VARIATION IN EMERGENCY PERCUTANEOUS CORONARY INTERVENTION IN VENTILATED PATIENTS IN THE UK: INSIGHTS FROM A NATIONAL DATABASE

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Highlights

• Regional variation exists in the UK in the management of people requiring emergency ventilation prior to PCI.

• Discrepant practice was not related to availability of cardiac surgery nor annual total PCI volume at an individual center.

• Provides the benchmark data from which to design Rrandomized controlled trials to examine this area and facilitate the development of effective treatment algorithms

Abstract

Aims

Pre-procedural ventilation is a marker of high risk in PCI patients. Causes include out-of-hospital cardiac arrest (OHCA) and cardiogenic shock. OHCA occurs in approximately 60,000 patients in the UK per annum. No consensus exists regarding the need/timing of coronary angiography ± revascularization without ST elevation. The aim was to describe the national variation in the rate of emergency PCI in ventilated patients.

Methods and Results

Using the UK national database for PCI in 2013, we identified all procedures performed as 'emergency' or 'salvage' for whom ventilation had been initiated before the PCI. Of the 92,589 patients who underwent PCI, 1342 (5.5%) fulfilled those criteria. There was wide variation in practice. There was no demonstrable relationship between the number of emergency PCI patients with pre-procedure ventilation per annum and (i) total number of PPCIs in a unit ($r = -0.186$), and (ii) availability of 24 h PCI, (iii) on-site surgical cover.

Conclusion

We demonstrated a wide variation in practice across the UK in rates of pre-procedural ventilation in emergency PCI. The majority of individuals will have suffered an OHCA. In the absence of a plausible explanation for this discrepant practice, it is possible that (a) some patients presenting with OHCA that may benefit from revascularization are being denied treatment and (b) procedures may be being undertaken that are futile. Further prospective data are needed to aid in production of guidelines aiming at standardized care in OHCA.

Keywords
Cardiac arrest; Ventilated; Coronary intervention; Primary PCI

1. Introduction
Pre-procedure ventilation is a marker of high risk for emergency PCI [1]. The commonest reason for pre-procedure ventilation in these patients is presentation with OHCA. The majority of other cases that require ventilation occur due to pulmonary edema associated with an acute ischemic event, particularly STEMI with cardiogenic shock [1,2]. Out-of-hospital cardiac arrest (OHCA) occurs in approximately 60,000 patients in the UK per annum [3,4]. Only around half of cases have an attempt at resuscitation, and only 24% survive to hospital admission. Of these cases, under 10% survive to hospital discharge [5,6], and 50% of these individuals will have sustained brain injury associated with demonstrable cognitive impairment [6,7].

Despite the frequency with which OHCA is encountered, the optimal management for patients who have initial resuscitation, and thus survive to reach hospital, is uncertain and contentious. Since the commonest cause of an unheralded OHCA in adults aged over 35 years is ischemic heart disease [8], a key part of the management algorithm is the decision whether to offer emergency coronary angiography and revascularization. It is this decision that will largely dictate the proportion of such cases performed within a PCI center and by an individual PCI operator. In cases where a post-resuscitation ECG demonstrates ST-elevation, both the AHA and ESC guidelines advocate immediate reperfusion therapy [9,10], with coronary angiography and PCI where available. However, in patients without ST-elevation, the ideal management remains uncertain and the recommendations are ambiguous [11]. Around 25% of patients without ST-elevation will have a culprit obstructive coronary lesion [12]. If this can be successfully treated with PCI, then observational data suggest an association with improved survival at both 30 days and 1 year compared to those who do not receive PCI. [13] However, there remains no clear consensus regarding the need for, and/or timing of, angiography following an OHCA [14].

In the UK, immediate primary angioplasty for the management of acute ST-elevation myocardial infarction (STEMI) has been widely adopted [15]. However, in the group of patients who have suffered an OHCA and require mechanical ventilation, in whom a similar approach may offer a survival benefit, contemporary interventional practice remains variable. This is likely to be due to multiple factors, including the lack of randomized trial data and risk averse behavior that may be driven in part by publication of individual PCI operator outcomes, even those cases that are specifically excluded from public reporting in the UK to try to avoid potential adverse consequences for patients. Theoretically, there should not be a significant variation in the proportion of the overall number of PCI cases that are ventilated pre-procedure for these indications.

