Saurashtra region of India.
Methodology: From September 2009 to February 2010, a total of 773 patients with influenza virus attending different hospitals in Rajkot city were studied. Real-time reverse-transcriptase-polymerase-chain-reaction (RT-PCR) testing was used to confirm infection; the clinico-epidemiological features of the disease were closely monitored.
Results: Of the 733 patients, 35.4% (274/773) were cases of 2009 pandemic H1N1 influenza and 64.6% (499/773) were cases of seasonal influenza. Of the 274 patients with 2009 pandemic H1N1 influenza, the median age was 29.5 years, and 51.5% were males. Only 1.1% positive patients had recent travel history to an infected region. A median time of five days was observed from onset of illness to influenza A (H1N1) diagnosis, and a median time of six days was reported for hospital stay. All admitted influenza A (H1N1) patients received Oseltamivir drug, but only 16.1% received it within two days of onset of illness. One fourth of the admitted positive patients died. The most common symptoms were cough, fever, sore throat, and shortness of breath. The coexisting conditions were diabetes mellitus, hypertension, chronic pulmonary diseases, and pregnancy (p = 0.001). Chest radiography revealed 93% of the positive patients had pneumonia.
Conclusion: The clinical course and outcomes of the 2009 pandemic (H1N1) influenza virus are comparable to those of the currently circulating seasonal influenza, with high mortality in influenza A (H1N1) patients.

Introduction

The novel influenza A (H1N1) virus was first identified in Mexico in April, 2009 [1], and then in the United States (US) [2,3]. This was originally referred as "swine flu" because many of the genes in this new virus were found in pigs in North America. Later it was determined that this new virus has gene segments from the swine, avian, and human flu virus genes. The scientists call this a "quadruple reassortant" virus; hence this new (novel) virus was christened "2009 pandemic H1N1 influenza virus [4-6]. The World Health Organization (WHO) raised the pandemic level from 5 to 6, the highest level [7].

In May 2009, the first confirmed case of 2009 pandemic H1N1 influenza virus in India was reported [8]. Then large numbers of cases were reported throughout India. Saurashtra region is the western part of Gujarat state in India. The first H1N1 positive confirmed case in Gujarat state was found in June 2009 [9], while from Saurashtra region the first case was reported in August 2009 [10]. As soon as the first confirmed case was reported in Gujarat, patients with influenza-like illness were admitted to various hospitals, tested, and treated appropriately. Since this was a new and potentially serious infectious disease, all patients with confirmed infection were hospitalized in an isolation ward to prevent spread to the general population. All positive patients were carefully monitored, which allowed us to keep track of various clinical features, results of laboratory and radiographic tests, and outcomes of admitted patients. This report summarizes the clinical and epidemiological characteristics of 773 patients with 2009 pandemic (H1N1) influenza virus or seasonal influenza that were hospitalized in a tertiary care center and various other hospitals of Rajkot city in the Saurashtra region, from 1 September 2009 to 20 February 2010.

Figure 1.

Week & month wise distribution of hospitalized patients with influenza A (H1N1) & seasonal influenza
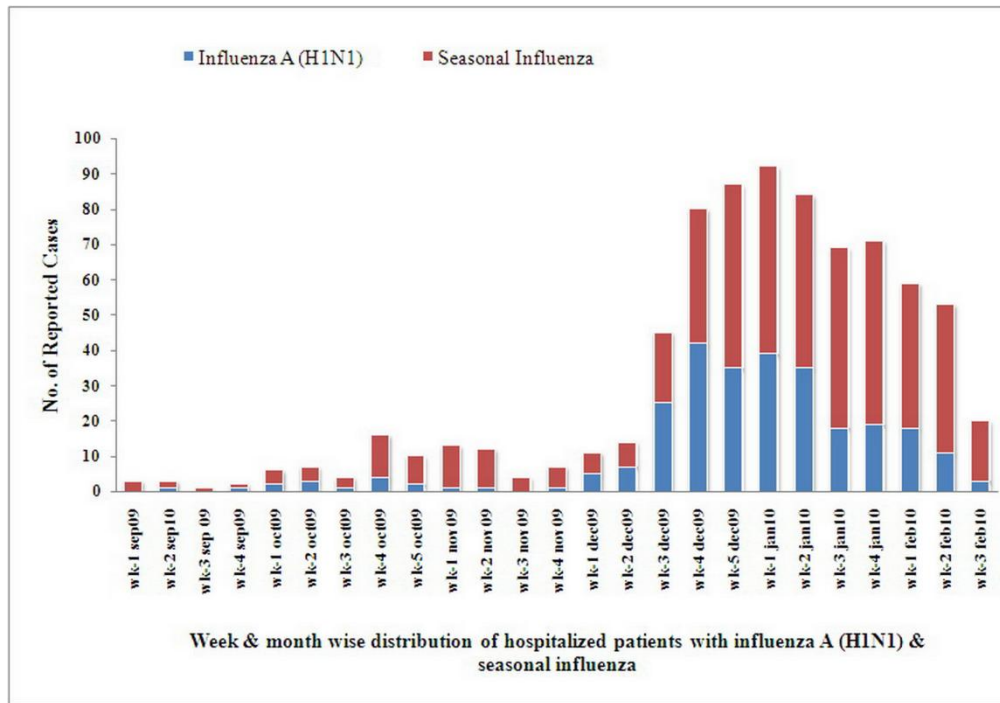
Methodology

