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National complicated acute diverticulitis (CADS) study: a protocol for a prospective observational scoping study for acute diverticulitis

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ABSTRACT

Background: Diverticular disease is a widely prevalent disease in western society, and acute diverticulitis is a common acute surgical presentation. However, there is a lack of level 1 evidence addressing the multifaceted presentations associated with acute diverticulitis. There is also a lack of robust epidemiological data that could be used to meaningfully inform randomised controlled trials. The National CADS project aims to generate baseline data for a cohort of patients managed for clinically suspected acute diverticulitis and evaluate the impact of variability in the management approach on patient outcomes in the short (3 months) and long (2 years) term.

Method: A Unit policy questionnaire will be completed by the principal investigator from all participating centres prior to study initiation. All patients aged above 18 years admitted with clinical suspicion of acute diverticulitis will be included from UK hospitals providing acute surgical care. Demographic, clinical, inpatient stay and outpatient follow-up data will be collected for index admissions between July and September 2014, 3 months follow-up and finally a 2-year follow-up.

Results: The study attracted participation from 108 centres nationally and has so far generated data on 2500 patients admitted between 1 July 2014 and 30 September 2014. Short-term follow-up data have been obtained for this cohort.

Conclusions: The National CADS study is currently ongoing with the long-term outcomes data anticipated to be submitted in autumn of 2016.

INTRODUCTION

Diverticular disease, as defined by the presence of diverticula along the colon, is widespread in the ageing western population and predominantly so along the left colon.[1] Its aetiology is unclear, presentation is varied and prognosis diverse. The generally accepted risk factors are advancing age, low-fibre diet and long-standing constipation. By itself, diverticular disease is asymptomatic. Inflammation within the diverticula can result in diverticulitis which usually presents with abdominal pain and tenderness sometimes accompanied with dark-coloured rectal bleeding. The more serious sequelae include formation of a diverticular abscess, perforation causing faecal peritonitis or formation of colovesical/colovaginal fistulae.[2]

While the management of uncomplicated diverticulitis is achievable within the community,[3] a certain proportion of patients are unfortunate enough to develop severe diverticulitis and require hospital admission and a more aggressive management approach.

Acute diverticulitis forms a common general surgical emergency workload. There are, however, gross inconsistencies in treatment strategies across centres within the UK and often even policies within general surgical units vary from consultant to consultant. The reasons for this are poorly understood and despite the commonness of this condition, anecdotal evidence reigns supreme in its management.[4–6]

Complicating the situation further is the progressively increasing presentation of younger and younger patients with complicated acute diverticulitis.[7] It is not difficult to imagine how each of the approaches alluded to above could be a dilemma in themselves when faced with patients sometimes as young as in their 20s.[8 9]

Rationale for study

Exploring the literature reveals numerous studies looking into various aspects of diverticulitis. Good-quality randomised controlled trials are few and their patient numbers are small.[10–16] The latest published review by McDermott *et al*[17] looking into laparoscopic and open management in diverticulitis, found trials with a cumulative of only 800 patients worldwide managed laparoscopically, has concluded that more data are needed.

This sets the scene for defining the existing trends and variability in approach within the UK. An evaluation of existing practice and related outcomes would enable identification of true issues, define the baseline and most importantly, aid formulation of appropriate research questions for future studies based on concrete data.

Study question

'Is there variability in the management of acute diverticulitis between centres and how is this related to patient outcome in the short and long term?'.

Study design

Multicentre prospective observational study.

Objectives

To define

1. Management trends across centres
2. Regional variations
3. Short-term outcomes
   - Conservative management
   - Stoma rate
   - Operative intervention
   - Minimally invasive intervention
   - ITU admission
   - Thirty-day mortality
   - Elective resection
   - Readmission rate
   - Restoration of bowel continuity
4. Long-term outcomes
   - Elective/emergency operative intervention
   - Stoma rate
   - Mortality
   - Readmission rate
   - Restoration of bowel continuity
5. Parameters for future trials/interventional studies

METHODS

Any UK-based centre providing acute general surgical inpatient service is eligible. Each centre must nominate a consultant surgeon as principal investigator (PI) who would support the smooth conduct of the study in that centre. The PI would also take responsibility of providing follow-up data at 3 months and nominate juniors as appropriate to collect these data as trainees would have moved on by this time. Preferably, a team of junior doctors involving registrars and SHOs should be recruited to collect data. The study will run over the period of 3 months and it should be ensured that a member from the team is able to collect data every day to avoid missing patients out. It is advisable that within each region, registrars form a network and pick up the project to the centre they would move to after the changeover in August/October 2014.

Each high-volume centre must provide at least 15 patients within the 3-month period with follow-up data to be eligible for inclusion in the analysis stage. Refer to the Expected recruitment section for more details. After considering the feedback from the consultation phase, the minimum patients provided by smaller/rural centres has been relaxed to 5 as these centres form an important component of the study question and their participation is thus highly desired.

Prior to the initiation of the study, an anonymised questionnaire would be sent out to all PIs evaluating the unit policies with regard to the management of diverticulitis. This is only for purposes of comparing approaches with outcomes and individual surgeons or units will not be identifiable in the analysis of results.

