# Health impact of the emissions from a refinery: case-control study on the adult population living in two municipalities in Lomellina, Italy

*Marco Gnesi [1], Maria Cristina Monti [1], Ottavia Eleonora Ferraro [1], Paola Borrelli [1], Francesca Gigli Berzolari [1], Mariangela Valentina Puci [1], Enrico Oddone [2], Marcello Imbriani [2], Gabriele Pelissero [4], Ennio Cadum [3], Simona Migliazza [3], Cristina Montomoli [1], Simona Villani [1]*

*(1) Unit of Biostatistics and Clinical Epidemiology, Department of Public Health, Experimental and Forensic Medicine, University of Pavia, Pavia, Italy*
*(2) Unit of Occupational Medicine "Salvatore Maugeri", Department of Public Health, Experimental and Forensic Medicine, University of Pavia, Pavia, Italy*
*(3) Agenzia di Tutela della Salute (Health Protection Agency), Pavia, Italy*
*(4) Unit of Hygiene, Department of Public Health, Experimental and Forensic Medicine, University of Pavia, Pavia, Italy*

***CORRESPONDING AUTHOR:*** *Maria Cristina Monti, Unit of Biostatistics and Clinical Epidemiology, Department of Public Health, Experimental and Forensic Medicine, University of Pavia, Pavia, Italy. Email: cristina.monti@unipv.it*

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## ABSTRACT

**Background:** In the municipalities of Sannazzaro de' Burgondi and Ferrera Erbognone (District of Lomellina, Pavia, Lombardy, Italy), an oil refinery is operating since 1963. In 2008, the company running the plant (eni S.p.A.) asked the competent bodies the permission for building a new facility ("EST"). The present work is aimed at evaluating the ante-operam health impacts of the existing facility refinery.
**Methods:** A case-control study design was implemented. Cases were subjects admitted to hospital in 2002-2014 due to acute respiratory, cardiovascular or gastrointestinal conditions. Controls were selected among those who had not been hospitalised in that timespan. Cases and controls had to be alive at enrolment, aged 20-64 years, and were frequency-matched by age, gender and municipality. Data were extracted from the health insurance registry and from Hospital Discharge Records (ATS Pavia). Enrolled subjects were asked to complete a mailed survey. Environmental exposure was the fallout of refinery emissions (PM10) at participants' homes, as predicted by an AERMOD model.
**Results:** 541 respondents (125 cases, 416 controls) were included in the analyses. Response bias was excluded. Individual PM10 exposure was not significantly different between cases and controls, while it was significantly associated with municipality (being higher in Sannazzaro). The crude effect estimate of PM10 over case/control status indicated a not-significant excess of hospitalisation with the increase in PM10 exposure. Multivariate analyses confirmed those results.
**Conclusion:** Findings indicate a possible excess of hospitalisation risk in most-exposed people, but the effect is not statistically significant and may be affected by bias.

*Key words: air pollution; particulate matter; environmental health; case control study*

# INTRODUCTION

Air pollution is perhaps the most relevant environmental risk of our era: it is considered responsible for a ninth of all the deaths occurring worldwide, affecting every component of the society in any corner of the world. In fact, its reduction is an indicator of sustainable development [1]. As specifically regards outdoor pollution, it carries a burden of more than 3 million deaths per year and 85 million DALYs (Disability-Adjusted Life Years) [1]. It affects every component of the society, disregarding socioeconomic status or other relevant factors [1], even though not all those groups are affected to the same extent [2]. Broadly speaking, the effects of air pollutants depend on their atmospheric concentration, their persistence and their physical and chemical characteristics, as well as the peculiarities of exposed subjects (i.e. "receptors") and the time of exposure [3]. The impact of pollutants on health can occur either in the short term (mainly because of high levels of contamination) or in the long term (with a prolonged, yet not necessarily high, exposure). In particular, the effects of chronic exposure to mixtures of different contaminants at low concentrations are far from being ascertained [3]. It is also important to remark how susceptibility to air pollution is also moderated by pre-existing conditions or predispositions: different individuals may not respond in the same way to the same exposure because of underlying intrinsic and extrinsic factors (e.g. age, gender, genetic background, socio-economic status, nutrition, lifestyle) determining inter-subjects variability [4].