Demographic characteristics, data collection and management

The Ministry of Health and Family Welfare, Government of India, started preparations regarding the management of infected patients as soon as the first case of 2009 pandemic H1N1 influenza was reported in May 2009. Gujarat state, including the Saurashtra region, also started monitoring and surveillance activities as soon as the positive cases were first reported in August. Rajkot city, the economic hub of the Saurashtra region, has several hospitals providing intensive care, including the Medical College and Civil Hospital. All positive patients in Rajkot were referred to these hospitals with advanced life-saving support.

From 1 September 2009 to 20 February 2010, a total of 773 patients were admitted in different hospitals in Rajkot with influenza-like illness. They were tested for influenza A (H1N1) and included for analysis. In this study several types of data were collected from the patients: date and time of admission to the hospital/intensive care units (ICU); age; sex; religion; residential status; pregnancy; co-existing conditions; date and time of first symptoms. Other variables were also collected from the medical

records and statistics department of the hospitals, including the presence of infection and type of influenza virus isolated; duration of treatment in hospitals and ICU; duration between onset of illness and diagnosis; outcome of hospital/ICU admission; time from onset of illness to death; time from antivirus drug started to death. Approval by the institutional review board was not required because this infectious disease fell under the jurisdiction of the Epidemic Disease Control Act (1897), which allows the collection of data on emerging pathogens when it is of public health interest, and was invoked by the state health department in August 2009 [11].

Categorization of Influenza A (H1N1) case [12]

The Ministry of Health and Family Welfare, Government of India, issued guidelines for the categorization of influenza A (H1N1) cases during screening for home isolation, testing, treatment, and hospitalization (Table 1).

Clinical case /suspected case definition [13]

A suspected case was defined as an influenza like-illness with a temperature of > 37.5°C and at least one of the following symptoms: sore throat, cough, rhinorrhea, or nasal congestion, and either a history of travel to a country where infection had

Table 1. Categorization of influenza A (H1N1) patients as per clinical features

Category & Clinical Features	Antiviral treatment	RT-PCR* testing & Hospitalization
Category A: Mild fever (body temperature 36.5-37.5°C), cough/sore throat, body ache, headache, diarrhea, vomiting. Patient should be monitored & reassessed after 24 to 48 hours	Not needed	Not needed
Category B (1): Signs of category A, and/or high grade fever (>37.5°C), sore throat. Home isolation is advisable.	May be given	Not needed
Category B (2): Signs of category A, and/or any of the high risk conditions like, children with mild illness but with predisposing risk factors; pregnant women; persons aged 65 yrs or more; patients with lung, liver, hear, kidney diseases, blood disorders, diabetes, neurological disorders, cancer, HIV/AIDS; long term steroid therapy.	Given	No testing required but hospitalization may be needed
Category C: In addition to signs & symptoms of category A & B, any of the following: breathlessness, chest pain, drowsiness, fall in blood pressure, hemoptisis, peripheral cyanosis; children with red flag signs like somnolence, high & persistent fever, inability to feed well, convulsions, shortness of breath, difficulty in breathing; worsening of underlying chronic conditions;	Start immediately	Immediate testing & hospitalization

*RT-PCR: Reverse transcriptase polymerase chain reaction.