Regional variation in the management and survival rates of OHCA has recently been demonstrated in the United States [16]. Prior to 2014, no systematic registry data were available in the UK specific for OHCA. However, using the field “ventilated pre PCI”, allows collation of data relating to patients who have required mechanical ventilatory support for any reason prior to PCI, of which the majority will be patients presenting with OHCA. The need for mechanical ventilation has been identified as an independent predictor for adverse outcome in a number of historical and contemporary series of PCI conducted in ACS [1,2].

The aims of this analysis are to describe, for the first time, the national variation in rate of PCI in ventilated patients treated in an emergency setting, and to evaluate its correlation with (a) the

absolute number of PCI undertaken in each center, (b) the availability of 24/7 PCI, and (c) the presence or absence of on-site surgical cover.

2. Methods

We performed a retrospective analysis of the national database of percutaneous coronary intervention (PCI) collected by the British Cardiac Intervention Society (BCIS) and collated by the National Institute of Cardiac Outcomes and Research (NICOR) [17]. All centers, and individuals, that perform PCI in the UK are obliged to return data on every PCI procedure to NICOR. The BCIS–NICOR database collects information on clinical, procedural and outcomes data and contains 113 variables with approximately 80,000 new records added each year. NICOR, which includes BCIS [16], has support under section 251 of the NHS Act 2006 to use anonymized patient information for medical research without consent. The study involved anonymous data and formal ethical approval was not required. Our cohort was defined by two fields in the dataset: 'ventilated pre PCI' to identify patients who had required mechanical ventilation during their PCi, and 'procedure urgency' recorded as 'emergency' or 'salvage'. Two cohorts were identified: a total ventilated PCI sample and further subset comprising only procedures recorded with an 'indication for intervention' of 'Primary PCI' (PPCI). Patients in whom the field was missing/blank were treated as if ventilation had not been undertaken.

Centers were characterized according to (a) whether there is on-site cardiothoracic surgery and (b) whether they provide a primary PCI service for ST elevation myocardial infarction, based on the NICOR–BCIS annual survey of 2013 and the NICOR strategy template 2011 [18].

The raw dataset was cleaned and analyzed using R version 3.1.1 (www.r-project.org). The output tables were then collated and further analysis was performed using Numbers (v3.5) and Wizard for Mac (V1.5.3). Distributions were tested for normality using the Kolmogorov–Smirnov test. Student's t-test was used to compare means in normally distributed continuous variables, with the Mann–Whitney U test used in continuous data that were not normally distributed. Correlations were assessed using Fisher's transformation test.

3. Results

Between Jan. 1st and December 31st 2013, 92,589 PCI procedures were carried out in 117 centers across the UK. In total, 24,379 procedures were conducted in the setting of primary PCI for STEMI. Forty-one centers were identified as being sites with cardiothoracic surgical cover, of which only a single site did not have data available for this analysis.

In total, 1342 emergency cases required ventilation pre PCI, representing 5.5% of the total number of PPCI in 2013. This has increased year on year from 3.5% in 2008 (Fig. 1). The demographics of this cohort are described in Table 1. The majority of patients in whom ventilation was required pre-emergency PCI were male (n = 1032 (76.9%)), and had no previous history of MI (n = 963 (71.8%)), previous PCI (n = 1096 (81.7%)) or CABG (n = 1213 (90.4%)). Cardiogenic shock was present in 811 (60.4%) cases.

