Smoking Ban: A Long-term Analysis of the Malta Paradox in a Population of over 400,000 Subjects

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Abstract

Objectives: The introduction of laws that make indoor public areas and workplaces smoke-free has resulted in a significant reduction in the incidence of acute coronary syndromes (ACS). Malta was the second European country to introduce the smoking ban legislation in April 2004. The purpose of the study was to investigate the impact of the smoking ban in Malta on ACS morbidity and mortality.

Methods: The number of ACS hospital admissions and the number of cardiovascular deaths were retrospectively analysed. The annual data for 5 years prior to and following the introduction of the Tobacco Act were obtained according to age-groups for both genders. Poisson regression analyses were performed to assess for decline in ACS admission and cardiovascular death.

Results: The ACS admission rate increased throughout the 5 years following the introduction of the smoking ban. There was no change in mortality rate in the 5 years following the legislation, except in 2007 when a small but significant decline was noted.

Conclusions: The Malta smoking ban did not have a significant impact on cardiovascular mortality and ACS admissions rates, indicating the need for proper enforcement of the public smoking ban and increase in public awareness regarding the adverse effects of smoking.

Key words: Coronary heart disease; Mortality; Prevention; Smoking.

Introduction

The introduction of legislation that prohibits smoking in indoor public spaces leads to an immediate reduction in inhalation of second-hand smoke by non-smokers, encourages smokers to attempt to quit smoking[1], and reduces the prevalence of smoking[2,3]. Smoking ban legislation has been shown to lead to an immediate and significant reduction in acute myocardial infarction (AMI) risk in a number of studies[2-11]. Furthermore, the community risk reduction brought about by smoking bans increases with time[9]. However, the extent of the reduction reported varies widely, ranging from 11% in Italy[2], to 40% in Montana[4]. It has thus been suggested that the plausible effects of the smoking ban on AMI may be lower than the estimates reported so far[11].
Malta, an archipelago consisting of 3 islands (Malta, Gozo, Comino) at the center of the Mediterranean Sea, with an area of 316 square kilometres, a total population of approximately 0.4 million, and mild winters and warm to hot summers, was only the second European country to introduce a smoking ban in public places, on 5th April 2004[12]. The archipelago has only one major general hospital/ interventional cardiology centre based on the island of Malta and therefore provides an ideal epidemiological background and experimental setting for the study of the medium-to-long-term impact of the smoking ban on cardiovascular events.

The purpose of the study was to investigate the effect of the introduction of the smoking ban on acute coronary syndrome (ACS) admissions and mortality in the Maltese Islands.

Methods

Study Population

The number of hospital admissions with ACS (defined as angina pectoris and AMI) and the number of hospital deaths and community deaths secondary to a cardiovascular event in the Maltese population was retrospectively analyzed. The data were obtained from the Hospital Activity Analysis Registry for St. Luke's Hospital/ Mater Dei Hospital. The only major general teaching hospital in Malta migrated from St Luke's Hospital to the new and upgraded Mater Dei Hospital in November 2007. The Gozo General Hospital Activity Analysis database is only available from 2005. ACS admissions to the Gozo General Hospital during the sample year 2009 were analyzed to assess whether these could have an influence on the total admission rates. Admissions to private hospitals in Malta for ACS are small in number and were not taken into account.

During the study period, Creatine Kinase (CK) MB isoenzyme (CK-MB) had already been introduced while Troponin I was introduced in May 2009. High sensitivity troponin I (hs-Troponin I) was consequently introduced in December 2012. In view that the introduction of hs-Troponin might have led to increased

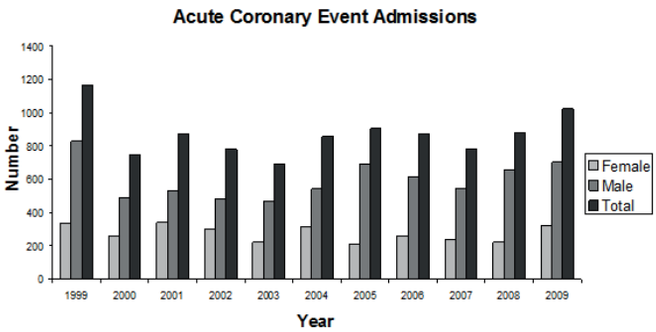

Figure 1: Estimated admissions with a main diagnosis falling within the ICD codes I20, I21, I23, I24.1, I25.3, I46, I47.2, I49, and R57.0 (ischaemic heart diseases) during study years 1999 to 2009. Source: Hospital Activity Analysis database.

