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Title: Surgery, complications and quality of life: a longitudinal cohort study exploring the impact of psychosocial factors.

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ABSTRACT

Objective:

To determine if psychosocial factors moderate the relationship between surgical complications and quality of life (QoL).

Summary Background:

Patients who experience surgical complications have significantly worse post-operative QoL than patients with an uncomplicated recovery. Psychosocial factors, such as coping style and level of social support influence how people deal with stressful events, but it is unclear if they impact on QoL following a surgical complication. These findings can inform the development of appropriate interventions that support patients post-operatively.

Methods:

This is a longitudinal cohort study; data were collected at pre-op, 1 month post-op, 4 months post-op and 12 months post-op. A total of 785 patients undergoing major elective gastro-intestinal, vascular or cardio-thoracic surgery were recruited from 28 National Health Service (NHS) sites in England and Scotland took part in the study.

Results:

Patients who experience major surgical complications report significantly reduced levels of physical and mental QoL ($p<0.05$) but they make a full recovery over time. Findings indicate that a range of psychosocial factors such as the use of humor as a coping style and the level of health care professional support, moderate the impact of surgical complications on QoL.

Conclusion:

Whilst surgical complications impact upon physical and mental functioning over a 12 month

period, other factors also contribute to changes in QoL. Whilst the results presented here may not be generalisable to all types of surgery, interventions that increase the availability of healthcare professional support and promote more effective coping strategies prior to surgery should be further explored, particularly in the earlier stages of recovery where QoL is most severely compromised.

INTRODUCTION

Surgical complications range from seemingly minor incidents that resolve relatively quickly and without consequence to more serious events that require multiple interventions, delay patients' discharge and may lead to multi-organ failure, longstanding disability or even death.[1] In addition to the physical harm caused to patients, surgical complications can lead to psychological distress and worse quality of life.[2, 3] A recent systematic review reported that patients who suffered surgical complications had significantly worse post-operative wellbeing than patients with an uncomplicated recovery, even after controlling for a range of clinical and demographic factors.[4]

Whilst the impact of a surgical complication will depend on the severity of the complication itself and the amount of pain and disability that it causes, either temporarily or permanently, psychosocial factors, such as threat appraisal, coping style and social support can have a significant impact on how people deal with stressful events,[5-7] including surgery - even when surgical complications do not arise.[8, 9] To date, the impact of psychosocial factors on moderating the effect of surgical complications on wellbeing remains unknown. In light of this, the aim of the research presented here was to determine how surgical complications impact on quality of life (QoL). In addition, we aim to explore what influence clinical, socio-demographic and psychosocial factors, in particular the amount of social support a person experiences and their individual coping style, may have upon QoL. We anticipate that understanding the implications of surgical complications for patients' wellbeing and the factors that determine patients' reactions to them will shed light on how to better support patients who suffer medical harm.

METHODS

Study Design

This was a longitudinal cohort study. Pre-operative collection of data included patient demographics, current health status and type of operation. For those patients who had a post-operative (post-op) complication, information was collected on the type and severity of the complication and the subsequent treatment it required. A range of patient reported outcome measures (PROMs) were completed by patients 24 hours before surgery, and then 1 month, 4 months and 12 months post-op.

Ethical approval

Ethical approval for the study was received from National Health Service (NHS) Research Ethics Committee (reference number 11/LO/1253) along with local Research &Development approval from each participating site.

Setting

Patients were recruited from 28 NHS sites in England and Scotland.

Participants

Patients were eligible to participate if they underwent major elective gastro-intestinal, vascular or cardio-thoracic surgery (these specialties were chosen as they include high risk procedures where more complications are likely to occur),[10] were over 18 years old, were able and willing to give informed consent and spoke and understood English. Major surgery was defined based on the Bupa schedule of operations[11] as any surgical procedure that was listed as major (or higher) in the hospital category. Patients were excluded from the study if their surgery was a reoperation aimed at ameliorating the complications of a recent operation.

