Clinical effectiveness and cost-effectiveness of emergency surgery for adult emergency hospital admissions with common acute gastrointestinal conditions: the ESORT study

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Scientific summary

The ESORT study

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Scientific summary

Background

Patients with common acute gastrointestinal conditions who require emergency hospital admissions may receive emergency surgery (ES) or non-emergency surgery (NES) strategies, which include medical management, non-surgical procedures (e.g. radiological-guided drainage of abscess) or surgery deferred to the elective setting. For some common acute conditions, such as diverticular disease, there are well-developed NES strategies, and little evidence that ES leads to better outcomes. For other conditions, such as acute cholelithiasis, randomised controlled trials (RCTs) have found that NES strategies may have unintended consequences, with patients having recurrent symptoms and delayed surgery, therefore, leading to further pressure on surgical waiting lists. However, to the best of our knowledge, none of these RCTs have included routine emergency admissions to hospitals. Hence, for many patients with common conditions, the relative benefits and costs of ES compared with NES strategies are unknown, and there is wide variation across NHS hospital trusts in ES rates and outcomes.

To provide evidence to inform future service provision, this observational study evaluates the relative effectiveness and costs of ES compared with NES strategies for common acute conditions.

Aims and objectives

The study's aim was to evaluate the clinical effectiveness and cost-effectiveness of ES compared with NES strategies for adults admitted as emergencies for five common gastrointestinal conditions. Our objectives were to evaluate the:

1. clinical effectiveness of ES compared with NES strategies for the five selected acute gastrointestinal conditions
2. relative cost-effectiveness of ES compared with NES strategies for the five conditions
3. clinical effectiveness and cost-effectiveness of ES compared with NES strategies for specific patient subgroups.

Methods

Overview

The Emergency Surgery OR noT (ESORT) study assessed the clinical effectiveness and cost-effectiveness of ES compared with NES strategies for adults with common acute gastrointestinal conditions who presented as emergency admissions to NHS hospitals in England. The target population included adults admitted as emergencies with acute appendicitis, cholelithiasis, diverticular disease, an abdominal wall hernia or an intestinal obstruction. We included these five acute conditions because there is clinical uncertainty about the relative benefits of ES compared with NES strategies, and wide variation in ES rates across NHS hospitals. We defined the target population and comparator strategies from emergency admissions within a single data source [i.e. Hospital Episode Statistics (HES)] to ensure consistent definitions across the patient cohort. Eligibility was determined using *International Statistical Classification of Diseases and Related Health Problems*, Tenth Revision (ICD-10), diagnosis codes that were agreed by clinical panel consensus. We applied 'target trial' principles to define explicit eligibility criteria and the comparator strategies from HES data.

Ethics

The research was approved by the London School of Hygiene and Tropical Medicine Ethics Committee (reference 21687). The study involved the secondary analyses of existing pseudoanonymised data and did not require UK National Ethics Committee approval.

Data and study design

We collated information on diagnosis (ICD-10), case mix, surgical procedures received, resource use and outcomes, including all-cause mortality from HES data linked to Office for National Statistics (ONS) mortality data. The study addressed confounding by indication with an instrumental variable (IV) design, as this can provide accurate estimates of treatment effectiveness and cost-effectiveness even when there are unmeasured differences between the groups being compared. 'Tendency to operate' (TTO) was used as the IV, which was previously validated for evaluating the clinical effectiveness of ES in the USA. The IV in the ESORT study was defined as each hospital's propensity to use ES and NES strategies for each of the acute conditions. The rationale for the IV was that patients of similar prognosis were more likely to receive ES in some hospitals, and NES strategies in others. The ESORT study assessed whether or not the TTO met the two requisite conditions for an IV, that is (1) that the hospital's TTO was associated with having ES and (2) that the TTO was not related to outcomes, except through the receipt of ES.

Definitions of cohorts, and emergency surgery and non-emergency surgery strategies

The target populations included hospital admissions for patients aged $\geq$ 18 years that (1) occurred between 1 April 2010 and 31 December 2019; (2) included a main diagnosis with a relevant ICD-10 diagnosis code, or for the intestinal obstruction cohort a relevant diagnosis in the second diagnosis field if the main diagnosis was colorectal cancer; (3) was within an emergency admission through the emergency department or from a primary care referral; (4) was under a consultant general surgeon, subspecialty general surgeon or any other surgeon working in the general surgery specialty; and (5) was the first or second episode within the admission. Admissions for which there was a prior emergency admission with a relevant diagnosis in the previous 12 months were excluded.

Emergency surgery was defined from a list of Office of Population Censuses and Surveys codes and had to be within a maximum time window, which was defined by the consensus of the clinical panel. The maximum time windows were within 3 days for a hernia, within 7 days for appendicitis, cholelithiasis or a intestinal obstruction, or any time within the emergency admission for diverticular disease. The NES strategy included antibiotic therapy, non-operative procedures, including interventional radiology, and operative procedures that did not meet the ES criteria.

