

## **TITLE PAGE**

### **Title: Adherence to Treatment Guidelines as a Care Quality Indicator in Acute Gallstone Pancreatitis**

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## **ABSTRACT**

### **Background**

To investigate whether early definitive treatment for acute gallstone pancreatitis (in relation to cholecystectomy or ERCP) can be used as a care quality indicator for the condition.

### **Design**

A retrospective cohort study of 19,510 patients was conducted using the Hospital Episode Statistics (HES) database. We examined all emergency admissions to NHS hospitals in England with a first time diagnosis of Acute Gallstone Pancreatitis (GSP) in the financial years 2008, 2009 and 2010. Trends in early definitive treatment between trusts were examined and patient morbidity outcomes were calculated.

### **Results**

The overall rate of early definitive treatment in England between April 2008 and March 2010 was 34.7%. Substantial trust variation was seen ranging from 9.4 % to 84.7%. Early definitive treatment resulted in a 39% reduction in readmission risk (ARR: 0.61 95% CI 0.58,0.65), the risk was further reduced for acute pancreatitis readmissions to 54% in the guideline adherent group (ARR: 0.46,95%CI 0.42,0.51)

### **Conclusion**

This study demonstrates that early definitive treatment for acute gallstone pancreatitis (either early cholecystectomy or ERCP) is measurable on a national scale, exhibits substantial variation and has a direct impact on patient outcomes. It is also likely to be modifiable by local teams. We therefore suggest that it is an ideal process indicator to use in improving the care of patients with gallstone pancreatitis.

## **INTRODUCTION**

Acute pancreatitis is one of the most common intra-abdominal emergency conditions and is rising in incidence, with a year on year rise in English hospital admissions from 11,949 in 2000 to 20,682 in 2012 [3]. This has contributed to an additional 54% rise in the number of bed days used to treat acute pancreatitis over the same time period <sup>1</sup>. The incidence varies across the United Kingdom from 150 to 420 cases per million of the population <sup>2,3</sup> and is associated with multiple aetiologies, the most common being gallstones; in 35-40% of cases <sup>4,5</sup>. Despite advances in treatment, it still causes significant morbidity and mortality <sup>6,7</sup>.

In recognition of this therefore, in 2005 the UK British Society of Gastroenterology (BSG) Working Party on Acute Pancreatitis released a revised version of their 1998 guidelines for best practice management of acute gallstone pancreatitis (GSP) <sup>8</sup>. This advised that patients with mild GSP should undergo definitive treatment of their gallstones (either cholecystectomy or Endoscopic Sphincterotomy (if too unfit for the former)) during the same hospital admission or within two weeks of discharge. There is strong evidence that adherence to these recommendations improves patient outcomes with a reduction in hospital stay and further episodes of acute pancreatitis <sup>9-11</sup>. However, previous studies have shown variable adherence to these guidelines <sup>9,11</sup>. What is lacking in the literature is an assessment of the variation that exists between Trusts of varying size and structure at the national level and how these may impact patient outcomes. These factors have been investigated in colorectal and breast cancer surgery with studies producing differing results <sup>12-16</sup>.

Likewise, there is increasing evidence of variation in the quality of care provided to patients in hospitals in England and a resulting increasing

emphasis on empirical monitoring to help reduce it <sup>17-19</sup>. The most common measures of the quality of surgical care are outcome measures such as mortality, surgical complication rates and 30 day readmission rates <sup>20</sup>. Although clearly important by representing what ultimately happens to the patient, there are limitations with such measures; such as lack of sensitivity, their multifactorial nature (making it difficult for individual clinicians or teams to know what to alter) and the need for standardised definitions <sup>21</sup>. Alternatively, process measures are viewed as the 'closest approximation of actual health care offered' and are more 'clinically specific' <sup>22</sup>. Accordingly, the development of new process indicators may enable the design of new strategies to complement outcome measures to better monitor and improve care quality <sup>23</sup>.

The national BSG guidelines are available to improve outcomes, but the extent of adherence to guidelines (and hence the proportion of patients receiving early definitive treatment) across the country is variable. The first aim of this study therefore was to examine variation between hospital trusts in patients receiving early definitive treatment of gallstones following an episode of acute gallstone pancreatitis. Secondly it was to examine the relationship between early definitive treatment and outcomes at a trust level and the relationship with hospital structure. The third aim was to determine the validity of early definitive treatment as an indicator of quality of care for acute pancreatitis.

