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ORIGINAL SCIENTIFIC REPORT

The Role of Planned and On-Demand Relaparotomy in the Developing World

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Abstract

Introduction/background This study compares planned repeat laparotomy (PR) with on-demand repeat laparotomy (OD) in a developing world setting.

Materials and methods This study was conducted over a 30-month study period (December 2012–May 2015) at Greys Hospital, Pietermaritzburg, South Africa. All trauma and general surgery adult patients requiring a single relaparotomy were included in this study. Prospectively gathered data entered into an established electronic registry were retrospectively analysed. Full ethical approval for the registry and this study was granted by the University of KwaZulu-Natal Biomedical Ethics Committee.

Results A total of 162 patients were included, with an average age of 36 years (standard deviation 17) and 69 % male predominance. Appendicitis and stab abdomen were the most common underlying diagnoses. PR strategy was used in 46 % and an OD approach in 54 %. Patients selected for the PR strategy had higher admission pulse rates, higher Modified Early Warning System (MEWS) scores and significantly higher rates of diffuse intra-abdominal sepsis at initial laparotomy. However, findings at relaparotomy were similar in both groups. The PR group had a much shorter time between operations, but much higher need for intensive care unit (ICU) admission. There was no difference between the groups in terms of open abdomen at discharge, length of hospital stay, morbidity or mortality.

Conclusion In our environment, a planned approach to relaparotomy shows no major outcome advantages over an on-demand approach. There is however increased need for ICU admission with the PR approach. This is in keeping with international literature. Of concern is the much longer time delay between index procedure and repeat operation in the OD group. Improved post-operative decision making may help address this.

Introduction

Intra-abdominal sepsis requires adequate surgical source control as the cornerstone of therapy, and repeat laparotomy may be needed to achieve this. Deciding on the need for repeat laparotomy and the optimal timing of the operation is often highly subjective. The decision to re-operate is challenging to make, especially in the setting of a

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critically ill patient with non-specific features of partially treated sepsis [1–4]. There are two approaches to the management of complex abdominal sepsis. These are the so-called planned relaparotomy (PR) and on-demand relaparotomy (OD) approaches [1–4]. The PR approach takes all patients with complex sepsis back to the operating room at regular 48 h intervals until such time as adequate source control has been achieved. With the OD approach, all patients are treated expectantly and only patients who manifest signs of unresolved intra-abdominal sepsis are subjected to repeat operation. Much has been written in the literature comparing the PR and OD strategies, but for ethical purposes, devising studies comparing the two strategies is challenging and the available literature is thus at best level II evidence. The literature from the developing world on this topic is scarce. Problems in the developing world include patient delay to initial presentation and resource limitations, particularly intensive care resources and limitations in the post-operative monitoring of these patients [5, 6]. These limitations make an OD strategy more challenging, as any delay to reoperation has been shown to increase morbidity and mortality [7]. It is evident that in our developing world setting, planned repeat laparotomies are still commonly performed and the practice remains popular [6, 8]. This retrospective study aims to audit the practice of planned relaparotomy in the developing world setting and compare it to an on-demand approach, with the hope of clarifying these issues and refining management algorithms for our environment.

Materials and methods

Greys Hospital is a tertiary level hospital that drains the city of Pietermaritzburg and the western third of KwaZulu-Natal province. It serves a population of more than three million people who mostly reside in rural districts. We manage abdominal sepsis with aggressive attempts to obtain surgical source control. The decision as to whether a PR or an OD approach is followed depends on the managing surgeon. In our institution, there is a difference of opinion amongst attending staff as to which approach is optimal. This difference in practice provides us with two cohorts of patients for comparison. This study was conducted over a 30-month study period (December 2012–May 2015) at Greys Hospital. All surgical patients at Greys Hospital have admission, discharge and operative data prospectively entered into a computerised electronic registry [9]. Ethics approval to maintain this registry has been obtained from the Biomedical Research Ethics Committee (BCA221/13 BREC) of the University of KwaZulu-Natal and from the Research Unit of the Department of Health. Full ethical approval for this study was granted by the University of KwaZulu-Natal Biomedical Research Ethics Committee (BE047/14). All patients aged 13 years and older, requiring a single relaparotomy, were included in this study. This included both general surgical and trauma patients. Children younger than 13 years and any patient requiring more than one relaparotomy were excluded from this study. Furthermore, patients requiring a relaparotomy secondary to an initial damage control operation or an initial elective procedure were also excluded. The decision as to which relaparotomy strategy each patient should undergo was left up to the individual surgeon at the index laparotomy and was not influenced by this study in any way.