Data sources/measurement

The main outcome measure, quality of life (QoL), was assessed with the SF-12. The SF-12 provides a self reported measure of perceived health status which is made up of the physical (PCS) and mental health domains (MCS) of QoL.[12] Patients were asked to complete the SF-12 at four time-points: 24 hours before surgery, at one month post-op, at 4 months post-op and 12 months post-op. Scales to measure patient coping style and perceptions of social support were assessed in the 24 hours prior to surgery. Patients' style of psychological coping was assessed with the Brief COPE.[13] As the Brief COPE had not been validated with a sample of surgical patients, we evaluated the Brief COPE's factor structure to establish psychometrically robust scales for use in the surgical setting.[14] The exploratory factor analysis identified seven factors that were interpreted as Approach coping, Avoidant coping, Use of social support, Humour, Substance use, Religion and Self-distraction. Patient perception of social support was assessed with the 'adequacy of social support from confidants' and 'adequacy of social support from healthcare professionals' scales of the Multi-dimensional Support Scale (MDSS).[15, 16]

Recording of complications

Patients' medical records, electronic discharge summaries and clinical and laboratory tests were reviewed by members of the clinical team at each site in order to identify any post-op complications that occurred during the index hospitalisation. Surgical complications were recorded based on Dindo et al.'s definition as "any deviation from the ideal postoperative course" and were rated in terms of severity based on the Clavien-Dindo framework, displayed in Box 1.[1, 17] Details of complications and their grades were recorded by the local clinical team before sign-off by the Chief Investigator at each site. Once all research records were received from the 28 sites, they were scrutinised independently by two surgeon-

researchers (MJ &BB) who recorded the severity of complications using the Clavien-Dindo Scale[1] and then compared and combined their results to ensure consistency of analysis. A randomly generated total of 10% of records were analysed by both raters to assess the reliability of data analysis. Points of disagreement were resolved by direct discussion.

Within the analysis, complications were classified as either minor (grades 1 and 2) or major (grade 3a or higher) based on the Clavien-Dindo Scale.[1]

Followup

Patients were followed up at 1 month, 4 months and 12 months post-op by post. In the event that patients did not return questionnaires to the participating site, staff contacted the patient by telephone and/or post to collect data regarding their non-participation. Whilst every effort was made to collect this 'off-study' data, completion was sporadic, and as such, has not been included as a variable in the following analyses.

Statistical Methods

All analyses were performed with Stata version 12.0. Initially, hierarchical regression analyses were conducted to take into account the potential clustering of data (since patients were selected from 28 NHS sites). This utilised the "xtreg" command in Stata; as the effect of site was negligible (with an intraclass correlation coefficient close to zero) the analyses were performed using the standard regression command with the "robust" and "cluster" options. The results of this analysis are presented here. To investigate the association between post-op QoL and complications we ran three regression models: model 1 adjusted for baseline QoL scores only, model 2 additionally adjusted for clinical and socio-demographic variables and model 3 additionally adjusted for psychological coping and support. All three models are sequentially presented to build a picture of how the variables interact as well as highlighting

the potential value of including clinical, socio-demographic and psychosocial variables in this analysis.

RESULTS

Participants

Data were collected from 28 NHS sites from England and Scotland, with a total of 961 patients consenting to participate. Data from 785 (81.7%) patients were used in the final analysis (see table 1 for patient characteristics and table 2 for the frequency of operation types); data were excluded from the final analysis if participants had withdrawn their consent to participate, had not completed all items on the SF-12, had their surgery re-graded as minor surgery or had their surgery cancelled as it was no longer needed.

The rate of attrition increased over time; the following number of patients remained in the study at each time point: 1 month n=561 (71.46%), 4 months, n=501 (63.82%) and 12 months, n=421 (53.63%). Loss to follow up analysis was conducted using chi-square and independent samples t-test to further explore this. Results indicated that there was no significant association between those who remained in the study and those who did not with regards to ethnicity or gender at any time point. When investigating age, there were no differences between those who did and did not provide data at pre-op. However, at all post-operative time points, those who provided data were significantly older than those who did not. With regards to relationship status at 12 month post-op, married people tended to remain in the study, and single people tended not to. When exploring condition type, those who underwent general surgery were more likely to remain in the study and those having cardiac surgery were less likely at 4 months post-op. At 12 month post-op, those who had general surgery were more likely to provide data for the study, with those undergoing vascular surgery less likely. With regards to employment status, at 12 months post-op, un-employed people were less likely to provide data and retired were more likely.

