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Unintended consequences of policy change to watchful waiting for asymptomatic inguinal hernias

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ABSTRACT

INTRODUCTION In 2009 the Department of Health instructed McKinsey & Company to provide advice on how commissioners might achieve world class National Health Service productivity. Asymptomatic inguinal hernia repair was identified as a potentially cosmetic procedure, with limited clinical benefit. The Birmingham and Solihull primary care trust cluster introduced a policy of watchful waiting for asymptomatic inguinal hernia, which was implemented across the health economy in December 2010. This retrospective cohort study aimed to examine the effect of a change in clinical commissioning policy concerning elective surgical repair of asymptomatic inguinal hernias.

METHODS A total of 1,032 patients undergoing inguinal hernia repair in the 16 months after the policy change were compared with 978 patients in the 16 months before. The main outcome measure was relative proportion of emergency repair in groups before and after the policy change. Multivariate binary logistic regression was used to adjust the main outcome for age, sex and hernia type.

RESULTS The period after the policy change was associated with 59% higher odds of emergency repair (3.6% vs 5.5%, adjusted odds ratio [OR]: 1.59, 95% confidence interval [CI]: 1.03–2.47). In turn, emergency repair was associated with higher odds of adverse events (4.7% vs 18.5%, adjusted OR: 3.68, 95% CI: 2.04–6.63) and mortality (0.1% vs 5.4%, $p<0.001$, Fisher's exact test).

CONCLUSIONS Introduction of a watchful waiting policy for asymptomatic inguinal hernias was associated with a significant increase in need for emergency repair, which was in turn associated with an increased risk of adverse events. Current policies may be placing patients at risk.

KEYWORDS

Inguinal hernia – Emergency surgery – Commissioning – Guidelines

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Inguinal hernia repair is one of the most commonly performed surgical operations, at an estimated annual rate of over 70,000 in the UK and 20 million worldwide.[1–3] Conventional wisdom has been to arrange prompt surgical repair owing to the perceived risk of hernia related emergencies. Elective repair as a day procedure is an established, safe and effective treatment for uncomplicated hernia.[4] In contrast, emergency repair for incarcerated, obstructed or strangulated hernia can be associated with significant morbidity and even death. While the mortality rate following elective repair is less than 1%, it is over 5% in emergency repair.[5,6]

Two recent randomised controlled trials (RCTs), one from North America[7] and one from the UK,[8] have rekindled interest in non-operative management of asymptomatic or minimally symptomatic inguinal hernias, by comparing watchful waiting versus surgical repair. Both trials reported extremely low need for emergency repair in the observation arm.[7,8] Based on these two RCTs, watchful waiting has been recommended as the first-line treatment for asymptomatic inguinal hernias in guidelines published by the European Hernia Society.[9] However, the active follow-up provided in these trials may not reflect 'real world' practice. Crossover rates to surgery were high (23% and 29%),[7,8] which, paired with the low emergency intervention rate, we believe reflects the strict, active observation of a RCT. Such observation may not be possible in a 'real world' setting, which would rely on routine community-based patient–doctor interaction.

In 2009 the Department of Health instructed management consulting firm McKinsey & Company to provide advice on how commissioners might achieve world class National Health Service (NHS) productivity.[10] Asymptomatic inguinal, umbilical and femoral hernias were identified as interventions with limited clinical benefit that could be decommissioned to drive financial savings. Widespread policy changes were implemented by NHS clinical commissioners, who withdrew funding for elective repair of asymptomatic hernias. To date, as far as we are aware, no assessment of this policy change has been published. This

study aimed to describe how this change has manifested itself at a large NHS foundation trust.

Methods

This study was a retrospective analysis of patients at the Heart of England NHS Foundation Trust, one of the largest trusts in the UK, serving a population of over one million people. Permission to perform this study was granted from the hospital's clinical audit department.

Intervention

A policy of watchful waiting and prior approval for elective asymptomatic hernia repair, introduced by the Birmingham and Solihull primary care trust cluster,[11] was implemented in the trust in December 2010. The new policy supported surgical treatment for patients with symptomatic inguinal hernias, hernias not amenable to simple reduction or strangulated hernias. Based on the date of this policy change, patients were divided into two groups: those from the 16 months before implementation (1 August 2009 – 30 November 2010) and those from the 16 months after (1 December 2010 – 30 March 2012).