The data were processed and analysed using Stata 13.0 [10]. Comparison of continuous data by planned/on-demand classification was made using the standard t test or Wilcoxon rank-sum (Mann–Whitney) test if the data were not normally distributed, while categorical cross tabulation (association) were compared using the Pearson Chi square (χ^2) test. If any expected cell count had fewer than five observations, the Fishers exact test was used instead. Furthermore a multivariable regression was performed for each outcome versus PR/OD to adjust for the confounding influences of covariates which may not have been accounted for in the unadjusted univariate analyses. A linear regression was used for length of hospital stay and length of Intensive Care Unit (ICU) stay. A log transform was applied to ensure normality of these distributions prior to the regression model. For binary outcomes (such as temporary abdominal closure after Index Laparotomy and ICU admission), a logistic formulation was used. An adjusted p value of <0.05 was considered statistically significant.

Findings were analysed in terms of basic demographics, underlying diagnoses and number of operations in both PR and OD groups. These two groups were then compared in terms of baseline characteristics (on admission), operative findings at index laparotomy and relaparotomy, whether the relaparotomy benefitted the patient, and in terms of major outcomes, which included average time between operations, length of hospital stay, need for intensive care admission, rates of morbidity and mortality.

Results

Overview

During the defined 30-month study period a total of 162 patients were included in the study. Average age was 36 years [standard deviation (SD) 17, range 13–89 years] with a male predominance of 69 %. General surgical patients accounted for 73 % and trauma patients for 27 %. A total of 74 patients (46 %) had a planned relaparotomy

Table 1 Breakdown of the most common diagnoses for both general surgical and trauma patients

Diagnosis	Numbers	Percentage
General surgery	($n = 119$)	
Appendicitis	62	52
Malignancy	11	9
Small bowel obstruction	10	8
Peptic ulcer disease	10	8
Iatrogenic injuries	5	4
Herniae	4	3
Sigmoid volvulus	3	3
Mesenteric ischaemia	3	3
Other	11	9
Trauma surgery	($n = 43$)	
Stab abdomen	19	44
Gunshot abdomen	16	37
Blunt abdominal trauma	8	19

Table 2 Comparison of operative findings at initial laparotomy between PR and OD Groups

	Planned (74)	On-demand (88)	p value
Diffuse sepsis	52 (70 %)	19 (22 %)	**<0.001**
Localised sepsis	10 (14 %)	31 (35 %)	**0.002**
Necrosis/ischaemia (without sepsis)	9 (12 %)	2 (2 %)	**0.024**
Bile/blood	3 (4 %)	8 (9 %)	0.230
Nil sepsis	0 (0 %)	24 (27 %)	**<0.001**
Turbid/serosanguinous fluid	0 (0 %)	4 (5 %)	0.126

Statistically signficant p values are given in bold

while the remaining 88 patients (54 %) had an on-demand relaparotomy. Complicated appendicitis accounted for 52 % of the underlying diagnoses in the general surgical group, while stab abdomen was the most common diagnosis in the trauma group (44 %). Please see Table 1 for a breakdown of the most common diagnoses in each group.

Operative findings

Patients selected for the PR group had significantly higher rates of diffuse intra-abdominal sepsis or ischaemia/necrosis found at initial laparotomy, while those selected for the OD group had significantly higher rates of localised sepsis or findings of no sepsis at the initial laparotomy (Table 2).