Table 1 and Table 2 here

Descriptive Data

A total of 379 patients (48%) had a complication after surgery, with 89 of these being classified as major (grade 3a or higher on the Clavien-Dindo Scale). Of 38 cases independently assessed by both researchers, there was absolute agreement in the number, type and severity of complications in 33 patients (86.8%). Disagreements between raters centred on grade 1 and 2 complications, specifically the classification of drugs such as antipyretics and analgesia. Agreement between raters was 100% after discussion.

Quality of life by complications

Mean scores and standard deviations for patients classified within each complication severity grade over the 4 time points are displayed in tables 3a and 3b and figures 1a and 1b.

Table 3a and 3b here

Figure 1a and 1b here

Regression analysis

The following section reports the hierarchical regression analyses performed on the data collected from the 28 sites. Each variable was scrutinised with univariate analyses in the first instance; only those showing a significant relationship with QoL were entered into the hierarchical regression models. Only one variable, the presence of cancer, did not display a significant relationship with QoL at any time point, so was omitted from additional analyses.

In the following analysis, three models are presented: model 1 adjusted for baseline QoL scores only, model 2 additionally adjusted for clinical and socio-demographic variables and

model 3 additionally adjusted for pre-operative levels psychological coping and support. The coefficients and confidence intervals for all regression analyses are included in eTables1a-1f. Baseline reported levels of mental and physical functioning were significant predictors of later reported levels in all three models and at all three time points ($p<0.001$)

Model 1: Adjustment for Baseline QoL scores (eTables 1a-1f)

At 1 and 4 months post-op, minor and major complications were significant predictors of lower levels of physical functioning after adjustment for baseline QoL values. However, at 12 months post-op, neither minor nor major complications were significant predictors of physical functioning ($p>0.05$).

With regards to mental functioning, after adjustment for baseline QoL values, major complications were a significant predictor of reduced mental functioning at 1, 4 and 12 months post-op ($p<0.05$). Minor complications predicted a significant reduction in mental functioning only at 4 months post-op ($p<0.05$).

Model 2: Additional adjustment for clinical and socio-demographic variables (eTables 1a-1f)

When additionally adjusting for clinical and socio-demographic variables, minor and major complications predicted reduced levels of physical functioning ($p<.0.05$). Patients who were male reported higher levels of physical functioning ($p<0.001$). At 4 months post-op, minor complications predicted reduced levels of physical functioning ($p=0.01$) and a similar trend was observed for major complications but this was not significant ($p=0.11$), despite having a larger coefficient. Those who underwent general and vascular surgery reported lower levels of physical functioning ($p<0.001$), as did those who were older ($p<0.05$). Males continued to report improved physical functioning ($p<0.001$). At 12 months post-op, neither minor nor major complications predicted physical functioning. Those who underwent general and vascular surgery continued to report significantly lower levels of physical functioning

($p<0.001$) as did those with an employment status listed as 'other' ($p<0.05$).

With regards to mental functioning, minor complications were significant predictors at 1 and 4 months post-op ($p<0.05$), but not at 12months post op. Major complications were a significant predictor of reduced mental functioning at 1 month post op only ($p<0.05$). Those who underwent general and vascular surgery reported significantly reduced mental functioning at all three time points ($p<0.05$). Being unemployed was a significant predictor of reduced mental functioning at 12 months post-op. Significant predictors of improved mental functioning were being in a relationship at 4 months post-op ($p<0.05$) and being male at 12 months post-op ($p<0.05$).

Model 3: Additional adjustment for pre-operative coping and support (eTables 1a-1f)

When further adjusting for pre-op levels of psychological coping and support, major complications were significant predictors of physical functioning at 1 month post-op ($p<0.05$), although minor complications were not. Being male, using social support as a coping style and reporting higher levels of social support from healthcare professionals were all significant predictors of improved physical functioning at 1 month post op ($p<0.05$). At 4 months post-op minor and major complications were not significant predictors of physical functioning. Those who underwent general and vascular surgery reported significantly reduced mental functioning ($p<0.05$), as did those who were married, listed their employment status as 'other' and those who used social support as a coping style ($P<0.05$). Those who were male, who used substances as a form of coping mechanism as well as those that were in receipt of social support from a healthcare professional reported improved physical functioning at 4 months post-op. At 12 months post-op those who underwent general and vascular surgery continued to report significantly reduced physical functioning ($p<0.05$). Those in receipt of social support from a healthcare professional reported improved physical functioning ($p<0.05$).