The idea of the environment being a determinant of health is recapped in the concept of *environmental health*, proposed by the WHO, which comprised in this definition all the physical, chemical and biological determinants that are extrinsic to a person but can have an effect on health, well-being or behaviour [5]. Investigation in *environmental health* is intricate, as it requires to integrate epidemiology, medicine and toxicology with environmental sciences. The socioeconomic dimension adds a greater complexity: robust scientific methodology cannot ignore the specific circumstances and urgencies expressed by stakeholders. Industrially contaminated sites [6], in particular, are a relevant issue for *environmental health* because they may be harmful to public health [5]. At the same time, those sites are often located in socio-economically deprived districts [7], a fact that could strengthen their negative impacts by interacting with other health determinants: in other words, they are a concern also for environmental justice [6].

In the district of Lomellina (Province of Pavia, Region of Lombardy, Italy), specifically in the municipalities of Sannazzaro de' Burgondi and Ferrera Erbognone, an oil refinery is operating since 1963, still representing a relevant player for the socio-economical and occupational standards of the area. The area around the refinery in Sannazzaro de' Burgondi and Ferrera Erbognone, except for the refinery itself, is a land of strong agricultural vocation. Remarkably, Lomellina is located in the Po Valley, one of the areas with the worse air quality standards in Europe [8]. In 2008, the private company running the plant (eni S.p.A.) asked the competent authorisation bodies to set up a new facility ("EST"), which theoretically should increase the yield of the refining process and reduce the emission of pollutants (except for carbon dioxide). The authorisation decree, issued in 2010, was conditional to the implementation of surveillance activities and, notably, of an epidemiological study investigating public health before and after the commissioning of EST (*ante-operam* and post-operam); the company was mandated to assume all the costs of these activities, without taking part in any decision about the study and its methods.

According to the authorisation decree, the Department of Public Health, Experimental and Forensic Medicine at the University of Pavia designed and implemented the CONSAL Project (Conoscenza e Salute, in English Knowledge and Health), aimed at investigating the health status of the adult population living in Sannazzaro de' Burgondi and Ferrera Erbognone. The protocol was approved by the competent Ethical Committee. The Project included four epidemiological studies both *ante-operam* and post-operam and, as of 2020, it was not concluded yet. The present work refers to the *ante-operam* phase of CONSAL Study 1, which started in 2015 and was completed in 2018. Its specific aim was to investigate the health impacts of the emissions from the point sources of the refinery on the adult population living nearby, and to produce mutually adjusted estimates of the effects of environmental exposure and other additional information collected through a survey.

# METHODS

## Setting and participants

The target population of this study is composed by adults aged 20-64 years, living in the municipalities of Sannazzaro de' Burgondi and Ferrera Erbognone (Lomellina district, Province of Pavia) during the *ante-operam* timespan (2002-2014, before the commissioning of the new "EST" facility).

## Study design and outcome

The study was designed using a population-based case-control design. The health outcomes were an acute condition of the respiratory, cardiovascular or gastrointestinal systems. Cases and controls were identified based on hospital admissions using codes of the International Classification of Diseases (ICD) related to those health outcomes (ICD-IX-CM Chapters 7-8-9 and codes 785-786). In detail, cases were those admitted to hospital between 2002 and 2014 for the abovementioned causes; in the event of multiple hospital admissions, only the first one in chronological order was considered to identify cases. Controls were selected among people that were not hospitalised in the same timespan (2002-2014). Three controls were enrolled per each case; frequency-matching by age, gender and municipality was set up.