Despite the significant differences in findings at the initial operation, findings at relaparotomy were not significantly different between the PR and OD groups (Table 3). A total of 58 patients were considered to have positive findings at relaparotomy and included macroscopic residual sepsis, bowel ischaemia or necrosis, anastomotic breakdown or significant amounts

Table 3 Comparison of operative findings at relaparotomy between PR and OD groups

	Planned (74)	On-demand (88)	p value
Positive findings (total)	31 (42 %)	46 (52 %)	0.188
Diffuse sepsis	8	5	
Localised sepsis	11	15	
Turbid/serosanguinous fluid with positive culture	7	12	
Necrosis	3	3	
Anastomotic breakdown without contamination	0	4	
Significant bile/blood	2	7	
Negative findings (total)	36 (49 %)	35 (40 %)	0.257
Clean abdomen	26	23	
Turbid/serosanguinous fluid with negative culture	10	12	
Unclear	7 (9 %)	7 (8 %)	0.734
Turbid/serosanguinous fluid—no microbiology found	7	7	

of intra-abdominal bile or blood requiring surgical drainage. A total of 49 patients were found to have a macroscopically clean abdomen at relaparotomy, which was considered a negative finding. The remaining 55 patients had findings of turbid or serosanguinous fluid, which was of unclear significance. Microbiological cultures were used to correlate whether this encountered fluid was infective or not. Cultures showing pathogenic organisms were found in 19 patients and were considered a positive finding, while those without pathogenic organism growth (22 patients) were considered negative. A total of 14 patients with such turbid or serosanguinous fluid either did not have a microbiological sample taken at the time of relaparotomy or the sample could not be traced. However, these patients were evenly distributed between the two groups.

A further analysis was then made to identify whether the relaparotomy was of benefit to the patient or not. Benefit for the patient was defined by positive findings (as shown in Table 3). Furthermore, any patient without significant findings, but who underwent a definitive surgical procedure during the relaparotomy, was also considered to have benefitted from the relaparotomy (Table 4). Those patients with both negative findings and who did not undergo a definitive surgical procedure were considered to have had a negative relaparotomy. There was a significant difference between the groups both in terms of benefit from the relaparotomy and in the negative relaparotomy rate. The PR group benefitted more from the relaparotomies performed and had a lower rate of negative relaparotomy. However, when multivariate regression analysis was performed for the negative

Table 4 Comparison of benefit from relaparotomy between PR and OD groups

	Planned (74)	On-demand (88)	*p* value
Benefit	60 (81 %)	59 (67 %)	**0.044**
Reason for benefit			
Residual sepsis/necrosis	29 (39 %)	35 (40 %)	0.940
No sepsis, but therapeutic intervention	31 (42 %)	24 (27 %)	**0.050**
Definitive sheath closure	25	3	
Evisceration reduced	2	2	
Bile/blood drained	1	5	
Obstruction released	0	6	
Anastomotic breakdown (no sepsis)	0	4	
Other	3[a]	4[b]	
No benefit (negative relaparotomy)	9 (12 %)	23 (26 %)	**0.026**
Unclear	5 (7 %)	6 (7 %)	0.772

Statistically signficant *p* values are given in bold

[a] PR group other interventions: ileostomy refashioned; new colonic perforations found, needing hemicolectomy; missed ureteric injury needing intervention

[b] OD group other interventions: colostomy refashioned; completion appendicectomy; missed gastric injury repaired; left oophorectomy performed for tubo-ovarian complex

relaparotomy rate, the difference between the groups was not considered statistically significant (Table 5).

Baseline characteristics

Comparison of the PR and OD groups in terms of age, gender, comorbidities (which included any major comorbidity such as hypertension, diabetes, chronic cardiac or respiratory disease, and human immunodeficiency virus infection—in total and patients on antiretroviral drugs), blood pressure, respiratory rate, Glascow Coma Scale (GCS) of less than 15/15, level of surgeon at operation and serum lactate on admission showed no statistically significant differences. However, the PR group did have higher average pulse rates, slightly higher temperatures on admission and higher Modified Early Warning Score (MEWS) [11], indicating they were slightly sicker than the OD group (Table 6). Importantly, a number of patients did not have data entered on admission for specific parameters—of note is the large number of patients who did not have a documented serum lactate on admission. These numbers are presented in the last column in Table 6, listed as "ND" (not documented).