Outcome measures

The primary outcome measure was the relative proportion of emergency surgery before and after implementation of the new policy. The proportion of emergency surgery acts as a surrogate marker for worse outcome. Since the overall rate of adverse events is low, a more frequent proxy marker makes differences easier to show. The adverse event rate was therefore a secondary outcome measure, alongside postoperative mortality and length of stay.

Patients

Patients aged 18 years and older undergoing repair of unilateral or bilateral inguinal hernia during the study period were included. They were identified from the prospectively maintained hospital theatre database. Clinical data were obtained from discharge summaries, clinical letters and recorded inpatient episodes using the electronic integrated hospital information system.

Adverse events

Postoperative complications were classified according to the internationally standardised and validated Clavien–Dindo scoring system for postoperative complications.[12] In this classification, the factor determining the severity of the unexpected complication is the treatment required. Intraoperative complications are not considered, except intraoperative death (grade V). For this study, major complications were defined as grades III–IV, with grades I–II indicating a minor complication. All documented postoperative adverse events up to 30 days were included and the highest grade complication for each patient was recorded. Postoperative mortality was defined as death from any cause in the 30-day postoperative period.

Statistical analysis

Differences between demographic groups of categorical data were tested using the chi-squared test or Fisher's exact test as appropriate. In order to take account of the effect of confounding variables, binary logistic regression modelling was used. The first model assessed the likelihood of need for emergency surgery (with emergency surgery coded as '1'). The summary statistic was the odds ratio (OR), which was assumed to approximate the relative risk. An OR of >1.0 with a 95% confidence interval (CI) that did not cross 1.0 indicated a significantly higher association with the outcome of interest. Subsequent models were constructed using occurrence of any complication and major complications as a target. Mortality was not included as a specific target of regression analysis alone owing to its low occurrence. It was, however, included as an adverse event and compared using Fisher's exact test.

The age and sex of the patient, and the primary versus recurrent type of the inguinal hernia were judged *a priori* to be likely to be relevant to the rate of emergency presentation and adverse events. In order to prevent a loss of data associated with categorising age, it was maintained as a continuous variable and log transformed. As interpretation of log-transformed ORs are difficult owing to their magnitude, these values were transformed to allow the OR to relate to a 10% increase in age. Models were repeated using age as an unadjusted continuous variable to confirm validity.

These variables were included in multivariate binary logistic models based on their clinical importance (rather than reliance on their statistical importance in stepwise models, which can be misleading).[13] Interaction between categorical variables was tested sequentially and significant pairings were included in the model if they improved the Akaike information criterion (a measure of quality of model selection). Overall model performance was assessed using the C statistic as a measure of discrimination, which is equivalent to the area under the receiver operating characteristic curve for fitted values. Data handling was performed in SPSS® version 21.0 (IBM, New York, US) and statistical modelling in R statistical software version 3.0.0 (R Foundation for Statistical Computing, Vienna, Austria).

Results

Patient demographics and outcomes in the period before and after the policy change are shown in Table 1. Patient age, sex and hernia type were similar in both groups. The most common reason for emergency repair was incarceration (ie irreducibility without obstruction or strangulation, *n*=50, 54.3%), followed by acute pain (*n*=14, 15.2%), bowel obstruction (*n*=12, 13.0%) and strangulation (*n*=10, 10.9%). In six cases (6.5%), the indication was not recorded.

One hundred and seven patients (5.3%) suffered at least one recorded postoperative complication. This was associated with a minor complication rate of 4.4% (*n*=88) and a major complication rate of 0.9% (*n*=19).

Effect of policy change on presentation type

There was a crude relative increase of 52.8% in the rate of emergency repair (Table 1). When adjusted for age, sex and hernia type, policy change was associated with 59%

Table 1 Demographics and outcomes before and after policy change

		Before change	After change	*p*-value
Demographics				
Median age (IQR)		63.6 (48.6–74.1)	63.9 (49.0–74.7)	0.663
Sex	Male	917 (93.8%)	969 (93.9%)	
	Female	61 (6.2%)	63 (6.1%)	0.902
Type of hernia	Primary	872 (89.2%)	940 (91.1%)	
	Recurrent	106 (10.8%)	92 (8.9%)	0.148
Day case	Yes	712 (72.8%)	779 (75.5%)	
	No	266 (27.2%)	253 (24.5%)	0.170
Outcomes				
Presentation	Elective	943 (96.4%)	975 (94.5%)	
	Emergency	35 (3.6%)	57 (5.5%)	**0.037**
Any complication	No	933 (95.4%)	970 (94.0%)	
	Yes	45 (4.6%)	62 (6.0%)	0.160
Major complication	No	970 (99.2%)	1,021 (98.9%)	
	Yes	8 (0.8%)	11 (1.1%)	0.566
Postoperative death	No	976 (99.8%)	1,028 (99.6%)	
	Yes	2 (0.2%)	4 (0.4%)	0.688