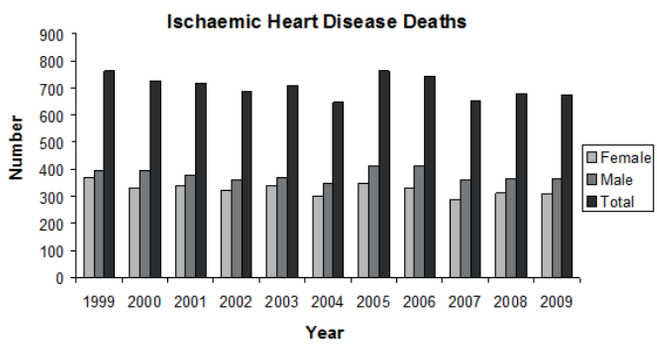

Figure 2: Deaths with an underlying cause of death falling within the ICD codes I21, I22, I24, and I25 (ischaemic heart diseases) during study years 1999 to 2009. Source: National Mortality Register.

diagnosis of AMI, we analysed the hospital admission rate and mortality rate secondary to ACS rather than AMI, The former included patients who were misdiagnosed as having unstable angina rather than AMI in the years prior to the introduction of Troponin I and hs-Troponin I.

Data regarding ACS admissions were collected on a yearly basis for 5 years prior to the introduction of the Tobacco Act (January 1999 to December 2003), for the year the public smoking ban was put into force (2004), and for 5 years after the introduction of this legislation (January 2005 to December 2009). These data were obtained according to age in 5-year age-groups (40-44 years, 45-49 years, 50-54 years, 55-59 years, 60-64 years, 65-69 years, 70-74 years, 75-79 years, 80-84 years, 85-89 years, and 90-94 years). Subjects <40 years were grouped together since the number of admissions with an ACS and the number of deaths due to a cardiac cause was low in this population. Similarly, subjects >95 years were grouped together. Data were collected for both genders.

All hospital and community deaths secondary to a cardiovascular event occurring in Malta during the study period were obtained from the National Mortality Register. Population data were obtained from the Malta National Statistics Office.

Data Acquisition

Data were acquired from 3 reliable population and hospital registers. The data on hospital admissions with angina pectoris and AMI were acquired from the Hospital Activity Analysis database. This database stores case-based records

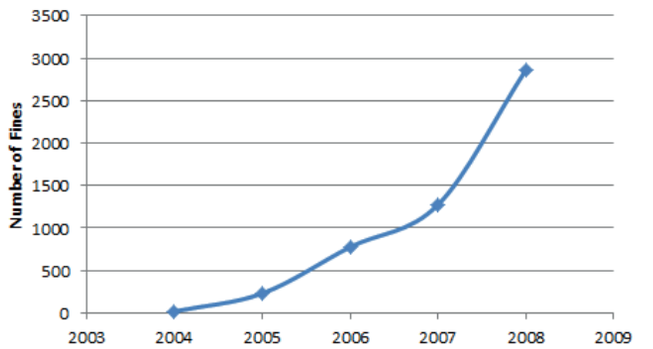

Figure 3: Number of fines issued by the Police regarding smoking in public since the introduction of the smoking ban in 2004[13].