Outcomes

In terms of overall outcomes, a total of 64 patients (40 %) required admission to the intensive care unit (ICU); 91 patients (56 %) had at least one documented morbidity, with a total of 127 specified morbidities (Fig. 1). Overall mortality in this study was 9 % (15 patients).

When comparing outcomes between the PR and OD groups (Table 5), there was no significant difference in terms of length of hospital stay, morbidity or mortality rates. However, the PR group had an ICU admission rate of more than twice the OD group (55 vs 26 %), although there was no significant difference in average length of ICU stay between the 2 groups. The PR group also had a significantly higher rate of temporary abdominal closure after initial laparotomy (78 vs 10 %); however, this did not translate into a significantly higher rate of open sheath after relaparotomy. Lastly,

Table 5 Comparison of major outcomes between PR and OD groups

Outcomes	Planned (74)	On-demand (88)	*p* value	Adjusted *p* value*
Median length hospital stay (days) (IQR)	12 (8–19)	13 (7–20.5)	0.638	0.579
Median time between operations (h) (IQR)	49 (39–59)	97 (66–185)	**<0.001**	**<0.001**
Negative relaparotomy rate	9 (12 %)	23 (26 %)	**0.026**	0.104
TAC after index laparotomy	58 (78 %)	9 (10 %)	**<0.001**	**<0.001**
TAC after relaparotomy	22 (30 %)	16 (18 %)	0.084	0.124
ICU admission	41 (55 %)	23 (26 %)	**<0.001**	**0.006**
Median length of ICU admission (days) (IQR)	4 (3–7)	6 (3–12)	0.276	0.768
Morbidity	38 (51 %)	53 (60 %)	0.257	0.239
Mortality	10 (14 %)	5 (6 %)	0.087	0.055

Statistically signficant *p* values are given in bold

TAC temporary abdominal closure

* Based on multivariable adjusted regression model including age, gender as well as covariates statistically associated with PR/OD identified in Table 5—namely admission GCS 15/15, pulse, temperature and overall MEWS

Table 6 Comparison of baseline admission characteristics between PR and OD groups

Characteristic	Planned ($n = 74$)	On-demand ($n = 88$)	p value	ND
Median age (years) (IQR)	31 (23–44)	32 (24–47)	0.707	–
Gender	48 (65 %) male	63 (72 %) male	0.359	–
Comorbidity	27 (36 %)	31 (35 %)	0.868	–
HIV positive (total)	21 (28 %)	23 (26 %)	0.808	–
HIV positive on HAART	13 (18 %)	11 (13 %)	0.654	–
Specialist surgeon at index laparotomy	26 (35 %)	30 (34 %)	0.889	–
Specialist surgeon at relaparotomy	21 (28 %)	27 (31 %)	0.749	–
Median systolic BP (mmHg) (IQR)	118 (107–133)	121 (112–130)	0.468	PR:4/OD:1
Mean diastolic BP (mmHg) (SD)	73 (7.47)	75 (14.11)	0.444	PR:4/OD:1
Mean MAP (mmHg) (SD)	89 (18.32)	91 (14.34)	0.470	PR:4/OD:1
Median respiratory rate (IQR)	20 (18–24)	20 (16–23)	0.153	PR:6/OD:7
Median serum lactate (IQR)	2.25 (1.3–4.2)	1.46 (0.9–2.9)	0.061	PR:31/OD:36
Glascow Coma Scale 15/15	66 (89 %)	85 (97 %)	0.062	PR:4/OD:2
Median temperature (°C) (IQR)	**36.9 (36.3–37.7)**	**36.6 (36.3–37.0)**	**0.046**	PR:8/OD:2
Mean pulse (SD)	**113 (19.57)**	**103 (20.50)**	**0.002**	PR:4/OD:1
Median MEWS (IQR)	**3.56 (2-5)**	**2.39 (1–3)**	**<0.001**	PR:13/OD:8

Statistically signficant p values are given in bold

ND not documented (number of patients where the parameter was not documented on admission), *IQR* interquartile range, *SD* standard deviation, *HIV* human immunodeficiency virus, *HAART* highly active antiretroviral therapy, *BP* blood pressure, *MEWS* Modified Early Warning System [11]