[Insert Fig. 1 here]

[Insert Table 1 here]

The rate of ventilated emergency PCI as a proportion of the total number of procedures in the UK performed in 2013 ranged from 0 to 4.74% between PCI centers. Specifically, there was a weak, but statistically significant positive correlation between the total number PCIs performed within a unit and the number of emergency ventilated PCIs per annum (Fig. 2) ($r = 0.386$). There was, however, no correlation between the number of PPCIs performed in a center and the relative percentage of emergency ventilated PCIs (Fig. 3) ($r = -0.186$). The proportion of ventilated PCI patients did not vary in the presence of on-site surgical cover (median on-site surgery 4.4% vs. 4.9%, $p = 0.535$). Overall, centers that offered 24/7 primary PCI had a significantly higher proportion of emergency PCI patients, relative to the total number of PCIs performed (24/7 vs. non 24/7: 1.6% vs. 0.5%, $p < 0.001$; median 1.29% vs. 0.49%, $p < 0.001$). However, no significant differences were observed between the proportions of emergency ventilated PPCI patients in centers offering 24/7 PPCI and those that were not (24/7 vs. non-24/7: median 4.08% vs. 4.76%, $p = 0.924$).

[Insert Fig. 2 and 3 here]

4. Discussion

This paper describes for the first time the wide variation in PCI that is undertaken for patients requiring ventilation pre PCI across the UK. Specifically, the rate of PCI in emergency ventilated patients, as a proportion of total PCIs performed varies from 0.09% to 4.74% and there was only a weak correlation between the total number of PCIs performed at a center. Importantly, no association was demonstrated between the number of primary PCIs performed within a unit, and the relative proportion of emergency ventilated PCIs performed per annum.

In the absence of a plausible alternative explanation for this variation in practice, which is consistent with recent evidence from the United States [16], these data suggest that management decisions taken by individual PCI operators in relation to offering PCI to patients requiring mechanical ventilation are heterogeneous.

Based upon the wide variation in current practice that has been described here it seems likely that some patients in the UK, including those patients who present with OHCA, that could benefit from early revascularization are not being afforded such treatment, and it is also possible that a proportion of such patients are receiving revascularization which may be futile.

Our observations highlight the need for further data, preferably derived from large scale randomized trials that can be used to produce management guidelines for this group of patients in order to standardize their care and ensure equity of access to potentially life-saving treatment. Indeed, current guidelines suggest an appraisal of an individual patient risk, but have few data to support any specific objective tools that could be used to predict futility. [14]

The challenge facing emergency care physicians and PCI doctors in regard to the management of patients with OHCA is to decide whether, as well as initiating conventional resuscitation measures, patients should be taken for emergency coronary angiography with a view to PCI revascularization. The tools currently available to aid in this decision-making are limited. Established factors that predict a positive outcome following an OHCA include a shockable initial rhythm, a short time to return of spontaneous circulation, witnessed cardiac arrest and good quality bystander CPR followed by prompt defibrillation (where appropriate) [5]. However, the population that survives to hospital is heterogeneous with regard to these factors. Other clinical parameters are then taken into account as part of an assessment including pH, arterial blood gases, and hemodynamic status. However, there is a paucity of high quality evidence describing factors that may offer predictive value for outcome to provide a robust platform for our decision-making. Further research is required to see if it is possible to develop a "futility index" that could be used at the time of an initial clinical assessment to identify patients in whom angiography and/or revascularization is unlikely to contribute to their survival.

Other factors that may influence the decision as to whether to offer emergency angiography include the lack of clear cut data as to the value of finding and treating "significant" coronary artery disease, in the absence of an obviously acutely occluded vessel or even a lesion that appears to be a "culprit lesion".

Additional factors that have previously been identified to be associated with better outcome include hospital size and access to interventional cardiology facilities [14,19]. Our data suggest only a weak association between the total number of PCIs performed at a center, and the proportion of patients that are ventilated prior to undergoing emergency PCI. Specifically, there is a wide distribution of data, as illustrated in Fig. 2, and despite the statistical correlation, the relationship is weak and not apparent from the scatter plot.