IQR = interquartile range

higher odds of emergency repair (adjusted OR: 1.59, 95% CI: 1.03–2.47). Increasing age and female sex were significant predictors of the need for emergency repair in the multivariate model (Table 2). The C statistic of this model was 0.73 (95% CI: 0.68–0.79), indicating adequate discriminative value. When this model was repeated for men only, the effect of the time period after the policy change remained significant, with an increase in odds to 68% (adjusted OR: 1.68, 95% CI: 1.04–2.71, p=0.033). The unadjusted OR in men was 1.69 (95% CI: 1.05–2.72, p=0.030).

Effect of emergency surgery on adverse event rate

Emergency presentation was associated with a significantly higher rate of any complications (18.5% emergency vs 4.7% elective, p<0.001), major complications (7.6% vs 0.6%, p<0.001) and postoperative mortality (5.4% vs 0.1%, p<0.001). When adjusted for age, sex, hernia type and time period, emergency presentation remained significantly associated with occurrence of any complications (OR: 3.68, 95% CI: 2.04–6.63) and major complications (OR: 12.96, 95% CI: 4.68–35.87).

Effect of policy change on adverse event rate

The postoperative mortality rate was not significantly different between the periods prior to and following the policy change (Table 1). In adjusted models, the time period after the policy change predicted neither occurrence of any complications (adjusted OR: 1.26, 95% CI: 0.85–1.88) nor major complications (adjusted OR: 1.12, 95% CI: 0.44–2.85). Successful completion of day-case surgery was not different before and after the policy change.

Discussion

To our knowledge, this is the first study to assess the impact of a change in clinical commissioning guidelines on elective surgery for inguinal hernia in the UK. In the catchment area of a large foundation trust, the proportion of patients undergoing emergency surgery increased significantly following the policy change. The absolute percentage change in the rate of emergency presentation was small (1.9%) but this is correlated to increased odds of 59% in an adjusted model (68% in men). Such relative increases may be important to the individual patient when considering the morbidity profile associated with emergency repair.

The main strength of this study is its assessment over a large geographical region. This allowed for high numbers and inclusion of patients from a 'real world' population. Although no direct link was made between timing of the study period (ie before or after policy change) and adverse events, when extrapolated across the country, such an increase is likely to be detected. Additionally, detailed clinical outcome assessment at source likely afforded higher accuracy than routinely collected administrative data alone.[14]

Table 2 Univariate and multivariate binary logistic regression association of patient and policy factors to adverse events (emergency presentation and complications)

	Univariate		Multivariate	
	OR (95% CI)	***p*-value**	**OR (95% CI)**	***p*-value**
Any complication				
Age*	1.12 (1.05–1.21)	**<0.001**	1.10 (1.02–1.17)	**0.009**
Female sex	1.43 (0.66–2.75)	0.324	1.13 (0.54–2.36)	0.742
Recurrent hernia type	1.34 (0.05–0.07)	0.705	1.13 (0.60–2.11)	0.713
After policy change	1.33 (0.90–1.98)	0.161	1.26 (0.85–1.88)	0.257
Emergency presentation	4.60 (2.54–7.95)	**<0.001**	3.68 (2.04–6.63)	**<0.001**
Major complications				
Age*	1.10 (0.10–1.30)	0.246	1.02 (0.88–1.19)	0.760
Female sex	1.43 (0.66–2.75)	0.324	0.51 (0.06–4.07)	0.526
Recurrent hernia type	1.14 (0.55–2.12)	0.705	1.63 (0.46–5.80)	0.448
After policy change	1.33 (0.90–1.98)	0.161	1.12 (0.44–2.85)	0.813
Emergency presentation	4.60 (2.54–7.95)	**<0.001**	12.96 (4.68–35.87)	**<0.001**

OR = odds ratio; CI = confidence interval
*OR relates to a 10% increase in age. All models were repeated using age as an unadjusted continuous variable; there were no alterations to significance and the maximum change to the Akaike information criterion was 0.8%.