### Exposure

The main environmental exposure for enrolled subjects was the fallout of refinery emissions. According to the *ante-operam* scenario as presented by the company during the authorisation application for the "EST" facility, the main pollutants were particulate matters (PM, 100 kg/h), sulphur oxides (and particularly SO2, 680 kg/h), nitrogen oxides (NOX, 780 kg/h) and carbon monoxide (CO, 340 kg/g) and dioxide (CO2, 290000 kg/h) [9]. Ground-level pollutants' concentrations were predicted by the AERMOD model; then, individual environmental exposure was assigned by linking the geocodes of participants' home addresses to the modelled surface, using a bilinear interpolation. Particulate matter (PM10) was chosen as a tracer, given that pairwise correlations with the other modelled contaminants were extremely high (Pearson's r in the range 0.95-0.99). Moreover, previous unpublished analyses using non-hierarchical K-means models identified 2 clusters as the best individual discrimination criteria with reference to PM10 exposure. The two identified clusters roughly correspond to the two municipalities of Sannazzaro and Ferrera; therefore, municipality was considered as a proxy of individual PM10 exposure.

### Data sources and data collection

Data were extracted from two databases held by the local Health Protection Agency (ATS Pavia), the Registry of insured citizens and the one of Hospital Discharge Records (Schede di Dimissione Ospedaliera, SDOs), with a deterministic linkage procedure. Personal information was also checked with the Municipal Registries.

A structured questionnaire, designed to collect relevant information at the individual level (factors that could influence the chance of being a case, along with potential confounders) was sent to all the enrolled subjects as a part of the survey. All these subjects firstly received the survey by mail; non-respondents were contacted three additional times.

Besides demographic variables (age and gender), some variables from the questionnaire were included in the analyses together with the main exposure (PM10 concentration). Choice of those variables depended on two criteria, namely a priori semantic relevance and quality based on a critical assessment of consistency and reliability of the information collected through the questionnaires. The variables were: a. Marital status (single, married, divorced, widowed, other); b. Education (primary, secondary, or high school, university, other); c. Type of house (isolated, detached, semi-detached, flat, terraced, other); d. Alcohol consumption (yes/no); e. Cigarette smoking, lifetime (yes/no); f. Cigarette smoking, current (yes/no); g. Traffic near the house (high/low); h. Physical activity (at least one/none); i. Other diseases (yes/no), recording if the subject declared to be affected by a condition that could determine the status of case if it resulted in hospital admissions or declared to be regularly administered treatments for such conditions.

### Sample size

A minimum sample size of 840 subjects (210 cases, 630 controls) was estimated a priori by using the formula for unmatched case-control designs, as proposed by Fleiss [10]. The unadjusted OR was assumed to be 1.6 from previous researches [11], and exposure was considered to affect a share of 40% of the general population. Case:control ratio was 1:3. The significance threshold was set at 5% ($\alpha$=.05) and power at 80% ($\beta$=.20). The number was increased to account for a rate of unavailable subjects of 10%. After estimating the minimum sample size, 1046 subjects were enrolled, of which 257 cases (all the available cases) and 789 controls (for Ferrera, all the available ones).

### Statistical analysis

Quantitative variables were expressed in terms of means and standard deviations (SDs), or medians and IQRs if normality was not met. Qualitative ones were described with their frequency distributions.

Associations between qualitative variables were inspected by means of Pearson's Chi-squared (or Fisher's exact) test. Differences in quantitative variables between groups were investigated with unpaired t-test or one-way ANOVA, as appropriate, or non-parametric methods (Mann-Whitney's and Kruskal-Wallis' tests) if assumptions of parametric tests were not met.

Respondence bias was investigated by testing the association between respondence and municipality, gender, age, case/control status. The unadjusted Odds Ratio (crude OR) was estimated to assess the relationship between case/control status and individual exposure to PM10. In order to identify potential confounders, associations between PM10 and other exposures were also inspected.