Patient eligibility

Inclusion criteria

All patients aged 18 years or above admitted acutely with 'clinically suspected acute diverticulitis' and/or 'radiologically confirmed acute diverticulitis'. Patients discharged within 24 hours of admission without any investigations, radiological or otherwise, should also be included. Patients with a subsequent radiological (or endoscopic) diagnosis of diverticulitis or related complications during the course of their index admission should also be included even if the initial working diagnosis was otherwise.

Exclusion criteria

Patients admitted without an initial clinical suspicion of diverticulitis and happen to have diverticular disease as a comorbidity. Which means, for example, they were admitted with large bowel obstruction and CT revealed diverticular disease but NO acute diverticulitis, then such patients are to be excluded since their reason for admission was unrelated to acute diverticulitis. Thus, a diagnosis of incidental diverticular disease unrelated to current presenting illness has to be excluded because clearly such a patient is not presenting with complicated diverticulitis but with just incidental diverticular disease.

Study period

Phase I

Data collection will start on 1 July 2014 from 08:00 hours and cease on 30 September 2014 at 17:00 hours.

Phase II

Follow-up data will be obtained for all patients in the month of January 2015 as this will be at least 3 months follow-up for the last patient from 30 September 2014.

Phase III

Follow-up data will be obtained for all patients in the month of October 2016 as this will be at least 2 years follow-up for the last patient from 30 September 2014.

Mode of data collection

All data must be entered in the secure online database using the provided access details only. Any hard copies

of data must either be destroyed or kept safely until the data have been uploaded on the database.

For the purposes of follow-up, names and hospital numbers must be kept locally on the secure, password protected excel database. The local data protection is the responsibility of the local audit team.

Each centre would be allocated a unique centre ID, which should be used to allocate study IDs to each patient. An excel sheet will be provided where patient study IDs and their hospital unit numbers could be stored to enable retrieval of follow-up data. These excel sheets should only be saved responsibly on secure networks and desktops as per individual trust's data protection policy. On completion of phase I, the excel sheets should be emailed to our team on our email ID info@cadsaudit.org.uk. We could then send reminders nearer the time for phase II and also save these as backup copies if needed.

Expected recruitment

As per the HES data for 2012/2013, the total number of hospital admissions for 'acute diverticulitis' were 277 773 which is in excess of 27 000/month nationally. Similarly, the number of admissions for 'perforated diverticulitis' was 8994 which is around 750/month nationally. It is anticipated that each centre would have at least 1 patient/week and at most 5–7 patients/week. Thus, over a 3-month period, it should not be difficult to get 15 patients per centre for most urban centres.

Outcome measures

Primary

All-cause 30-day mortality will be the primary outcome measure based on the rationale that a variation in management approach would have an impact on mortality.

Secondary

The following would be evaluated:

- Patient demographics
- Presenting symptoms
- Radiological classification of severity; Hinchey classification
- Open/laparoscopic operative intervention
- Radiological intervention
- Conservative management
- Multiplicity of interventions
- Stoma rate/restoration of bowel continuity
- ITU admission
- Length of index hospital admission
- Acute readmission
- Elective resection

CADS committee structure

The CADS Study group would be a corporate author in all publications/output and would comprise of the following.

Core committee

Chief Investigators (SS, Chris Macklin, David Jayne)

The responsibility and final authority with data handling, analysis and manuscript writing and submission will rest with the core committee. Any future work generated on the basis of this audit will also be under the initiative of the core committee.

Steering committee

YSRC—SS; Greg Taylor; Stephen Chapman.

National Surgical Research Collaborative: Represented by one contact from each regional collaborative. Refer to the contributorship statement for details.

All registered participants from registered centres. It is the responsibility of the PI to ensure that names of all members of their local team are communicated to us.

Dissemination

Participants may present their local data at their department audit/clinical governance meeting. National data shall be presented at a national conference and will be submitted for publication in a peer-reviewed journal.

Authorship

One trainee contact from each participating centre and PIs would be recognised as part of the steering group for the study. All other named local investigators from a centre would be recognised as citable authors in the manuscript. We recommend not more than four investigators in total per each centre which includes PI, lead trainee and up to two local investigators. As stated above, at least 15 patients must be submitted by each centre (at least 5 by small/rural centres) to be considered for the analysis and publication stage. A minimum of 10 cases must be submitted per each local investigator (this excludes PI and lead trainee), that is, a centre claiming three local investigators must submit at least 30 patients' data. There is no upper limit for patient numbers per authors and the lower limit is only to discourage unwarranted numbers of local investigators. A minimum of three centres must participate for the regional collaborative to be recognised.

Any publications/presentations arising out with the remit of the project must first obtain permission from the CADS Core Group. Such publications/presentations using the national data set must include members of the CADS Core group as named authors and the 'CADS Study group' as a corporate author. Publications using only local or part of the national data set must include members of the CADS Core group as named authors.

Disclaimer

The CADS core committee reserves the right to review and amend this protocol within reason during the course of the audit to enable delivery of the project to the highest standards.

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Contributors SS is responsible for concept, study design, conduct, manuscript writing, submission. DGJ is responsible for manuscript review, supervision. CM is responsible for manuscript review, web support. CADS study group is responsible for manuscript review, recruitment and data collection.

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