Table 2. Demographic characteristics, diseases history and outcome of 2009 pandemic influenza A (H1N1) and seasonal influenza in hospitalized patients of Saurashtra region from September 2009 to February 2010

Characteristics	Influenza A (H1N1) (n = 274) No. (%)	Seasonal Influenza (n = 499) No. (%)
Gender		
Male	141 (51.5)	294 (58.9)
Recent travel to infected origin*		
Yes	1 (0.4)	2 (0.4)
No	273 (99.6)	497 (99.6)
Time interval from onset of illness to hospitalization & diagnosis		
Median (in days)	5	5
<1 day	18 (6.6)	0
1-4 days	115 (42.0)	244 (48.9)
5-10 days	129 (47.1)	235 (47.1)
>10 days	12 (4.4)	20 (4.0)
Hospital stays in days		
Median (in days)	6	4
≤2 days	41 (15.0)	94 (18.8)
3-5 days	72 (26.3)	321 (64.3)
6-10 days	115 (42.0)	57 (11.5)
≥11 days	46 (16.8)	27 (5.4)
Outcome of hospitalization		
Survived	203 (74.1)	466 (93.4)
Expired	71 (25.9)	33 (6.6)
Age group of expired patients	(n=71)	(n=33)
<1 year	4 (5.6)	5 (15.2)
1-14 year	13 (18.3)	10 (30.3)
15-45 years	38 (53.5)	11 (33.3)
> 45 years	16 (22.5)	7 (21.2)
Time interval from onset of illness to death		
<1 day	1 (1.4)	0
1-4 days	8 (11.3)	7 (21.2)
5-10 days	33 (46.5)	22 (66.7)
>10 days	29 (40.8)	4 (12.1)

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* An infected region was defined as an area where one or more confirmed cases of 2009 pandemic (H1N1) influenza virus infection had been found in the preceding 7 days.

Table 3. Clinical features and coexisting conditions of 2009 pandemic (H1N1) influenza virus and seasonal influenza in hospitalized patients of Saurashtra region

Characteristics	Influenza	
	A (H1N1) (n = 274) No. (%)	Seasonal (n = 499) No. (%)
Clinical Features		
Cough	265 (96.7)	457 (91.6)
Fever (≥37.5 ˚ Celsius)	252 (92.0)	474 (95.0)
Sore Throat	149 (54.4)	240 (48.1)
Shortness/difficulty in breathing	146 (53.3)	292 (58.5)
Nasal Catarrh	68 (24.8)	118 (23.6)
Headache	59 (21.5)	42 (8.4)
Vomiting	27 (9.9)	21 (4.2)
Coexisting conditions		
Any one condition	90 (32.8)	95 (19.0)
Diabetes Mellitus	27 (9.9)	26 (5.2)
Hypertension	24 (8.8)	36 (7.2)
Chronic Pulmonary Diseases (Asthma, COPD, Tuberculosis)	15 (5.5)	17 (3.4)
Pregnancy	15 (5.5)	6 (1.2)
Chronic Heart Diseases	13 (4.7)	10 (2.0)
Seizure disorder	7 (2.6)	11 (2.2)
Chronic Renal Failure	2 (0.7)	0

been reported in the previous seven days or an epidemiologic link to a person with confirmed or suspected infection in the previous seven days.

A confirmed case was defined by a positive result of a real-time reverse transcriptase polymerase chain reaction (RT-PCR) assay performed at a laboratory operated under the auspices of the state government.

Laboratory confirmation of infection

The 2009 pandemic (H1N1) influenza virus was detected with the use of an RT-PCR assay in accordance with the protocol from the US Centers for Disease Control and Prevention, as recommended by the WHO [14]. Persons suspected of being infected and persons identified as close contacts were investigated by taking two naso-pharyngeal swabs and one swab from pharynx for detection of the virus by RT-PCR assay.

Statistical analysis

All data was entered in MS Excel (Microsoft, Redmond, USA), and analyzed by using Epi Info software (version 3.5.1, CDC, Atlanta, GA, USA) from the Centers for Disease Control [15].

Results

Demographic & clinical characteristics of patients

From 1 September 2009 to 20 February 2010, a total of 773 patients were admitted in hospitals and tested for influenza A (H1N1) infection. Out of these, 499 patients were found negative and 274 were diagnosed with 2009 pandemic (H1N1) influenza virus infection (Table 2).

Week-wise distribution (Figure 1) of hospitalized patients with influenza A (H1N1) and seasonal influenza in the Saurashtra region shows that the number of cases increased gradually from the third week of December 2009. The highest influenza A (H1N1) positive cases (42) were reported in the fourth week of December 2009, and in the first week of January 2010, the maximum number of cases (53) of seasonal influenza were reported.