Multivariable logistic regression models were implemented in order to estimate mutually adjusted ORs for the predictors. Municipality was the main environmental exposure, while age, gender, lifetime cigarette smoking were included based on a priori specification of the model. The inclusion of remaining exposures was evaluated based on their contribution to the model fit (Likelihood-Ratio test) and their informativity (Akaike and Bayesian Information Criteria).

A secondary multivariate logistic model was implemented to investigate the effect of several variables on the self-perceived general health status. The variable, which had a Likert-like structure with 5 levels ("poor", "passable", "good", "very good", "excellent"), was dichotomised by grouping together the answers described with a negative adjective ("poor" or "passable") against positive terms (from "good" to "excellent"). In this case, distance from home to the refinery served as the main "environmental" exposure instead of clustered PM10, as it was assumed to be closer to people's perception.

The threshold for statistical significance was 0.05; in the case of multiple testing, the significance level was adjusted according to Bonferroni's correction. All the analyses were performed in Stata 13 [12].

## RESULTS

Survey respondents were 563 (54.6%), but 22 subjects declared to actually live elsewhere; thus, only 541 (125 cases and 416 controls) were included in the analyses. Respondence was higher in Ferrera than in Sannazzaro (75.7% vs 49.1%, $\chi^2$=48.48, p<.001). However, respondence was not different by case/control status ($\chi^2$=0.20, p=.66) or gender ($\chi^2$=1.29, p=.26). A slight difference in age was observed between respondents and non-respondents (57.1 vs 54.4 years, t=-3.44, p=.0006).

The share of subjects from Sannazzaro was slightly higher among cases, while there was no significant difference between cases and controls in terms of gender, age, and most other variables (Table 1). Most participants self-reported a positive attitude towards their health status. 331 subjects (83.5% of cases, 59.3% of controls) reported being affected by clinical conditions (diagnoses or therapeutic regimens, as self-reported in the questionnaire) that could be related to the conditions used to define cases.

PM10 exposure had a bimodal distribution (Figure 1); the two peaks in the PM10 distribution plot were significantly associated to the two municipalities, which can be considered two different PM10 exposure clusters (Figure 2): concentrations were higher in Sannazzaro de' Burgondi than in Ferrera Erbognone (MW=18.16, p<.0001, Table 2). Exposure to PM10 was not significantly different between cases and controls (MW=-0.82, p=.41), even stratifying by municipality.

Regarding possible confounders of the association between PM10 clusters and acute conditions of respiratory, cardiovascular or gastrointestinal systems, municipality was significantly associated with gender ($\chi^2$=6.86, p=.009), and a borderline difference was observed also with regard to age (MW=1.89, p=.059), but survey respondents were only three years older in Sannazzaro de' Burgondi than in Ferrera Erbognone. Lifetime cigarette smoking was less prevalent in Ferrera than in Sannazzaro (47.7% vs 59.8%, $\chi^2$=6.48, p=.011).

The crude effect of exposure to PM10 indicated an excess of health "risk" (hospitalisation due to acute conditions of respiratory, cardiovascular or gastrointestinal systems) in Sannazzaro de Burgondi with respect to Ferrera Erbognone; however, the effect estimate was not statistically significant (Sannazzaro vs Ferrera, OR 1.595; 95%CI 0.990-2.569, p=0.51).

Multivariable analyses, using unconditional logistic regression models, disclosed similar (and still non-significant) effect estimates for the main exposure (p=0.12) while adjusting for age (p=0.27), gender (p=0.36), lifetime cigarette smoking (p=0.79) and other diseases (p<0.001) (Figure 3).

In the secondary analysis, evaluating the influence of several factors on self-perceived health (Figure 4), it was disclosed that living further from the refinery reduced by 15% the "risk" of having a negative self-perception of health (+1km distance from the refinery, OR=0.859, 95%CI 0.629-1.173, p=0.34), albeit the effect was not statistically significant. On the contrary, age (p<0.001), female vs male gender (p=0.007), and status of case vs control (p<0.001) were significant predictors of a worse perceived health, and physical activity was significantly improving it (p=0.006).