## **METHODS**

### **Data source**

The study used the Hospital Episode Statistics (HES) database, an administrative database of all admissions to English NHS hospitals. Each admission episode record consists of over 40 information fields; including patient details, diagnoses coded according to the International Classification of Diseases-10<sup>th</sup> Revision (ICD-10) and the use of the Office

of Population, Censuses and Surveys classification of surgical operations and procedures-4<sup>th</sup> revision (OPCS 4) codes. Types of admission and discharge details are also recorded. A unique patient identifier within HES allows each patient's hospital experience to be tracked. Using this identifier, admission and discharge details were identified and patients who underwent inter-hospital transfer during their initial hospital stay were included.

## **Definitions**

Index admission for acute gallstone pancreatitis

A patient was defined as presenting with their first episode of acute gallstone pancreatitis (GSP) if no previous related diagnosis of pancreatitis or related operation was evident in the preceding year's HES data for that patient. An episode of acute GSP required a diagnosis of acute pancreatitis (K85X) plus a diagnosis of acute gallbladder pathology; Cholelithiasis (K80\*), Cholecystitis (K81\*), Cholangitis (K830) or Obstruction of bile duct (K831) and be an emergency admission to hospital (HES method of admission codes 21-24, 28). HES records were available up to the end of April 2012. All GSP patients admitted during the British Fiscal Years 2008-10 were eligible for inclusion in the study.

Patients were excluded if they had a previous diagnosis of acute pancreatitis or operative fields with codes for Cholecystectomy or Endoscopic Sphincterotomy in the 12 months preceding the identified emergency admission with acute GSP (termed the 'index admission'). Cholecystectomy is contra-indicated in severe pancreatitis. Therefore patients who were determined to have severe pancreatitis were also excluded from the study. Pancreatitis severity is not coded in HES. Therefore surrogate markers were used, namely death on the same admission and critical care admission (identified using the treatment speciality field in HES). Patient records from Fiscal years 2007 and 2011 were also used to extract preadmission co-morbidity data and one year follow up data respectively. Using data beyond 2007 allowed one

year to give the opportunity for the new revised 2005 guidelines to be incorporated into hospital practice.

### Definition of timing of treatment

We defined early definitive treatment as being treatment in accordance with the 2005 BSG guidelines, namely a cholecystectomy or Endoscopic Sphincterotomy (ES) during the same hospital admission or within two weeks of discharge <sup>24-26</sup>.

### Other study variables

Specific factors with potential associations to surgical risk and more widely applied determinants of health were identified for all cases: age at time of index admission, sex, ethnicity and socioeconomic status (as measured by the English Indices of Deprivation 2004 ranking of the super output areas and further grouped according to quintiles). Co-morbidities were assessed using the Royal College of Surgeons (RCS) Charlson score <sup>27</sup> by examining HES records during the year prior to the index admission.

Variation of structural aspects at a Trust level were considered and identified a priori as potential confounders. Two variables were constructed. The first was specialist hepatopancreaticobiliary (HPB) centre status; as major HPB surgery has now been centralised into specialist centres in the UK in a “hub-and-spoke”-type system. These were defined as trusts with one or more hospitals performing at least 10 major liver or pancreatic resections (J56 (Excision of head of pancreas) or J02 (Partial excision of liver)) per year over the three years. The second was the average annual cholecystectomy volume (providing a proxy measure of benign HPB surgical experience in the trust).

### Outcome variables

Readmissions at 30 days, 90 days and cumulative incidence in the first year were defined as emergency admissions diagnosed with acute pancreatitis (K85x) or gallbladder associated diagnoses (K80\*, K81\*, K830, K831) compared to those not requiring a readmission. Death in hospital was identified using the discharge method field in HES. . For those patients who died during a GSP related readmission the mortality rates are described based on hospital mortality only, due to unavailability of ONS mortality data.

## **Statistical analysis**

Patient characteristics are summarised as frequency (%), mean (standard deviation (sd)) or median (interquartile range (IQR)) as appropriate. Multivariable log-binomial regression was used to assess the association between guideline adherence and outcomes. This approach was used to estimate risk ratios rather than odds ratios due to the large baseline rate. Patient characteristics and hospital structural variables were included in the models to adjust for case mix. Results are presented as adjusted risk ratios (ARR) with 95% confidence intervals (95% CI). Kaplan-Meier plots are used to show cumulative readmission rates. A funnel plot is used to illustrate the extent of variation in the proportion of patients receiving early definitive treatment across trusts. The funnel plot was generated using two-sided control limits defining differences corresponding to two standard deviations (inner limits ) and three standard deviations (outer limits) from the national average. Low volume trusts (<15 patients admitted for GSP) were excluded from the funnel plot. Scatter plots are also presented to illustrate the association between the proportion receiving early definitive treatment and key patient outcomes at trust level.