This study has a number of limitations. The data are dependent upon self-reporting in regard to ventilatory status in emergency cases. We acknowledge that rarely there are other reasons for emergency ventilation pre PCI including cardiogenic shock without cardiac arrest. Indeed, shock was present in 60.4% of cases within this cohort. No data are available to delineate which of these shocked patients suffered a cardiac arrest. Secondly, the BCIS dataset only captures patients that proceed to PCI or an attempt at PCI. It does not record patients that undergo diagnostic cardiac catheterization only, such as those patients with "normal coronary arteries" or those in which coronary artery disease is not flow limiting or in patients who it is felt that a PCI would be futile. While this may influence the rates on an invasive strategy that we report, it will not contribute to the variation in practice between centers that we have reported. The UK PCI dataset has been updated and from 2014 additional fields that describe specific features of OHCA have been added, thus future analyses should more accurately delineate this population. In addition, a UK randomized trial is ongoing (the ARREST trial—ISRCTN96585404) that is investigating the role of immediate angiography (±revascularization with PCI) in OHCA.

In conclusion, our data confirm that there is currently a wide variation in practice across the UK in the number of patients being offered emergency PCI following mechanical ventilation. This may reflect a variation in practice in the treatment of patients who have suffered an OHCA. This should be a cause for concern with regard to consistency and equity of clinical care and should represent a stimulus for seeking an improved evidence base, preferably derived from randomized trials, in order to generate robust evidence-based clinical guidelines. In addition, by collecting additional data in the national audit datasets, large scale observational analyses of outcome in these patients could result in the development of a clinical Futility Index score that allows for a robust predictive model to indicate when unacceptably poor outcome very early after arrival in hospital might be expected. For

now, given the degree of variation in practice seen here, it is likely that some patients that may benefit from revascularization after OHCA are being denied treatment in some centers and/or by some operators, and similarly procedures may be being undertaken that offer no additional benefit to increase the patients' likelihood of survival.

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Impact on Daily Practice: This article serves to highlight the wide variation in practice in a commonly encountered clinical scenario — namely, emergency PCI in ventilated patients. Operators should consider this when faced with decisions making in this group of complex critically unwell patients. Further randomized trial data are required to assist in optimizing patient outcomes.

Table 1. Demographic information study population: all patients undergoing percutaneous coronary intervention that received pre-procedural ventilation during 2013.

Demographics	**Mean**	**Median**	
Age	62.7 ± 12.98 y	63 y	
	Male	**Female**	**Unknown**
Sex	1032 (76.9%)	309 (23%)	1 (0.1%)
	Yes	**No**	**Unknown**
Smoker (inc ex and current)	579 (43.1%)	346 (25.8%)	417 (31.1%)
Previous MI	220 (16.4%)	963 (71.6%)	159 (11.8%)
Vascular disease	86 (6.4%)	1011 (75.3%)	245 (18.3%)
Previous CVA	61 (4.5%)	1036 (77.2%)	245 (18.3%)
Previous PCI	145 (10.8%)	1096 (81.7%)	101 (7.5%)
Previous CABG	57 (4.2%)	1213 (90.4%)	72 (5.4%)
Previous hypercholesterolemia	365 (27.3%)	732 (54.5%)	245 (18.3%)
Family history of CAD	226 (16.8%)	636 (47.4%)	245 (18.3%)
Any diabetes	195 (14.5%)	952 (70.9%)	195 (14.5%)
Any renal disease (creat > 200)	51 (3.8%)	1089 (81.1%)	202 (15.1%)
Cardiogenic shock	811 (60.4%)	521 (38.8%)	10 (0.7%)

Fig. 1. Histogram illustrating the progressive year-on-year increase in the relative proportion in emergency patients ventilated prior to undergoing PCI. In 2013, 1342 cases were recorded in the BCIS database, representing 5.5% of the total PPCI performed in the UK.