## DISCUSSION

Results from the present study suggest that the higher the exposure to the emissions from the refinery, the higher the "risk" of being a case, albeit the effect does not reach statistical significance. The findings are substantially consistent with previous epidemiological studies of populations living close to refineries and petrochemical plants and are toxicologically coherent. Nonetheless, results in the present study might have been affected by various biases. Among others, the identification of cases and controls might have been affected by the use of databases that are not primarily conceived for epidemiological research. Also, restricting to hospitalised cases might have excluded those with a less severe condition (although this was addressed by specific questions in the survey, coded in the variable "Other diseases"). At the same time, restricting to those who were alive at the time of assessment might have excluded the most-severe ones because of death.

Moreover, the unexpectedly strong association

**TABLE 1. Baseline characteristics of survey respondents. Percentages by case/control status.**

| Variable | | Cases (n=125*) | Controls (n=416*) | Test |
|---|---|---|---|---|
| **Municipality,** *Sannazzaro* | | 98 (78.4%) | 289 (69.5%) | $\chi^2$=3.76 p=.052 |
| **Gender,** *Females* | | 51 (40.8%) | 190 (45.7%) | $\chi^2$=0.92 p=.34 |
| **Age in years,** *Mean (SD)* | | 58.1 (1.1) | 56.8 (0.6) | t=-1.0 p=.28 |
| **Distance from refinery in metres,** *Median (IQR)* | | 2838 (698) | 2689 (1004) | MW=-2.537 p=.011 |
| **Marital status** | *Single* | 20 (16.1%) | 73 (17.6%) | $\chi^2$=2.32 p=.68 |
| | *Married* | 84 (67.7%) | 294 (70.8%) | |
| | *Divorced* | 7 (5.6%) | 20 (4.8%) | |
| | *Widowed* | 10 (8.1%) | 23 (5.5%) | |
| | *Other* | 3 (2.4%) | 5 (1.2%) | |
| **Education** | *Primary school* | 39 (31.2%) | 87 (20.9%) | $\chi^2$=7.95 p=.094 |
| | *Secondary school* | 35 (28.0%) | 131 (31.5%) | |
| | *High school* | 37 (29.6%) | 151 (36.3%) | |
| | *University* | 10 (8.0%) | 41 (9.9%) | |
| | *Other* | 4 (3.2%) | 6 (1.4%) | |
| **Employment status** | *Unable* | 6 (4.8%) | 3 (0.7%) | $\chi^2$=17.12 p=.009 |
| | *Unemployed* | 9 (7.2%) | 18 (4.3%) | |
| | *Occasional* | 4 (3.2%) | 9 (2.2%) | |
| | *Permanent* | 24 (19.2%) | 131 (31.5%) | |
| | *Housewife* | 14 (11.2%) | 48 (11.5%) | |
| | *Retired* | 57 (45.6%) | 173 (47.6%) | |
| | *Other* | 11 (8.8%) | 34 (8.2%) | |
| **Regular physical activity,** *At least one* | | 68 (58.6%) | 253 (64.2%) | $\chi^2$=1.20 p=.27 |
| **Alcohol consumption,** *Yes* | | 58 (47.9%) | 183 (44.2%) | $\chi^2$=0.53 p=.47 |
| **Cigarette smoking (lifetime),** *Yes* | | 71 (58.2%) | 231 (55.8%) | $\chi^2$=0.22 p=.64 |
| **Other diseases,** *Yes* | | 101 (83.5%) | 230 (59.3%) | Not tested** |
| **Self-reported perceived health status** | *Poor* | 17 (13.8%) | 16 (4.0%) | Fisher's exact p<.001 |
| | *Passable* | 48 (39.0%) | 103 (25.5%) | |
| | *Good* | 49 (39.8%) | 219 (54.2%) | |
| | *Very good* | 7 (5.7%) | 61 (15.1%) | |
| | *Excellent* | 2 (1.6%) | 5 (1.2%) | |