Prior to the regression analysis we used multiple imputation by chained equations <sup>28</sup> to deal with any missing values of case-mix factors (age,

deprivation, ethnicity and trust cholecystectomy volume). Missing values were replaced with 10 sets of plausible values. Rubin's rules were used to combine estimates and obtain overall adjusted odds ratios <sup>29</sup>.

## **RESULTS**

### **Participants**

21,850 patients were identified as having had an emergency admission for acute gallstone pancreatitis between April 2008 and March 2011 in NHS Hospitals in England. The following patient records were consecutively deleted: 133 were aged 17 or less; 883 patients had either a previous diagnosis of acute pancreatitis or had operative fields with codes for Cholecystectomy or Endoscopic Sphincterotomy in the 12 months preceding the identified emergency admission with acute GSP termed 'index admission'; 70 records were excluded due to missing or incorrectly coded data preventing determination of an accurate discharge date from the index admission. A further 1,254 were excluded if they had died or had had a critical care episode on their index admission. Of these patients 286 had had a critical care episode only, 850 died without a critical care episode while 118 died and had a critical care episode. Of the 1,254 excluded 250 (20.0%) had undergone definitive treatment with a cholecystectomy, ES or both whilst in hospital. .

This left 19,510 patients who met the study criteria and were included in the analysis. 6,733 patients received definitive treatment (either a cholecystectomy or an Endoscopic Sphincterotomy) within two weeks of admission (i.e. guideline adherent treatment) while 12,777 patients either had no treatment or treatment after two weeks (Figure 1). Patient characteristics in each of the analysis groups are presented in Table 1.



## **Treatment patterns**

Figure 2 shows the cumulative pattern of patients receiving definitive treatment on index admission and during the year following. Definitive treatment was undertaken on 5,553 (28.5%) patients during the index admission. Of these, 2,168 had a cholecystectomy, 3,111 had an Endoscopic Sphincterotomy and 274 had both procedures; 13,957 were discharged without any treatment. In the first two weeks post discharge, a further 1,180 patients (6.0%) went on to have definitive treatment: 386 ES alone, 794 cholecystectomy alone; none had both.

By the end of the follow up period (one year), a total of 14,474 (74.2%) patients had received definitive treatment. 9,249 (47.4%) had a cholecystectomy alone, 2,572 (13.2%) an ES alone and 2,653 (13.6%) had both procedures. 5,036 (25.8%) patients had no definitive treatment by the end of the follow up period.

## **Variation in early definitive treatment between Trusts**

151 trusts were identified which treated patients with acute GSP across all three years. To minimise errors arising from miscoding, 5 of these trusts were excluded from the analysis as they had fewer than 15 admissions over the study period these 146 trusts that were included.

The proportions of patients receiving early definitive treatment varied substantially between trusts, ranging from 9.4 % to 84.7% (mean 34.7%; Figure 3). In twenty one hospital trusts (14.4%), fewer than 1 in 5 patients presenting with acute gallstone pancreatitis received definitive treatment for gallstones within a fortnight of discharge.

## **Impact of early definitive treatment on patient outcome**

Table 2 summarises the association between early definitive treatment and key patient outcomes.

### Emergency Readmissions

In the one year follow up period 4,661 (23.9%) patients had one or more emergency readmissions for GSP related complications. Of these 2,692 (57.2%) were admissions for acute pancreatitis. Of the 2,692 patients readmitted with acute pancreatitis, 33.8% occurred within the first 2 weeks of discharge, with the remaining 66.2% occurred after the point at which they should have received definitive treatment. Those receiving early definitive treatment had a lower estimated risk of readmission except for a brief period at the very start of the follow-up after discharge, as shown in the Kaplan-Meier plot (Figure 4). Early definitive treatment was associated with a 39% reduction in readmission rate (ARR: 0.61 95% CI 0.58 - 0.65). The risk was further reduced for acute pancreatitis readmissions to 54% (ARR: 0.46, 95% CI 0.42 - 0.51)

Readmission rate was highest in the first 30 days for both groups. Multivariable analysis showed that patients receiving early definitive treatment were 15% less likely to be readmitted as an emergency within 30-days (ARR 0.85 95% CI 0.78 - 0.92) as well as 39% less likely to have an emergency readmission by 90 days (ARR: 0.61 95% CI 0.59 - 0.65). Readmission associated mortality

Of the 4,661 patients having an emergency readmission, 162 (3.5%) died in the same admission. 29 of those patients were in the EDT group; the remaining 133 patients were in the non EDT group.