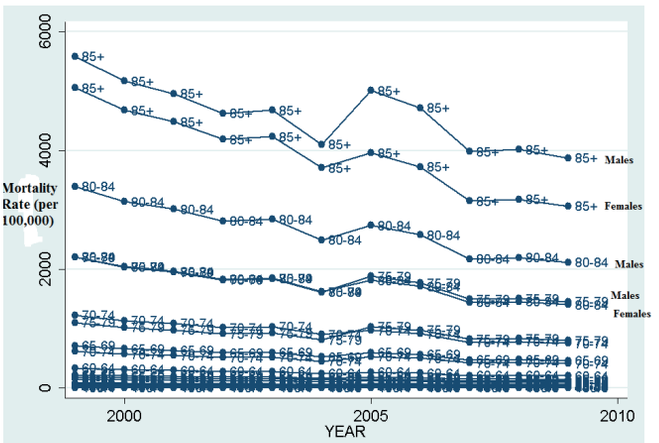

Figure 4: Adjusted mortality rate per 100,000 population by year for each age-group and gender (top line for males, bottom line for females)

which include age, gender, and date of admission. Diseases are classified according to the International Classification of Diseases, 10th revision (ICD-10). Hospitalizations for ACS included in the study were those listed under a principal diagnosis of “angina pectoris” (ICD-10) - code I20 and “AMI” - code I21. The diagnosis of angina pectoris also comprised of: unstable angina - code I20.0; angina pectoris with documented spasm - code I20.1; other forms of angina - code I20.8; and angina pectoris unspecified - code I20.9. AMI complications were also included: haemopericardium - code I23.0; atrial septal defect - code I23.1; ventricular septal defect - code I23.2; rupture of cardiac wall without haemopericardium - code I23.3; rupture of chordae tendineae - code I23.4; rupture of papillary muscle - code I23.5; thrombosis of atrium, auricular appendage, and ventricle - code I23.6; other complications - code I23.8; and Dressler’s syndrome - code I24.1. The following conditions where the principal diagnosis indicated underlying AMI were also included: aneurysm of the heart - code I25.3; cardiac arrest - code I46; paroxysmal ventricular tachycardia - code I47.2; ventricular fibrillation and flutter - code I49.0; and cardiogenic shock - code R57. Two events occurring within 28 days of each other were considered as a single episode.

During data collection, it was noted that there were fewer number of admissions recorded on the Hospital Activity Analysis database when compared to those recorded on the Patient Administration System (PAS). The discrepancy in the

Table 1: Poisson regression analysis for (a) ACS admission rate & (b) mortality rate pre- and post- introduction of smoking ban legislation in 2004, following adjustment for all possible confounders (* indicates significant p value)

(a) ACS Admission Rate			
Year	**Relative Risk**	**Confidence Interval**	**P Value**
Pre/ post 2005	1.32	1.20-1.46	<0.001*
Pre/post 2006	1.14	1.05-1.24	0.003*
Pre/post 2007	1.11	1.03-1.20	0.007*

(b) ACS Mortality Rate			
Year	**Relative Risk**	**Confidence Interval**	**P Value**
Pre/ post 2005	1.08	0.97-1.21	0.16
Pre/post 2006	0.95	0.86-1.04	0.27
Pre/post 2007	0.90	0.83-0.97	0.01*

number of admissions was estimated on a yearly basis. The average (± standard deviation) percentage of missing data throughout the study period was estimated to be 32.1 % (±11.8%). To adjust for the missing data, estimated admissions were calculated by looking at the percentage of Hospital Activity Analysis forms received from the Coronary Care Unit and from the Medical Wards when compared to the number of admissions from the PAS. We consider the missing data to be a random error secondary to lost forms during a time period when a computer-based database on admissions and discharges was not yet in action.

The hospital deaths and out-of-hospital deaths secondary to ACS were derived from the Malta National Mortality Register. The same codes were used to derive the underlying cause of death. Population figures by gender, 5-year age-groups, and calendar year were obtained from the Malta National Statistical Office.

During analysis of the data, concern about the effect of lack of law enforcement of the smoking ban became an issue. Consequently, the number of charges issued by the Police regarding smoking in public was obtained from the Ministry of Justice and Internal Affairs reply to Parliamentary Question 24373 asked on 11th March 2011[13].