Data on patient characteristics were extracted from HES and used to define prespecified subgroups, including age (years), number of comorbidities (using the Charlson Comorbidity Index) and frailty [according to the Secondary Care Administrative Records Frailty (SCARF) index]. The SCARF index is based on the concept of frailty as an accumulation of deficits. The SCARF index uses 32 deficits, with each one defined from ICD-10 codes.

Outcomes

The primary outcome measure was the number of days alive and out of hospital (DAOH) at 90 days. The DAOH is a composite measure, which encompasses mortality and total length of hospital stay (LOS), including re-admissions. The DAOH has been previously validated as an outcome following surgery, and its choice was supported by the study's panel of ex-patients and public contributors. The calculation of DAOH used HES data on the total duration of hospitalisation over the 90-day period, and the date of death from linkage to the ONS death record. The sample size for each condition was projected to be sufficient to assess overall differences between the comparison groups in the mean DAOH of at least 1 day, with 80% power and 95% levels of statistical significance. The secondary outcomes were the two aspects of DAOH: (1) 90-day mortality and LOS and (2) any emergency re-admission within 30 days.

Analysis

For each qualifying emergency admission, the TTO was calculated as the proportion of patients admitted as eligible emergency admissions in that specific hospital who received ES in the previous 12 months, therefore, suggesting that the hospital's past preference for ES strongly predicts treatment choice for the current patient. The IV was used to address confounding in estimating the relative effectiveness of ES compared with NES strategies for the overall cohort and for the above prespecified subgroup variables. To further support the conditions underlying the IV, the analysis adjusted for the covariates described above, together with the time period and proxies for the quality of acute care in each hospital.

The sensitivity analyses assessed whether or not the results were robust to alternative assumptions, including different definitions of ES and the quality of acute care, and the use of regression adjustment, which assumed that there were no unmeasured confounders, rather than the IV approach.

Cost-effectiveness analysis

The cost-effectiveness analysis (CEA) took an acute hospital perspective and included all inpatient costs up to 1 year. Information on individual-level resource use was extracted from the HES data and included the procedures received and the total hospital LOS, including critical care and re-admissions. Unit costs were taken from a literature review and the NHS Payment by Results database, and combined with resource use, to report total costs per patient up to 1 year. We reported quality-adjusted life-years (QALYs) up to 1 year by combining survival time with health-related quality-of-life (HRQoL) estimates from the literature.

We estimated the relative cost-effectiveness of ES compared with NES strategies for each of the five acute conditions for the overall cohort and for each of the prespecified subgroups, adjusting for confounding with the IV approach. The cost-effectiveness metric was the incremental net monetary benefit (INB) with incremental QALYs, defined as the difference in QALYs between ES and NES strategies, which were then valued at £20,000 per QALY. We tested whether or not the results were robust to alternative sources for the HRQoL estimates, to different time horizons (i.e. 5 years vs. 1 year) and to adjustment for confounding with regression instead of the IV approach.

Results

Cohorts and instrumental variable validity

Cohort sizes were as follows: 268,144 admissions with appendicitis, 240,977 admissions with cholelithiasis, 138,869 admissions with diverticular disease, 106,432 admissions with a hernia and 133,073 admissions with an intestinal obstruction. The proportions of patients who had ES were 92.3% of admissions with acute appendicitis, 21.6% of admissions with cholelithiasis, 11.4% of admissions with diverticular disease, 58.8% of admissions with an abdominal wall hernia and 30.5% of admissions with an intestinal obstruction. There was wide variation in ES rates across NHS hospitals. The greatest variation was for cholelithiasis, with a median ES rate across hospitals of 8.4% (minimum, 2.3%; maximum, 66.4%), followed by hernia (median, 59.8%; minimum, 30.8%; maximum, 79.2%) appendicitis (median, 93.0%; minimum, 67.5%; maximum, 98.6%), intestinal obstruction (median, 30.0%; minimum, 20.4%; maximum, 51.4%) and diverticular disease (median, 11.2%; minimum, 3.5%; maximum, 21.0%). For each acute condition, the hospital-level TTO was strongly correlated with ES receipt (i.e. IV condition 1). The TTO balanced the observed baseline covariates, which increased confidence that the IV also balanced unmeasured confounders (i.e. IV condition 2).

Overall clinical effectiveness and cost-effectiveness results

Overall, the average numbers of DAOH were similar following ES and NES strategies, with mean differences of −0.73 [95% confidence interval (CI) −2.10 to 0.64] days for appendicitis, 0.60 (95% CI −0.10 to 1.30) days for cholelithiasis, −2.66 (95% CI −15.7 to 10.4) days for diverticular disease,

−0.07 (95% CI −2.40 to 2.25) days for hernias and 3.32 (95% CI −3.13 to 9.76) days for intestinal obstructions, after adjusting for confounding. Overall all-cause mortality and LOS at 90 days, and average costs and QALYs at 1 year, were all similar following ES and NES strategies for each of the five acute conditions. The sensitivity analyses generally reported similar results to the base-case analyses, aside from the regression analyses, the results of which highlighted the importance of adjusting for unmeasured confounding with the IV approach.