### **Association between early definitive treatment rates and outcome rates at Trust level.**

Figure 5 shows the relationship between early definitive treatment rates and readmission rates at Trust level. All show a statistically significant ( $p < 0.001$ ) negative association with correlation coefficients -0.44, -0.53,

-0.57 and -0.56 for 30-day, 90-day, 1 year and AP readmission rates respectively.

### **Relationship between structural aspects of Trusts to early definitive treatment rates**

Patients were 36% more likely to receive early definitive treatment if they were treated within a trust with a specialist HPB centre (ARR: 1.36 95% CI 1.30 - 1.42). Trusts which performed high volumes of cholecystectomies each year were also significantly more likely to treat patients within two weeks.

## **DISCUSSION**

The results of this study give substantial support for the use of early definitive treatment of gallstones following an episode of acute GSP (and hence adherence to the BSG guidelines. After adjusting for available case-mix factors, patients who did not receive early definitive treatment were significantly more likely to be readmitted to hospital. The study also indicates that the rate of early definitive treatment for gallstones following an attack of acute GSP is a potentially valid quality of care measure. Firstly, the early definitive treatment rate has proved to be measurable on a national scale using routinely collected data. Secondly we have demonstrated variation in practice at Trust level. We have also shown that early definitive treatment is independently associated with improvements in patient outcomes.

### **Relationship between early definitive treatment and outcome**

Early definitive treatment significantly improved all patient outcomes considered in this study. Disease specific readmission rates demonstrated a significant difference between patients who received early definitive

treatment and those who did not (7.8% and 17.0% respectively). This is an association seen in other studies with index treatment readmission rates of 1.7% and 5.3% increasing to 13.2% <sup>30</sup> in those not treated on index admission, and a similar reduction in rates seen in those treated within 4 weeks 6% and after 4 weeks 21% <sup>31</sup>. The overall readmission rates are higher as they take into account readmissions with other biliary conditions. Readmissions are of particular importance in this study as the primary aim of treatment is to prevent further attacks of acute pancreatitis and the resulting morbidity and mortality. The separate acute pancreatitis readmissions rate was useful to demonstrate the burden of readmissions for this specific reason. The reduction in readmission rates also has implications for potential cost saving as well as reducing patient morbidity. Several studies have found earlier treatment could be potentially cost neutral <sup>19,32</sup>.

## **Variation between Trusts**

Despite the strong evidence for early definitive treatment, this study has demonstrated wide variation between Trusts across England in this (and hence adherence to the BSG guidelines). Prospective audits in different UK centres have previously documented early definitive treatment rates ranging from 33% <sup>33</sup> to 89.6% <sup>34</sup> with one audit finding only 44.7% of patients had received definitive treatment by 8 months <sup>35</sup>. Concerns regarding feasibility of early definitive treatment in District General Hospitals in particular have been raised in several studies "owing to limited capacity on emergency theatre lists, which are often shared with other specialties" <sup>36,37</sup>.

This study, making novel use of HES to examine the link between early definitive treatment and hospital structure, on the one hand provides further evidence for such concerns, with patients being significantly more

likely to receive early definitive treatment if they were treated in a trust with an HPB specialist centre or a hospital with a high annual cholecystectomy volume. This may be due to lack of access to the required specialist expertise such as surgeons trained in acute gallbladder surgery or ERCP. On the other hand, this study illustrates an opportunity for service improvement as trusts of whatever size or specialist status can show improved outcomes if they improve their rate of early definitive treatment.

A range of novel solutions will therefore need to be found to reduce the wide variation in early definitive treatment found here. In particular, smaller hospitals with more limited theatre capacity and expertise in acute biliary surgery may need to work with adjacent trusts to help provide a more optimum level of service. One model may involve HPB emergency services working on a hub-and-spoke model, with the smaller hospitals working in partnership with their local centre, much as they do with HPB and oesophago-gastric cancer work and cardiac and neurosurgery. Such arrangements may be challenging, particularly given the implications for Trust remuneration. Currently trusts are paid for each operation they perform and smaller trusts would therefore be penalised if the operation was performed acutely elsewhere, rather than in the admitting trust at a later date. The overall cost to the system would however decrease due to the reduced costs from readmissions. Although challenging, these arrangements may be necessary for patients not to be disadvantaged by their lack of proximity to a HPB centre and to ensure optimum resource usage across the public health system. Another potential solution could be the use of specific care pathways, which, in some district hospitals and smaller non-specialist trusts, have led to higher rates of early definitive treatment <sup>38,39</sup>.