Statistical Methods

The data were analysed by a medical statistician using Intercooled STATA version 9.0. The ACS admissions and deaths secondary to a cardiac event were analyzed for the whole population using Poisson regression models to assess for any changes in admission and mortality rate after 2004, given that the smoking ban was introduced in 2004. Adjustment for gender, age, year, diabetes mellitus, hypertension, lack of physical activity, and a diet lacking in fresh vegetables and fruit as possible confounding factors was performed. The information on the mentioned possible confounders before and after the introduction of the smoking ban was obtained from the Health Interview Surveys which were carried out in Malta in 2002 [14], and 2008 [15], respectively.

The study was approved by the University of Malta Research Ethics Committee and conformed to the principles embodied in the Declaration of Helsinki.

Results

Since the public smoking ban safeguards the health of all those residing on the Maltese Islands, the study population included both the local population and the foreign population. The mean study population (± standard deviation) between 1999 and 2009 was 402,212 (± 8572). The vast majority of the population studied was Maltese. The female population outnumbered the male population (50.4% vs. 49.6%). There was a small increase in the total population over the period studied, from 388,759 to 412,970. This increase was present for both genders.
The estimated ACS admissions over the study period are shown in Figure 1. There were more males admitted with an ACS than females until the 70 to 74 year age-group. In the >75 years age-groups, numbers for both genders tended to equalize. The total number of admissions for males was greater than the total number for females throughout the study years. Admissions peaked between ages 45 to 79 years. There was no decline in the admission rates during 2004, the year of the introduction of the smoking ban, or over the 5 year period following the smoking ban when compared to the 5-year period prior to the ban.

Analysis of the Gozo General Hospital Activity Analysis database showed that, during the year 2009, there were 42 admissions with a main discharge diagnosis of the ICD-10 codes for CAD, thus comprising only 4% of all admissions with an ACS in the Maltese Islands. With regards to foreigners, the Hospital Activity Analysis database revealed that, during the study period, 5.1% of admissions with ACS were registered in foreign patients.

The deaths secondary to ACS between 1999 and 2009 are shown in Figure 2. The peak age-groups for deaths due to ACS are the 70 to 84 year age-groups. More males died secondary to an ACS than females until the 70 to 74 year age-group. As observed with ACS admissions, the number of deaths in subjects >75 years tended to equalize for both genders. Although the total number of males dying from a coronary event is greater than the total number of females, this is not as pronounced as in the case of admissions. There was no decline in the mortality rates secondary to an ischaemic event during 2004 or over the 5-year period following the smoking ban when compared to the 5-year period prior to the ban (Figure 2). The mortality data does not include tourists.

Smoking ban violations are shown in Figure 3. The number of fines issued by the Police for smoking in indoor public places is substantial and has increased over the years.

The admissions and mortality data were analysed with Poisson regression models whereby adjustment for possible confounding factors were performed. An increase in the admission rate was noted throughout the 5 years following the introduction of the smoking ban (Table 1). There was no decrease in the mortality rate in the years following the introduction of the smoking ban, except during 2007 when a small but significant decrease in mortality was documented, as shown in Table 1 and Figure 4.

Discussion

There was no reduction in ACS admissions following the introduction of the Malta smoking ban but rather than an increase. This could be attributed to an ever increasing elderly population with associated increasing number of co-morbidities. The absence of a beneficial effect of the smoking ban on acute coronary events contradicts the findings of

other studies on smoking bans. There is a number of possible explanations. Persistent smoking both at workplace and at home could have contributed to the negative results obtained. Although the smoking ban in Malta is strictly adhered to in some indoor public areas such as clinics, hospitals, restaurants, cinemas, and theatres, it is not totally enforced in other indoor public places such as workplaces, bars, band clubs, political clubs, and night clubs[16]. Smoking is even allowed in designated smoking areas and in the outdoor spaces of restaurants. The law does not prohibit smoking on the doorsteps of these indoor public areas with the consequence that smokers gather outside and smoke filled air enters these places.