** Variables have a different occurrence of missing data, so the actual number of subjects on which descriptive statistics are computed may vary slightly.*
*** Given that this variable summarises information about the same diseases and condition used for the sake of the identification of "case", a significant association with case/control status would be meaningless.*

between predicted PM10 concentrations and municipality, combined with the fact that the sampling of cases and controls was frequency-matched by municipality, may have determined an underestimation of the effects of environmental exposure (i.e. the OR for the main exposure is biased towards a null effect because of overmatching). It should also be considered that exposures are measured at present times, while the outcome occurred in the past. Finally, albeit respondence bias and confounding bias were excluded, the response rate was lower than expected, thus reducing study power.

It is also important to remark that PM10 was

FIGURE 1. Distribution of PM10 exposure at participants' home addresses, as predicted by the AERMOD model .

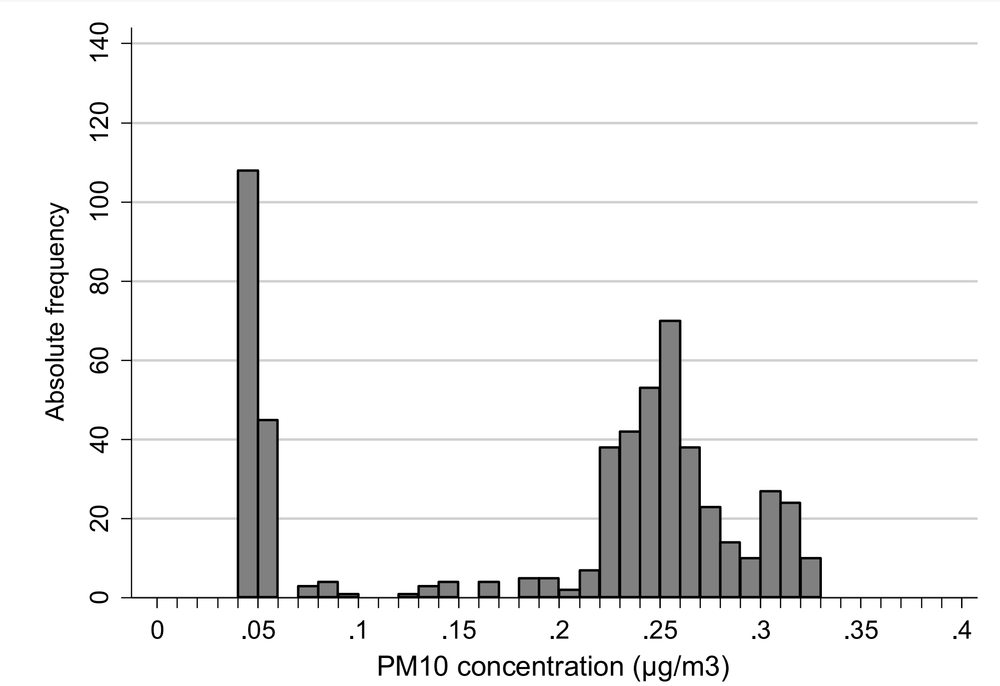



FIGURE 2. Map of the registered home addresses (white circles) for the 541 study participants, plotted over the grid of PM10 concentrations attributable to the fallout of gaseous emissions from the refinery (AERMOD estimates). The borders of the municipalities of Sannazzaro de' Burgondi and Ferrera Erbognone are represented, together with the area of the refinery.