A median age of 27 years was reported in positive A (H1N1) cases and 25 years in seasonal influenza cases. As Table 2 shows, the median duration of diagnosis of infection was five days after onset of illness (1-20 days range). On admission, the majority of patients reported cough (97%) and fever (92%), followed by complaints of sore throat (54%) and shortness of breath/difficulty in breathing (53%) (Table 3). Coexisting conditions were reported in 32.8% of the positive cases and 19.0% of the

Table 4. Laboratory and radiographic findings on hospital admission in influenza A (H1N1) infected 274 patients of Saurashtra region*

Characteristic	No. /Total No. (%)
Leukocyte count	
Leukopenia (<4,000/ mm^3)	59/238 (24.8)
Leukocytosis (>10,000/ mm^3)	51/238 (21.4)
Hemoglobin gm/dl	11.53 $\pm$ 2.52
Lymphocyte count	
<1500/ mm^3 in adults	118/178 (66.3)
<3000/ mm^3 in children	13/60 (21.7)
Platelet count	
Thrombocytopenia (<150,000/ mm^3)	49/214 (22.9)
Thrombocytosis (>350,000/ mm^3)	27/214 (12.6)
Elevated alanine aminotransferase (>40 U/liter)	99/115 (86.1)
Elevated aspartate aminotransferase (>40 U/liter)	36/110 (32.7)
Elevated total bilirubin (>1.2 mg/dl)	33/136 (24.3)
Antibiotic treatment received	242/274 (88.3)
Corticosteroid treatment received	126/274 (46.0)

* Plus-minus values are mean $\pm$ SD.

Table 5. Bivariate analysis of hospitalized influenza A (H1N1) patients don't require intensive care & survived with patients required intensive care/expired

Characteristics of hospitalized influenza A (H1N1) patients	Patients don't require intensive care & survived (N = 187) No. (%)	Patients required intensive care (N$^\epsilon$ = 87) No. (%)
Age		
Median – yr (range)	27 (0.5-68)	27 (0.5-68)
<15 years*	19 (10.2)	18 (20.7)
Clinical features		
Cough	180 (96.3)	85 (97.7)
Fever	171 (91.4)	81 (93.1)
Shortness of breath	96 (51.3)	50 (57.5)
Coexisting conditions		
Any one condition[†]	53 (28.3)	37 (42.5)
Diabetes Mellitus	17 (9.1)	10 (11.5)
Hypertension	17 (9.1)	7 (8.0)
Chronic pulmonary diseases	9 (4.8)	6 (6.9)
Pregnancy[‡]	4 (2.1)	11 (12.6)
Seizure disorder	6 (3.2)	1 (1.1)
Pneumonia on chest radiography on admission[§] – no. / total no. (%)	139/155 (89.7)	72/72 (100)
Antiviral treatment received <2 days after onset of symptoms	27 (14.4)	17 (19.5)
Corticosteroid treatment received[¶]	72 (38.5)	54 (62.1)

[€] **The number included** 71 patients who admitted in ICU and expired and 16 who admitted in ICU but survived * p = 0.01, † p = 0.01, ‡ p = 0.001, § p = 0.004, ¶ p = 0.00

seasonal influenza cases. Among the reported positive female patients, 15 (5.5%) were pregnant with range of five to nine months of amenorrhea.

Laboratory & radiographic findings

Leukopenia was observed in 24.8% (59/238) of the patients, and lymphopenia in 66.3% of the adult patients (118/178) and 21.7% (13/60) of the children (Table 4). Among the admitted patients, 34.6% (83/240) patients reported anemia. Thrombocytopenia was found in 22.9% of 214 patients tested. Chest X-ray was done in 82.8% (227/274) of the admitted patients and 93% of them had pneumonia.

Treatment outcomes

All the reported positive patients received the antiviral drug Oseltamivir. Out of 274 positive patients, 16.1% received the antiviral drug within two days of onset of illness. After hospital admission, 74% (203/274) of the cases survived and were discharged, while 26% of the patients died even after receiving treatment including antiviral drugs and life-saving support. Among 71 patients who expired, more than half of them (53.5%) were from the productive age group 15 to 45 years (Table 2).

Patients who required intensive care were more likely to be 15 years of age or less (p = 0.000); to have a coexisting condition (p = 0.01); to be pregnant (p = 0.001); or to have radiologically confirmed pneumonia (p = 0.004) than patients who did not require intensive care. They were also more likely to have received corticosteroids (Table 5).