The results shown in this study are in keeping with findings of the recent Eurobarometer survey whereby the attitude of Europeans towards tobacco was assessed. Malta ranked among the countries with the highest percentage of smoking inside drinking establishments where 35% of the respondents said that they saw people smoking inside bars in the previous 6 months[17]. On the other hand, control was shown to be more stringent in restaurants with only 9% of respondents claiming that they saw people smoking in restaurants in the previous 6 months[17].

It is interesting to note that during the study period the rate of imported cigarettes decreased. Between 1999 and 2009 Malta imported 6,388,728,000 cigarettes for local consumption. The highest number of imported cigarettes was seen in 2001 with over 621 million cigarettes while in 2007 Malta imported a 100 million less cigarettes with approximately 521 million, the lowest between 1999 and 2009. Nonetheless, it is difficult to derive conclusions regarding cigarette consumption in view that a significant number of cigarettes are smuggled. While in 2001 only 166,500 cigarettes were caught in smuggling, over 11 million and over 13 million cigarettes were caught in smuggled in 2007 and 2009, respectively[18].
Despite attempts at enforcing the smoking ban, as evidenced by the increasing number of fines issued by the police following the introduction of the smoking ban legislation, there is lack of cooperation on behalf of the persons in charge of these public indoor premises, who, according to the Tobacco (Smoking Control) Act[12], are the persons directly responsible for ensuring that no smoking takes place on their premises. This results from a fear that strict enforcement of the smoking ban will lead to a loss of business[19]. This however was not documented in a study in Italy which showed that the smoke-free legislation led to an increase in business for bars, cafes and restaurants with 10% of Italians going more often compared to 7% who went less frequently[20].

Our study thus demonstrates a new and previously undocumented facet to smoking bans. Legislation is not enough and lack of proper enforcement could result in the public smoking ban having no significant impact on ACS admission rates. Policy makers need to be aware that public smoking bans must be enforced to be effective.

There was no decrease in mortality across both genders and all age-groups in the immediate years following the smoking ban legislation. The decrease in mortality was only noted 3 years following the introduction of the legislation in the year 2007. Studies have shown that there is usually an immediate decline in mortality following smoking ban in public places[2-11]. The decrease in mortality in 2007 could be attributed to better enforcement of the smoking ban as evidenced by a marked increase in fines[13] and a decrease in the importation of cigarettes during that year[21]. A further reduction in ACS admissions was noted 2 years after implementation of the smoking ban in public places in Ireland[22], and 4 meta-analyses have also reported decreased ACS events over time[23-26]. Tan and Glantz (2012) have shown a dose–response whereby more comprehensive laws were associated with more significant declines in hospitalization for cardiac, cerebrovascular and respiratory disease[26]. Long-term studies of the effects of smoking bans in different countries on ACS events are necessary.

The study has some limitations. Although some data were missing from the Hospital Activity Analysis database, this was a random error and was corrected for. Being an epidemiological study, it is possible that unmeasured confounders were responsible for the results observed. In an attempt to correct for these confounders, adjustment was performed for the major cardiovascular risk factors.

An important strength of the study is that Malta, being an archipelago with only one major hospital, provides an ideal setting for such an epidemiological study. Another strength is that the data were collected and analysed for a significant number of years both before and after the introduction of the smoking ban legislation.

Conclusion

The Malta smoking ban study failed to show an immediate reduction in cardiovascular morbidity and mortality. This lack of effect persisted over a 5-year period, with regards ACS admissions, while a decline in mortality was only shown 3 years after the smoking ban legislation. It highlights the importance of not only legislating but also enforcing smoking bans in indoor public areas and workplaces. It also suggests that smoking bans may need to be extended to outdoor public areas, cars, and homes. This public health measure needs to be accompanied by a one-to-one physician-patient counseling not only to help smokers to stop smoking but also to advise non-smokers to avoid exposure to second-hand smoke in public areas, at work, and at home. Health promotion campaigns educating the public regarding the adverse effects of smoking and increase in taxation on tobacco consumption might also help to decrease the cardiovascular morbidity and mortality associated with cigarette smoking.

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