The main limitation is underlying assumptions that the increased number of patients presenting as emergencies were asymptomatic and had either been seen by their general practitioner (GP) but not referred or had been referred but were not offered surgery. These assumptions are important confounders of the theory that the changes observed were due to policy change. This study therefore provides evidence of association rather than direct cause. Other limitations should be considered. With only the catchment area of one UK hospital, the ability to generalise to other areas requires confirmation. However, the foundation trust is comprised of three hospitals with two emergency departments and is likely to be representative of other UK hospitals.

This study did not test quality of life or pain measures from patients. Large cohort studies have shown that elective repair of an inguinal hernia enhances life quality.[4] A key argument against surgical repair of an asymptomatic inguinal hernia is the risk of surgical morbidity, such as postoperative chronic pain, which is quoted to patients in the order of 5–10%.[15,16] Nevertheless, long-term follow-up of the UK trial by O'Dwyer *et al* showed equivalent median visual analogue scale pain scores between men randomised to operative and non-operative groups at five years.[8,17] This confirms findings from the North American trial, where analysis by both intention-to-treat and as-treated showed equivalence between observation and surgery for pain interfering with activity.[7] These findings suggest that the risk of chronic pain should not be a barrier when considering surgical repair.[18]

In order to answer the primary study question, it was decided *a priori* to adjust for the factors that we judged would be clinically relevant to affecting elective versus emergency presentation: age, sex and primary/recurrent hernia type. Data on pre-existing co-morbidity, use of laparoscopy and other desirable (but not necessary) factors were not included. These are unlikely to be relevant confounders following the adjustment already performed. Finally, the proportion of patients successfully managed conservatively by GPs was not investigated in this study. Such data may reveal a high success rate and reduce the proportional size of emergency presentations although it would not affect the relative increase seen.

Changes in commissioning policy were based on evidence from two RCTs. In the largest RCT, by Fitzgibbons *et al*, the estimated cross-over rate from observation to surgery, through Kaplan–Meier analysis, was 68% at ten years.[7,19] The second RCT did not find significant differences in pain scores but showed an overall change in SF-12® health status of 7.0 (95% CI: 0.2–13.7, p=0.045), favouring the operation group over the observation group.[8,17] Out of 80 men randomised to observation, 46 crossed over to operation, which was estimated by Kaplan–Meier methods as a rate of 72% at 7.5 years.

The high rate of conversion to operative intervention, accompanied by a low rate of emergency intervention, seen in the two RCTs is in contrast to the rates from the present study for before and after the policy change. This is likely explained by the careful, active observation afforded in RCTs, which may not be feasible in non-trial,

community settings. The North American authors suggested that watchful waiting is reasonable and safe (recognising the high likelihood of future operation)[19] but the UK authors suggested that there is little point in observation.[17]

The European Hernia Society issued guidelines in favour of watchful waiting for men with minimally symptomatic or asymptomatic inguinal hernias, without clarifying the method of implementation in practice.[9] While this may remain the best policy for some patients, the ideal candidate and process will only be identified after further research. Elderly patients with co-morbidity have been suggested as targets of this strategy although they may be at highest risk of morbidity and mortality if emergency surgery is required. In the present study, increasing age was associated with both emergency presentation and complications. This suggests that age alone should not be a barrier to elective surgical repair. Despite this, patients choosing observation may be reassured that the risk of emergency repair remained below 10%.

It is notable from this study that the proportion of patients undergoing elective repair differed only slightly between time periods (96.4% to 94.5%). Although the decrease is small, it reflects the important increase in emergency presentation. The fact that elective referrals are still being made in volume suggests that only a small proportion of patients are asymptomatic. Additionally, penetrance of guidelines may not yet be complete and if proportion of elective repair falls further, even more emergency presentations may occur in the future.

Day-case, ambulatory inguinal hernia repair may also prove to be more cost effective than active observation in community settings. Ongoing observation comes at a financial cost that should be quantified and compared with that of early repair. The UK RCT showed that operative strategies were over £400 more expensive per patient than for the observation group, taking into account clinic and observation costs.[8] However, with longer-term community-based follow-up and more adverse events (when applied to a wider population), these costs may increase and deserve prospective reassessment.

Conclusions

This study suggests that the current policy is associated with an increased proportion of emergency presentations and may be putting patients at risk. It may also be less cost effective than a policy of early elective surgery. For these reasons, we advocate further studies at a national level as well as a timely clarification of clinical commissioning policies to allow expert surgical assessment and follow-up if a watchful waiting policy is to be adopted.

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