## **Rates of early definitive treatment as a quality indicator**

Quality indicators need to satisfy multiple criteria: it needs to be acceptable and feasible to measure; clinically important and relevant to current practice; have a robust evidence base that links the indicator to improved patient outcomes and care and be sensitive to change <sup>23,40-42</sup>. We have shown firstly that the rate of early definitive treatment is easily measurable using existing administrative datasets. Although HES is UK specific, other countries or organisations have similar datasets (often, like HES, originally designed for the purpose of re-imbursement) in which this indicator would be equally measurable.

Secondly, the observed variation implies although does not directly indicate in itself that the rate is likely to be modifiable, either by local services themselves or through improved collaboration between trusts. An advantage of process over outcome indicators is that they act not only as a measure but as a strategy for improvement in themselves, pointing directly to what services need to do to improve care. This is in contrast to outcome indicators, which are often less sensitive and multi-factorial, meaning that a trust with poor performance may well not know what they need to do to improve.

Finally, as discussed above, we have highlighted previous studies that demonstrate a robust evidence base linking early definitive treatment to improved patient outcomes. The rate of early definitive treatment for gallstones in acute gallstone pancreatitis therefore satisfies the criteria necessary for a potentially effective quality indicator.

## **LIMITATIONS**

Several limitations of study design, data and analysis need to be considered in interpreting these results. Firstly, distinguishing patients

with severe pancreatitis from milder cases was difficult as calculating severity requires detailed clinical information not included in the HES data. Severe pancreatitis has a higher morbidity and mortality and requires different management strategies to milder cases. To try and mitigate for this, patients not surviving to initial discharge or who had an episode of critical care in their index admission were excluded. Another limitation is that we were unable to estimate the association between early definitive treatment and mortality because Office of National Statistics mortality data was unavailable.

A limitation of our estimate of hospital mortality after emergency readmission is the absence of cause of death data in HES. Thus the observed reductions in hospital mortality in the early definitive treatment group, by avoidance of recurrent pancreatitis, is difficult to attribute to the early definitive treatment itself; we can only state the association, not conclude causality. The cause of death may have been helpful in determining those deaths attributable to an attack of pancreatitis. However, studies have found incidence of major error rates (wrong cause or manner of death) in death certification ranges from 10% <sup>43</sup> to 34% <sup>44</sup>, meaning accuracy still could not be guaranteed. In addition the cause of death, primary or otherwise, may not have been recorded as pancreatitis itself.

A large proportion of patients 5036 (25.8%) did not receive definitive treatment within one year. We are unable to determine whether these patients nonsurgical treatment was appropriate or not. Half of these patients had a Charlson comorbidity score of zero; indicating low surgical risk and providing some evidence against the argument these patients were too unfit for surgery. Further studies are required to better establish what factors are influencing a non-surgical management approach.

Finally, any study involving a large database is dependent on the quality of the data contained in it. The reliability and validity of HES data has been studied both in relation to missing data and coding errors. Studies have found HES data contains coding accuracy of 91% <sup>45</sup>, although this varies depending on the field studied. Importantly for this study fields relating to admission and discharge have improved substantially from 73.8% to 96.0%, with this increase being associated with the implementation of payment by results <sup>46</sup>. We cannot, however, exclude the possibility that the results may have been influenced by coding errors.

## **SUMMARY**

This study has demonstrated a strong case for the rate of early definitive treatment a quality indicator in the surgical management of patients suffering from acute GSP. We have shown that it is measurable using existing routinely collected data, that it has a direct impact on patient's health and outcomes and that it varies widely in English NHS services. It is also likely to be modifiable by the services involved or through improved collaboration between providers (although our data cannot demonstrate this directly). We therefore recommend its use in developing future quality assessment and improvement processes.

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**Contributorship:** TP conceived of the study. RG designed the research study, performed the research, analysed the data and wrote the paper. SC provided statistical expertise and conducted some of the statistical analysis. TP and SC critically revised the paper.



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