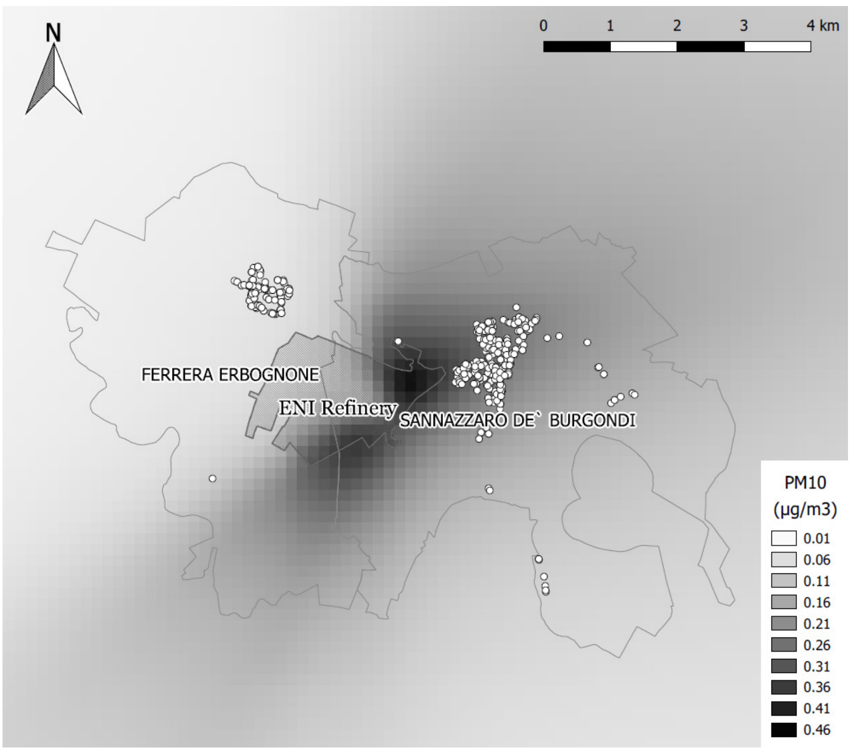
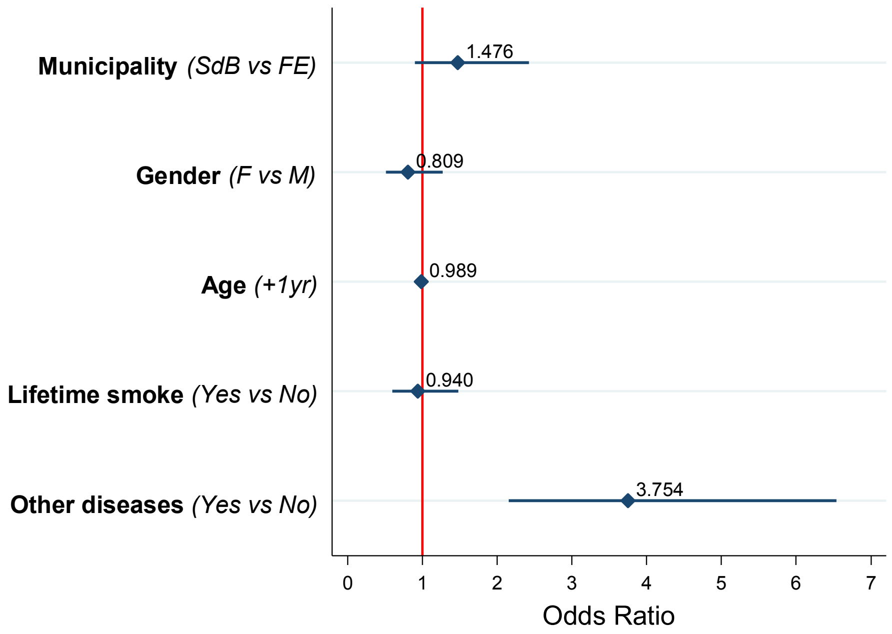


**TABLE 2. Predicted PM10 concentrations attributable to the fallout of refinery emissions at the home addresses of cases and controls, by municipality.**

| Municipality | Status | N | Median (IQR) | Min – Max |
|---|---|---|---|---|
| Sannazzaro | Cases | 98 | 0.2494 (0.0439) | 0.0821 – 0.3272 |
| | Controls | 289 | 0.2547 (0.0387) | 0.0780 – 0.3290 |
| Ferrera | Cases | 27 | 0.0468 (0.0058) | 0.0412 – 0.0529 |
| | Controls | 127 | 0.0465 (0.0061) | 0.0408 (0.0924) |

