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Original research

Outpatient management of biliary colic: A prospective observational study of prescribing habits and analgesia effectiveness☆

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ABSTRACT

Background: Uncomplicated biliary colic presents a significant health and financial burden to hospitals and primary care services alike. There is little guidance on the correct analgesia to use on an outpatient basis. This study aimed to evaluate the effectiveness of oral analgesics on biliary colic pain and to explore the prescribing habits of community doctors.
Methods: Consecutive patients with ultrasound proven symptomatic gallstones completed a questionnaire recording demographics and symptomatology. Pain was assessed using a visual analogue scale (VAS) based on the Biliary Symptom Score (BSS) to evaluate the effectiveness of various analgesic agents. Local General Practitioners were also surveyed to establish prescribing practices.
Results: Co-Codamol had the highest mean effectiveness VAS score (6.5/10). Patients with increased BMI, short symptom duration and a BSS >70 were most likely to suffer from severe pain. Patients in a subgroup with severe pain were most likely to have their pain reduced by NSAID analgesia compared to no NSAID (OR 2.20, $p = 0.027$). This effect remained significant upon multivariable regression (OR 2.52, $p = 0.018$) in a model containing age and NSAIDs. There was wide variation in the prescribing practice of GPs and hospital doctors.
Conclusions: The range of drugs prescribed for biliary colic is extensive with little evidence base. In this study NSAIDs were the most effective analgesia for patients with severe pain. In the absence of contraindications to their use, physician education or guidance emphasizing the benefits of NSAIDs may potentially reduce symptomatic hospital presentation and admissions for biliary colic.

1. Introduction

Biliary colic (BC) is the term used for gallbladder (GB) pain experienced by patients without overt infection around the gallbladder. The pain is located in the epigastrium or right upper quadrant of the abdomen and is typically colicky in nature due to muscular spasm of the GB wall secondary to outflow tract obstruction.[1] BC affects 1–4% of the adult population known to suffer with cholelithiasis (gallstones) and is the most common presenting symptom.[2]

In the United Kingdom (UK) episodes of BC are usually managed with oral analgesia at home and settle spontaneously. However, referral or self-presentation to hospital is often required if there is diagnostic uncertainty or severe pain uncontrolled by available analgesia. When a patient presents with biliary colic the most important immediate step is adequate symptom control including appropriate analgesia. There is good evidence for administration of NSAID analgesia for patients presenting to the Emergency Department with acute biliary colic.[2,3] It is less clear what analgesia these patients should be prescribed for outpatient management of their pain.

Where patient preference and general health permit surgery, the gold standard treatment for biliary colic and gallstones is laparoscopic cholecystectomy (LC). In the UK the timing of LC varies according to patient choice, waiting list length and local hospital policy. Current practice is divided between centres providing 'hot' gallbladder services involving LC during the index admission and those who schedule an elective interval LC. Both clinical and economic aspects of these approaches have been examined previously

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and remain under consideration.[4–7] Currently, there is a lack of clear guidelines recommending one option over the other. Thus many patients are discharged to manage symptomatic disease in the community while awaiting interval surgery or in preference to surgery. This results in a significant number of subsequent hospital admissions for patients with recurrent biliary colic, unable to control their pain with oral analgesia. These admissions present an additional healthcare burden; in the National Health Service (NHS) there were 105,910 hospital admissions for cholelithiasis in 2010–2011.[8]

There is a paucity of guidance in the published literature regarding the relative efficacy of analgesic regimes patients receive on discharge with the existing literature largely relating to inpatient or emergency department treatment.[9,10] Consequently, patients who present to their community General Practitioner (GP) rather than a hospital are given analgesia according to anecdotal factors such as personal preference or previous experience rather than evidence based practice.

This study investigated the relative patient-reported effectiveness of different analgesia regimes for outpatient management of BC and compared these to current community physician (General Practitioner) and hospital doctor prescribing practice.

2. Methods

2.1. Patients and setting

University Hospital of Coventry & Warwickshire is a large teaching hospital and tertiary referral centre offering a full range of general surgery services. Over an 8-month period, consecutive patients booked for laparoscopic cholecystectomy were included in the study and filled out a questionnaire during their pre-operative clinic appointment. Each patient had the presence of gallstones confirmed by ultrasonography. This study was undertaken as part of an audit of service in the general surgery unit. Clinical audit approval was granted by the hospital's Quality & Effectiveness Department.