Discussion

This observational study identified all patients with suspected/confirmed 2009 pandemic (H1N1) influenza virus belonging to category C [12], who were hospitalized in the Medical College and Civil Hospital, and in other hospitals that provide intensive care in Rajkot, India, from September 2009 to February 2010.

The present study found 35.4% cases positive for influenza A (H1N1), while positive cases were reported at 40.9% in Panama [16] and 45.9% in Chile [17]. In China, the majority (76.5%) of the infected patients had history of travel to a country of origin of the emerging infectious agent [18], while only 1.1% of the infected patients in the present investigation reported having travelled to such areas. The results of the current study show a median of five days between onset of illness and hospital admission and diagnosis

of infection, compared to three days in US [19] and four days in Australia and New Zealand [20]. The results in Mexico were similar to those observed in the present study [21]. The time duration between onset of illness and hospital admission and diagnosis is more than other countries [19, 20], because that patients from rural areas and small town areas were initially treated at local level by general practitioners and then if not improvement were seen they were refer to al higher center

Current interim CDC guidelines for pandemic and seasonal influenza recommend the use of either Oseltamivir or Zanamivir for hospitalized patients with suspected or confirmed influenza and for outpatients who are at high risk for complications [22]. The Ministry of Health and Family Welfare, Government of India, has recommended and supplied Oseltamivir to the state governments for distribution. In the present study, all the influenza A (H1N1) infected patients received Oseltamivir after hospitalization, but only 16.1% had received it within two days after the onset of illness, in contrast to 45% in the US [19]. Initial primary treatment by general practitioners or local physicians and delayed referral to a higher center may be the possible explanation for the delayed start of Oseltamivir in suspected or confirmed influenza A (H1N1) patients.

Admission rates for both 2009 pandemic (H1N1) influenza virus and seasonal influenza remained at high levels during December and January, followed by a gradual decline in February. In India, the monsoon season ends in September and October, followed by winter from November to February. The results of this study indicate an association between influenza virus infection and the colder season as the maximum number of cases occurred during the winter months; this observation has also been reported in other studies [19,20].

A low prevalence (33.2%) of underlying medical conditions was reported in influenza A (H1N1) patients in the present study compared to the results found in the US (73%) [19] and Australia (43.8%) [23]. In the current investigation, Diabetes mellitus (9.9%) and hypertension (8.8%) were the most common underlying conditions present in the hospitalized patients, in contrast to patients with seasonal influenza [24] and influenza A (H1N1) in the US [19], where asthma and COPD were the most common underlying conditions. The 5.5% prevalence of pregnancy (p = 0.001) in this study was higher than the expected prevalence in the general population (1%) [25]. In contrast, 7% was reported in

US [19] and 16.7% in Australia [23]. During periods of seasonal influenza and past pandemics, pregnant women have been at higher risk for influenza associated morbidity and mortality [25-27].

Chest radiography was done in 82.8% of 274 hospitalized patients, and 93% of these patients (p = 0.004) had findings that were consistent with pneumonia, the majority of whom had bilateral infiltrates. All hospitalized patients with evidence of pneumonia received antiviral drugs and antibiotics, which is higher than what was observed in United States patients (73%) [19]. In the absence of accurate diagnostic methods, patients who were hospitalized with suspected influenza and lung infiltrates on chest radiography should be considered for treatment with both antibiotics and antiviral drugs [28].

Limitations

The study reported here has some limitations. The data was taken from hospitalized patients, so patients who became infected in the community and did not go to the hospital were not included. Also, patients belonging to 2009 pandemic H1N1 influenza virus category B (i) or B (ii) who were treated on an outpatient basis and who were not tested were not included in the present study. All diagnostic testing was clinically driven, and other investigations were not obtained in a standardized fashion. Despite the use of a standardized data collection form, not all information was collected for all patients. The findings in this study may differ from observations made during future waves of epidemics, owing to differences in the deployment of an effective vaccine, viral mutation, and resistance to antiviral drugs.

Conclusion

This study represents one of the largest investigations involving a series of patients with severe 2009 influenza A (H1N1) infection and seasonal influenza covering two seasons of monsoon and winter. It includes both adults and children from geographically similar areas, which improves the generalizability of our results to other areas. These observations of epidemiological risk factors, typical clinical features, response to therapy, and prognosis should aid in the recognition, diagnosis, and clinical management of influenza A (H1N1).

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Conflict of interests: No conflict of interests is declared.