**FIGURE 3. Mutually adjusted estimates of the ORs (with 95%CIs) for the main exposure (PM10 concentration clustered in 2 groups, approximated as municipality) and other variables. Outcome: case or control status.**




picked as the "tracking pollutant" but, given the strong correlation between PM10 and other pollutants, effects might be due to other pollutants rather than to PM10, or the combination of several pollutants. Besides, ground-level PM10 concentrations related to the emissions from the refinery are an order of magnitude less than total PM10 concentrations, so the refinery is estimated to give little contribution to total PM10 levels.

Concluding, this work indicates a possible excess of hospitalisation risk for respiratory, cardiovascular or gastrointestinal causes among people living in Sannazzaro de' Burgondi, who are more exposed to the refinery's emissions, in comparison with those living in Ferrera Erbognone. However, these results cannot be taken as conclusive evidence, because a null effect cannot be excluded (perhaps because of the reduction in study power due to the lack of respondence) and because of potential biases affecting effect estimates.

In the future, another study will be repeated post-operam, and its results will be compared to the *ante-operam*; the results from Study 1 will also be integrated by other studies in the framework of the CONSAL Project.

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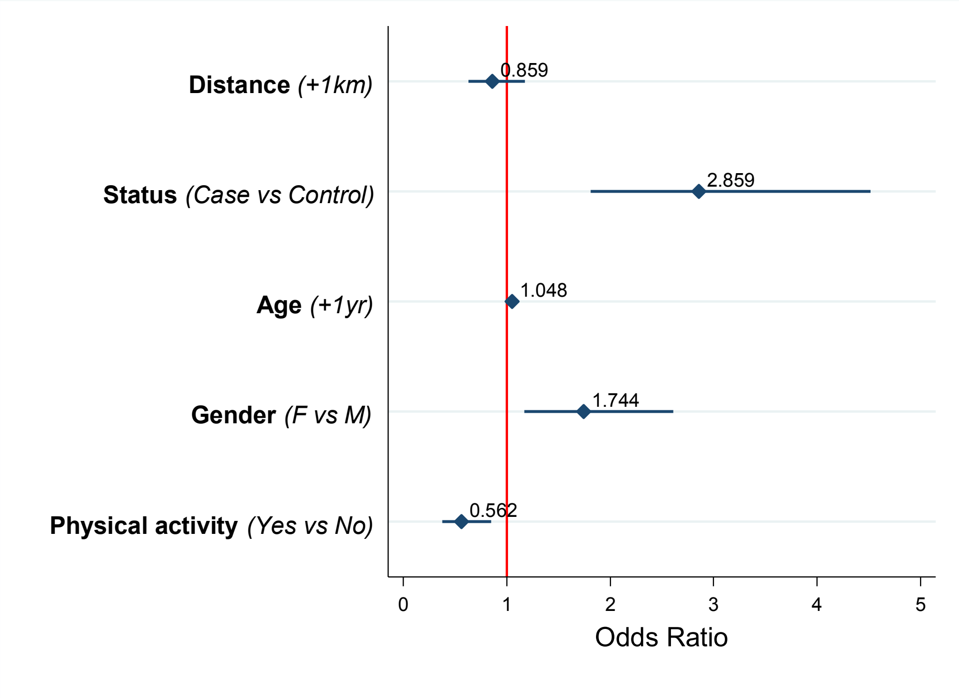
## Disclaimer

Marco Gnesi is currently an employee at AstraZeneca Italy. However, the full project was carried out during his doctoral studies at the University of Pavia, and his current employer had no role in the project or in this publication.

**FIGURE 4. Mutually adjusted estimates of the ORs (with 95%CIs) for the distance from the refinery and other variables. Outcome: self-perceived health status (negative vs positive attitude).**

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