Clinical effectiveness and cost-effectiveness by patient subgroup

The relative clinical effectiveness and cost-effectiveness of ES compared with NES strategies differed by subgroup according to levels of frailty and the number of comorbidities. For patients with severe frailty, the mean numbers of DAOH at 90 days were smaller following ES compared with NES strategies, with mean differences of −21.0 (95% CI −27.4 to −14.6) days for appendicitis,−5.72 (95% CI −11.3 to −0.2) days for cholelithiasis,−38.9 (95% CI −63.3 to −14.6) days for diverticular disease, −19.5 (95% CI −26.6 to −12.3) days for hernias and−34.5 (95% CI −46.7 to −22.4) days for intestinal obstructions. For patients with severe frailty, ES was less cost-effective than NES strategies, with INB estimates of −£18,727 (95% CI −£23,900 to −£13,600) for appendicitis, −£7700 (95% CI −£13,000 to −£2370) for cholelithiasis,−£9230 (95% CI −£24,300 to £5860) for diverticular disease, −£16,600 (95% CI −£21,100 to −£12,000) for hernias and−£19,300 (95% CI −£25,600 to −£13,000) for intestinal obstruction.

For patients who were categorised as 'fit' (i.e. without frailty) at presentation, mean numbers of DAOH were larger for ES than for NES strategies for diverticular disease (5.35, 95% CI −2.56 to 13.28 days), hernias (2.26, 95% CI 0.37 to 4.15 days) and intestinal obstruction (18.2, 95% CI 14.8 to 22.47 days), and were similar for appendicitis (−0.18, 95% CI −1.56 to 1.20 days) and cholelithiasis (0.93, 95% CI 0.48 to 1.39 days). ES was relatively cost-effective for patients who were fit, with estimated INBs of £5180 (95% CI £684 to £9,680) for diverticular disease, £2040 (95% CI £996 to £3090) for hernias, £7850 (95% CI £5020 to £10,700) for intestinal obstruction, £369 (95% CI −£728 to £1460) for appendicitis and £718 (95% CI £294 to £1140) for cholelithiasis.

For patients with two or more comorbidities, NES strategies were, on average, more cost-effective than ES for patients with acute appendicitis, cholelithiasis or a hernia, but ES was more cost-effective for patients with multiple comorbidities who had diverticular disease or intestinal obstruction.

Limitations

The IV approach reduced, but could not eliminate, the risk of confounding. HRQoL measures were not available from routine data sources. The costs of outpatient visits or of care home stays were not considered.

Conclusions

Implications for health care

- For patients presenting as emergency hospital admissions with common acute gastrointestinal conditions, the ES and NES strategies for the overall cohort led to similar average numbers of DAOH at 90 days, and similar average hospitalisation costs and QALYs at 1 year, after addressing confounding with the IV approach. The CEA did not provide strong evidence that either strategy was more cost-effective in the overall populations of patients with each of the five acute conditions.
- For patients with severe levels of frailty, NES strategies were relatively cost-effective for each of the five acute conditions. For patients who were fit, ES was, on average, more cost-effective than NES strategies for each condition.

- The evidence from the ESORT study supports ongoing national initiatives to encourage frailty assessment for patients with acute conditions as part of any preoperative assessment following emergency admission. Frailty assessment can help identify those patients who would benefit more from a NES strategy. For some patients, a NES strategy may include later planned surgery, which can enable a patient's long-term conditions to be optimised.
- The evidence from the ESORT study can help inform service providers, patient and carers about the relative benefits and risks of ES compared with NES strategies, recognising that these benefits and risks differ according to factors beyond the patients chronological age, including their frailty level and number of comorbidities.

Recommendations for further research

The following recommendations are listed in priority order:

- The ESORT study highlighted the importance of the appropriate choice of ES or NES strategy for patients with comorbidities, which includes patients with multiple long-term conditions. For patients with multiple long-term conditions, further research is required to assess the benefits and costs of prompt intervention with ES, compared with later surgery. Delaying surgery could help to 'optimise' the management of these patients by, for example, modifying concomitant medications.
- Future RCTs of ES compared with NES strategies are warranted, and may be most feasible and useful for some patients with an abdominal wall hernia, as this is the population for whom there appears clear equipoise between ES and NES strategies.
- Further research is required on patients' HRQoL following ES and NES strategies.
- Following the COVID-19 pandemic, in England, NHS waiting lists are projected to reach 13 million by 2025, with implications for hospitals' capacity for elective surgery and ES. Further research in other conditions would, therefore, be useful to identify which patient groups ES or NES strategies are clearly cost-effective. The approach taken in the ESORT study, that is, combining large-scale routine data with advanced analytical approaches to address confounding, could be extended to other acute conditions. This approach could identify patient groups for whom either 'early' or 'later' intervention is more cost-effective.

Study registration

This study is registered as reviewregistry784.

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