2.2. Patient questionnaire

The authors formulated a questionnaire based on the information required to calculate the Biliary Symptom Score (BSS).[11] Several iterations of this were trialed prior to a final version. Repeated practice meetings were held to ensure a consistent approach to data collection by the researchers. The questionnaire recorded information regarding both prescribed and over the counter medications and did not discriminate between them. Patients were asked to rate, on a visual analogue scale (VAS),[12] the severity of their pain with 0 rating as 'no pain' and 10 as 'severe pain'. VAS were also used to assess the subjective effect of the analgesic at reducing pain with 0 rating as 'no effect' and 10 as 'no pain'.[13] The questionnaire was non-mandatory and completion was taken as consent to participate. The questionnaire can be seen in Appendix 1.

In addition to the patient questionnaire general practitioners (GPs) from the local area were surveyed. All participants were asked to return an answer to each of the questions outlined below on a private digital keypad during an HPB surgery teaching session:

1. "Your patient has gallstones, what do you prescribe for future biliary colic attacks?"
2. "The patient returns asking for stronger analgesia, now what do you prescribe?"

The options given to the GPs were "Nothing, Buscopan, Codeine, NSAID, Pethidine tablets, Oramorph, Something else or Don't know." Answers were returned using digital keypads ensuring privacy.

2.3. Inclusion and exclusion criteria

Patients included were adults with a diagnosis of biliary colic undergoing elective laparoscopic cholecystectomy following ultrasound confirmation of gallstones within their gallbladder. Patients were excluded from the study if they were unable to remember the dosages of analgesia they were taking and this information could not be retrieved from the electronic discharge summary. Any medication that could not be administered orally was excluded from the study.

2.4. Data analysis

A previously reported Biliary Symptom Score[11] was calculated for patients based on their questionnaire responses. Patient characteristics were compared using the Chi-squared test. Patients were divided into subgroups according to the severity of their pain on presentation (a VAS score of >7 was considered to be severe pain). A significant reduction in pain was defined as a reduction of $\geq 50\%$ of the post-analgesia VAS compared to the presenting VAS.

Univariate and multivariate logistic binary regression models were built to determine predictors of significant pain reduction. An odds ratio (OR) and corresponding 95% confidence interval (CI) which were greater than 1.0 indicate an increased association of the predictor variable (e.g. analgesic use) with the outcome (significant pain reduction), indicating a useful outcome. Variables which carried a significance of $p < 0.1$ at univariable level were entered into a multivariable model, and were selected using a forward stepwise process and if their p-value remained <0.05.

Data were collected and entered into Microsoft Excel 2011 (Microsoft Corporation, Redmond, USA) for descriptive analysis. Data were analysed using SPSS 18.0 (SPSS Inc, Chicago, Illinois). Financial conversions from £GBP to $USD and €Euro are based on prevailing market rates on 22nd July 2013 using the UK Forex exchange rate, rounded to the nearest whole unit of currency.

3. Results

3.1. Demographics

A total of 210 consecutive patients were asked to complete the questionnaire, 7 patients were unable to remember the name or dose of analgesia they were taking and were therefore excluded leaving 203 patients in the study. Of these 155 (76%) were female and 48 (24%) were male. Almost half ($n = 97$ patients, [48%]) of the patients were >50-years-old with 71 (35%) being 30–50-years-old and 35 (17%) being 18–30-years-old (see Table 1). Ethnicity of patients was recorded with 171 (84%) classifying themselves as white

Table 1
A summary of basic patient demographics.

	Male	Female	Total
n total	48 (24%)	155 (76%)	203
n 18–30 years	2 (6%)	33 (94%)	35 (17%)
n 31–50 years	14 (20%)	57 (80%)	71 (35%)
n 50 + years	31 (32%)	66 (68%)	97 (48%)
Mean BMI	28.16	28.96	28.56
On pre-existing analgesia	9 (28%)	23 (72%)	32 (16%)