With regards to mental functioning, when further adjusting for pre-op levels of psychological coping and support, major complications were a significant predictor at 1 months post-op ($p<0.001$) whereas minor complications were not. Those who underwent general and vascular surgery also reported significantly reduced mental functioning ($p<0.05$), as did those who reported using avoidant coping techniques ($p<0.001$). Those who used humour as a coping technique and those who received social support from a healthcare professional reported improved levels of mental functioning ($p<0.05$). At 4 months post-op, neither minor nor major complications were significant predictors of mental functioning. Those who underwent general surgery, were unemployed or used avoidant coping strategies reported significantly lower levels of mental functioning. No other socio-demographic or psychosocial factors were associated with improved mental functioning at this time point. At 12 months post-op, those who underwent general surgery, were unemployed or used avoidant coping strategies reported significantly lower levels of mental functioning ($p<0.05$). However, the receipt of social support from family members and healthcare professionals alongside having experienced previous major surgery all contributed to increased levels of mental functioning ($p<0.05$).

DISCUSSION

To our knowledge, this is the largest UK based study to explore the impact of surgical complications on the QoL of patients undergoing major elective gastro-intestinal, vascular or cardio-thoracic surgery, and possibly the only existing study assessing the contribution of psychosocial factors to patient's QoL following post-op complications. We have presented data on clinical, socio-demographic and psycho-social variables from 785 patients across 28 different sites in England and Scotland over a 12 month period. Whilst care should be taken when generalising these findings to all surgical procedures and types of complication, , this research indicates that patients who experience major surgical complications report reduced levels of physical and mental QoL at one month post-op, however, they do make a full recovery over time. These findings are consistent with the existing literature on the impact of surgical complications.[4] However, the findings presented here also indicate that clinical, socio-demographic variables and psychosocial variables are also important predictors of quality of life, particularly as time goes on.

The importance of clinical, socio-demographic variables and psychosocial variables in recovery from surgery following complication is consistent with a much smaller proportion of the literature exploring the impact of surgical complications on patients' QoL. In a recent systematic review,[4] only three papers reported that complications were significantly associated with psychosocial outcomes in univariate but not in multivariate analysis.[18-20] From the data presented here it appears that the type of surgery alongside the individual's pre-operative QoL, socio-demographic status and coping styles/social support mechanisms may impact upon patients' QoL post-surgery. Whilst many of the clinical and socio-demographic factors cannot be modified, there may be opportunities to improve patients' QoL post-surgery by identifying those undergoing particular surgical procedure, those with low levels of pre-op QoL and those with particular coping and social support profiles.

There may be opportunities to introduce interventions to improve the provision of social support from healthcare professionals (HCPs); HCP support was a statistically and clinically significant predictor of improved QoL (physical and mental) at 1 month, and improved QoL (physical) at 4 months and 12 months post op. Conversely, the use of general social support as a coping style was found to have a negative impact on patient's QoL. Although these findings may be the product of measuring similar constructs with two different measures (the social support construct from the Brief COPE focuses on emotional and instrumental support from 'others', whereas the MDSS specifically looks at familial and HCP support), these contradictory findings may indicate that social support, including emotional support, from a general population of 'others' is not beneficial, whereas support from HCPs at the pre-operative stage is of use. This may reflect the specific nature of support that is required for post-surgical patients; it may be that HCPs are better placed to understand the needs and fears of those who have recently undergone surgery in comparison to other sources (e.g. family members) for social support. This would benefit from further exploration in future research.

In addition, the data suggest that a number of other coping strategies might impact on the QoL of those who have undergone surgery. When looking at factors affecting mental functioning, avoidant coping was a significant predictor of reduced QoL. This is unsurprising, and relates to the wider literature.[21-23] However, humour was cited as a potentially beneficial coping strategy for improving mental functioning at 1 month post op. This relationship is consistent with the extant literature which positions humor as a beneficial coping style for a variety of health conditions.[24-26] Whilst no other strategies were significant predictors of reduced physical functioning, substance use was found to significantly predict improved physical QoL. Whilst we can speculate that the use of

substances as a coping mechanism at the pre-op stage may be linked to improved post-op QoL due to the cessation of these behaviors, the link found here between improved QoL and substance use is not consistent with the broader literature on quality of life. Indeed, Ben-Zur et al., (2000) found that substance use was related to high distress in patients undergoing open-heart surgery, and research exploring the impact of substance use on HIV infected patients also found a significant link with decreased mental QoL.[27] As there is a lack of literature that confirms the relationship found in our study between increased physical QoL and substance use, further research should be conducted to explore and validate this finding.