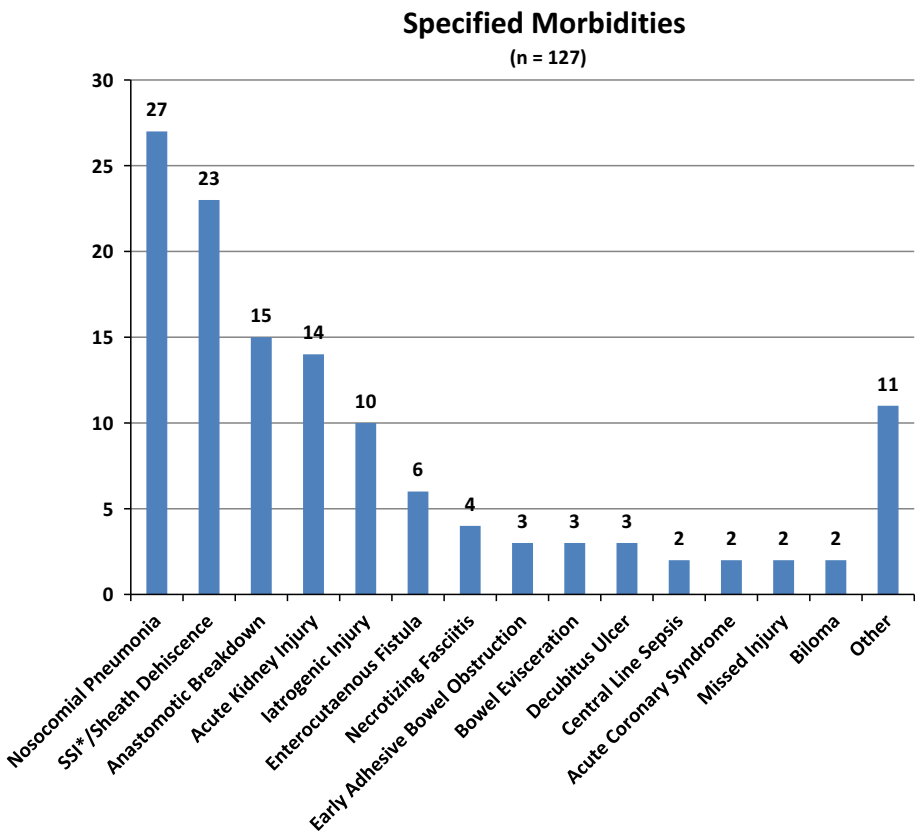

Fig. 1 Breakdown of major specified morbidities. **SSI* surgical site infection

the PR group had a significantly shorter time between initial laparotomy and relaparotomy (56 vs 133 h).

After multivariable adjustment, outcome differences between PR and OD groups remained for the following: median duration between operations (shorter in PR), TAC after Index Laparotomy (higher in PR) and ICU admission (higher in PR). Mortality was marginally statistically higher among PR group following multivariable adjustment ($p = 0.055$).

Discussion

The optimal approach to the problem of intra-abdominal sepsis is controversial. A meta-analysis of retrospective studies by Lamme et al. [3] and a subsequent randomized controlled trial by van Ruler et al. [4] (aptly named the "RELAP" trial), both concluded that PR does not infer a survival advantage, may in fact increase morbidity and leads to significant increases in healthcare costs. A subsequent cost analysis trial [12], which arose from the RELAP trial, concluded that the PR strategy was associated with an average increased cost of €17,682 per patient compared to the OD strategy. In a prior study by van Ruler et al. [13], the authors showed that the underlying cause for peritonitis or the findings at the initial laparotomy were poor indicators for the need for relaparotomy. They concluded that progressive or persistent organ failures in the early post-operative period were the best indicators that relaparotomy is needed, thus providing more support for an OD strategy. Although there is little support for a PR strategy in the international literature, it remains a popular approach in our setting and in our institution, with a high burden of delayed and complex intra-abdominal sepsis; a number of attending staff still practise planned repeat laparotomy. This has allowed us to generate two patient cohorts which are suitable for comparison.