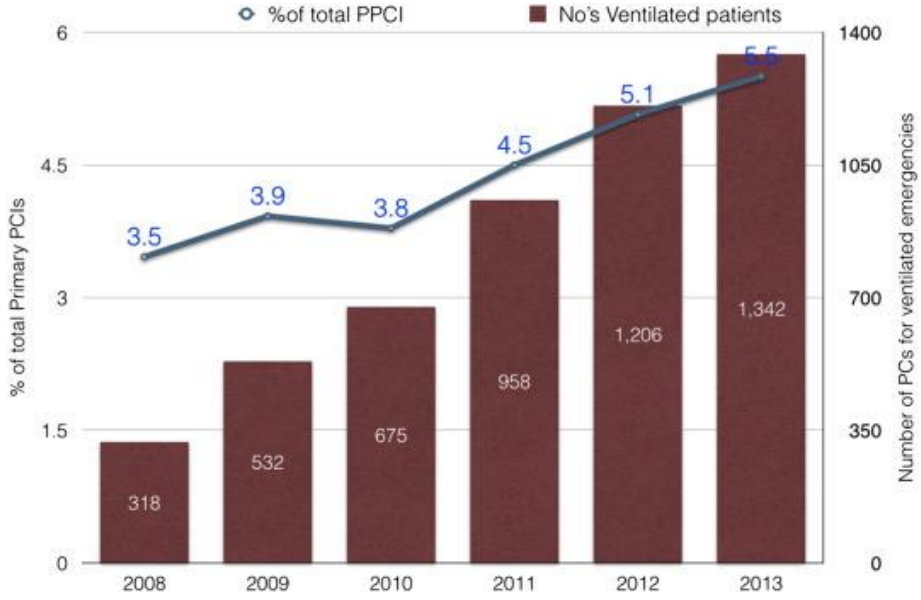

Fig. 2. Scatter plot describing the percentage of emergency ventilated patients undergoing PCI as a proportion of total PCIs in each individual PCI center. There is a wide distribution of activity with no demonstrable correlation between the total PCIs performed per center and the percentage of emergency ventilated patients.

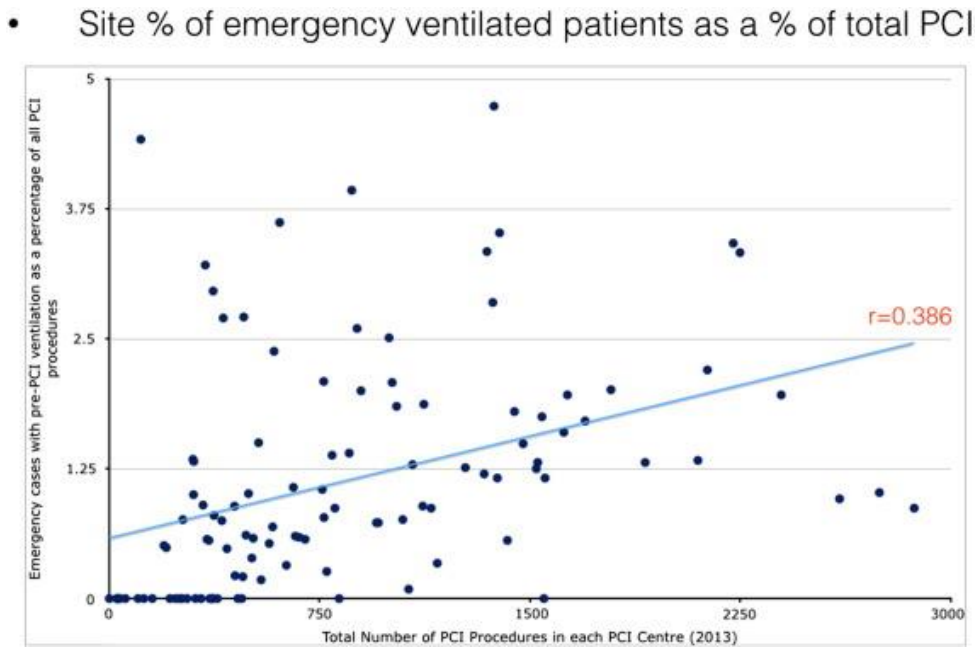

Fig. 3. Scatter plot describing the percentage of emergency ventilated patients undergoing PCI as a proportion of the number of PPCIs performed in each individual PCI center. Again, there is a wide distribution of activity with no demonstrable correlation between variables.

- Site % of emergency ventilated patients as a % of total Primary PCIs