The findings from this study raise considerations for clinical practice. It appears that a greater amount of HCP support is required and interventions to promote more effective coping techniques prior to surgery may moderate the impact of surgical complications should they arise. Whilst additional funding to provide a bespoke service in the current financial climate is unlikely, it may be something that can be delivered with some adjustments to normal care. For example, enhanced recovery after surgery (ERAS) programmes integrate enhanced surgical preparation during the pre-op appointment and feature a follow-up telephone call when patients return to their place of residence.[28] These features have been shown to be particularly important for improving patient support.[29, 30] Additionally, lessons may be learned from prehabilitation interventions that often include psychological support and behaviour change interventions. Whilst not yet widely adopted, these programmes have shown encouraging results for improved post-surgical outcomes.[31, 32]

Strengths and Limitations

This study adopted a research design associated with a high quality study – for example, we

have accounted for patients' baseline QoL and have conducted multivariate analysis. However, a number of limitations must be acknowledged As this is one of the first studies of this nature we cannot yet be sure how far these findings are generalizable to patients with of other specialties or different degrees of complications. Many variables were included in the final model in order to establish which socio-demographic and coping/support factors were related to QoL. Care must be taken to avoid Type I errors when interpreting models featuring a large number of relationships; however, it should be noted that decisions regarding the final model here, and all the predictors included, were theory driven. The sample was not representative of the diverse population of the UK; 99% of those recruited identified themselves as "white". Whilst it is unknown why this occurred within the current study, future research should adopt methods to promote participation from a diverse population, including the recruitment of those who do not have English as a first language. Figures on the number of patients who were approached, the number of those who declined to participate, and why they decided not to participate are unavailable. As a result, it is unknown how generalisable the findings from this study are, as we may have recruited a study population that had a particular clinical, socio-demographic and coping/support profile which was not representative of the population; future studies in this area should address this within their study designs. Whilst every effort was made to collect information about patients going off-study, we do not have complete information about participants' reasons for discontinuing their participation, including the levels of mortality; as a result, it is currently unknown what factors, mortality in particular, influenced loss to follow up, and the impact this may have had on the results of the study. There was some variation in the recording of complications between the medical teams based at the individual hospital sites, although every effort was made to standardise this including training at each site, site monitoring/visiting and internal standardisation of Clavien-Dindo grade allocation. Finally, the heterogeneity in the types of surgery can be seen as limitation, as the impact of surgery

on QoL may depend upon the condition being treated, outside of presence of a complication or not. This should be considered in future research.

CONCLUSION

The results presented here indicate that whilst surgical complications impact upon physical and mental functioning over a 12 month period, socio-demographic, clinical and psycho-social variables also contribute to changes in QoL. Whilst healthcare systems must do everything within their power to minimise surgical complications, interventions that increase the availability of healthcare professional support and promote more effective coping strategies prior to surgery should be developed and tested with a view to improving QoL for those who do experience a surgical complication. These interventions may be of most benefit in the earlier stages of recovery where QoL is most severely compromised. Future research exploring the impact of surgical complications on QoL should include socio-demographic and psycho-social factors in their design and further mediation analyses should be conducted on a range of data from homogenous surgical cohorts to further assess how psychosocial factors mediate impact of complications.

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Figure Legends

Figure 1a – Mean physical functioning over time

Figure 1b – Mean mental functioning over time

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Competing interests

There are no competing interests to declare.

Contributors

AP, OF, CB, and CV contributed to the design of the study, the collection of data and commented on numerous versions of the manuscript. SA collected data for the study, performed parts of the analyses and drafted the manuscript. SV, TA and PS performed the data analysis and contributed to the interpretation and write up of the data alongside critical appraisal of the final manuscript. BB and MJ provided support with the clinical aspects of the study, including the classification of the complications; they also provided critical review of the manuscript. AD and CV were responsible for obtaining funding for the study, designing the project, overseeing the work of the research team as well as providing critical feedback on the manuscript. All authors approved the final manuscript.

Ethical approval

Ethical approval for the study was received from NHS REC (reference number 11/LO/1253)

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