In general, the PR group had slightly worse physiological parameters on admission and had much higher rates of diffuse intra-abdominal sepsis at the initial laparotomy. Despite this, there were no major differences in the operative findings at relaparotomy between the two groups and also no significant differences in major outcomes between the two groups, including length of hospital stay, morbidity and mortality.

Patients selected for the PR group had fewer negative relaparotomies (although this was not statistically significant after multivariate analysis) and benefitted more from their repeat operations than the OD group. This is mainly attributed to the large numbers of PR group patients who benefitted from fascial closure at relaparotomy. Temporary abdominal closure is commonly required in the management of trauma and abdominal sepsis and primary fascial closure is an important subsequent surgical objective. Failure to achieve closure can result in significant morbidity. Despite the significantly higher rates of temporary abdominal closure after the initial laparotomy in the PR group, this did not relate into higher rates of open sheath at discharge, which is likely a reflection of the large number of patients who were aggressively managed with initial temporary abdominal closure but who had successful sheath closure at relaparotomy.

The PR group was shown to benefit from a much shorter average time between operations, with an average return to theatre 77 h earlier than the OD group. This likely reflects the difficulties in post-operative decision making in the OD group, as the indications for relaparotomy are non-specific and vague, and if the managing surgeon is not vigilant and alert to some of the more subtle signs of unresolved intra-abdominal sepsis, then the decision to re-operate may be unduly delayed. Despite evidence that delay to relaparotomy worsens outcome [7], the delay in the OD group in our study did not relate into significantly worsened outcomes. An important difference between the two groups was the much higher need for ICU admission in the PR group. This is in keeping with developed world literature [3, 4, 11]. However, this may also simply represent a form of selection bias, as the PR patients had worse physiology on admission and more severe sepsis at initial laparotomy.

As in previous studies from our institution and Edendale Hospital, our sister institution, appendicitis represents the major burden of disease requiring repeat laparotomy [6, 8]. Appendicitis in our setting is associated with higher rates of perforation, complicated intra-abdominal sepsis and worsened outcomes, as compared to developed world literature [6]. Reasons for this are varied but include significant delay in patient presentation to hospital [14]. Despite the increasing popularity of laparoscopy for the management of many abdominal pathologies, including appendicitis, its role in our setting remains limited. This is based on a combination of limited access to laparoscopy, especially during after-hours surgery, and because of the perceived severity of the pathology, we encounter. Appendicitis is managed laparoscopically in our institution, but this is generally reserved for patients with early presentation of uncomplicated appendicitis or were diagnostic doubt exists, e.g. young female patient with vague symptomatology. These patients usually do not require repeat operations and thus did not form part of this study. We have no experience with laparoscopy for patients with diffuse intra-abdominal sepsis nor with laparoscopy performed after an initial laparotomy and neither are practised in our setting.

Management of post-operative intra-abdominal collections via percutaneous drainage after appropriate radiological imaging is being performed more commonly in our setting, and successful percutaneous drainage allows for the avoidance of a repeat operation. For this reason, those

patients successfully managed in this manner were not included in this study's patient cohort.

Despite the retrospective non-randomized nature of this study, our data suggest that there is little advantage in a PR approach in comparison to an OD approach. The PR approach does seem to require more resources than an OD approach. Of concern with the OD approach, however, is the relatively long delay between index procedure and repeat operation. This suggests a degree of clinical complacency in the management of these patients. Traditionally, we have suggested that patients need to earn the right not to have a repeat operation rather than earn the right to have one. With this mind set, staff are less likely to be complacent and hopefully should recognize the need for repeat surgery at an earlier stage.

Conclusion

Planned repeat laparotomy is a popular strategy at our institution, and this study shows that it is associated with earlier return to the operating room, but greater need for postoperative ICU resources. However, PR and OD strategies were equal in terms of major outcomes and in terms of therapeutic intervention rates. In light of this, it is difficult to support a policy of routine PR except for patients with TAC who need definitive abdominal closure. If an OD approach is to be more widely adopted, we will need to reduce the delay between index procedure and repeat operation.

Compliance with Ethical Standards

Conflicts of Interest The authors declare no conflicts of interest.

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