

## Predictors of peri-operative risk acceptance by South African vascular surgery patients at a tertiary level hospital

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**Background:** Vascular surgical patients have an elevated cardiac risk following non-cardiac surgery. The decision whether to proceed with surgery is multidimensional. Patients must balance the considerations in favour of surgery with those favouring conservative treatment, which requires weighing peri-operative risk against morbidity associated with non-surgical treatment.

**Methods:** The aim of this prospective correlational study was to determine the proportional contributions of (i) pain, (ii) impulsivity, (iii) patients' perception of the benefits of surgery, (iv) patients' perception of peri-operative risk and (v) the predicted peri-operative risk on acceptance of peri-operative risk by vascular surgical patients. Sixty patients were prospectively recruited by convenience sampling from the Inkosi Albert Luthuli Central Hospital vascular surgery clinic between April 2014 and June 2014. Written informed consent was obtained. Patients completed a questionnaire which documented demographics, pain assessment, impulsivity screen (Barratt Impulsiveness Scale 11), patients' perception of surgery, predicted peri-operative risk (South African Vascular Surgical Cardiac Risk Index) and acceptance of peri-operative risk. Data were analysed using descriptive statistics and linear regression (SPSS version 22).

**Results:** The patients' perception of the benefits of surgery ( $\beta$  0.36, 95% CI 0.14–0.70,  $p = 0.005$ ) was the only predictor of peri-operative risk acceptance. The associations between the other potential predictors and the outcome were insignificant.

**Conclusion:** The perceived benefit of surgery was the most important predictor of acceptance of peri-operative risk in this cohort.

**Keywords:** pain, peri-operative risk, shared decision-making, vascular surgery

There has been a global increase in the number of patients undergoing non-cardiac surgery with an estimated 500 000 to 900 000 patients experiencing peri-operative cardiac events annually.<sup>1,2</sup> Vascular surgical patients have an increased cardiac risk following non-cardiac surgery and a high coexistent morbidity. The dilemma that these patients face involves balancing the risks and benefits associated with surgery against those of conservative management, which includes considering the peri-operative risk associated with the surgery (cardiac death, nonfatal myocardial infarction and nonfatal cardiac arrest) against the associated consequences without the surgery (intractable pain, limited mobility and death).<sup>2-5</sup>

Decision-making is a cognitive process that requires reflection on the consequences of a choice and deliberation on alternatives and contemplation of future outcomes.<sup>6,7</sup> Patient autonomy and readiness to give informed consent for surgery are affected by several factors.<sup>8</sup>

The aim of this study was to determine the proportional contributions of (i) pain, (ii) impulsivity, (iii) patients' perception of the benefits of surgery, (iv) patients' perception of peri-operative risk and (v) predicted peri-operative risk on the acceptance of peri-operative risk by vascular surgical patients.

### Methods

Ethical approval was obtained from the Biomedical Research Ethics Committee and the Postgraduate Education Committee of the University of KwaZulu-Natal, South Africa. The study was conducted at the vascular surgery clinic at the Inkosi Albert Luthuli Central Hospital. The hospital provides tertiary healthcare to patients residing in the province of KwaZulu-Natal. Written informed consent was obtained from all eligible patients.

We recruited patients 45 years or older who required vascular surgery but in whom the decision to proceed with vascular surgery had not yet been made. All patients had an initial consultation with a vascular surgeon, which lasted approximately 20–30 min and was conducted using plain language and in the patients' vernacular of choice. During the consult, the patients were presented with information regarding the risks and benefits of both surgical intervention and conservative therapy specific to their disease type, stage and severity. They were given time to consider their options and then reviewed at a later stage by the same vascular surgeon to discuss their treatment decision and preferences. We excluded patients from our study if they declined to participate or had a severe cognitive impairment. A pilot study was conducted at the same site in March 2014. These patients were not included in the study but their responses and queries were used to finalise the structured standardised questionnaire (Appendix 1).

All eligible patients completed a structured standardised questionnaire consisting of six sections. Section one contained demographic details.

Section two covered the pain assessment, which contained a pain visual analogue scale (VAS) from 0 mm (no pain) to 100 mm (worst possible pain), and an assessment of the efficacy of analgesic management.

Section three screened patients for impulsivity by using the Barratt Impulsiveness Scale 11 (BIS 11), which is a self-report instrument designed to assess impulsiveness and is composed of 30 items scored on a four-point scale.<sup>9,10</sup> A total score of 72 represents a highly impulsive individual, a total score of 52–71

represents impulsiveness within the normal range and a total score of less than 52 represents a 'cautious' individual.

Section four gauged the patients' perception of surgery. This section required the patients to contemplate how beneficial they believed undergoing surgery would be. This was assessed using an adapted VAS from 0 mm (death) to 100 mm ('cure') and the midpoint (50 mm) represented 'no change in current condition'. Furthermore, 'cure' was explained to the patients as a complete resolution or abatement of current symptoms e.g. removal of rest pain, restoration of mobility, cessation of claudication etc. Patients also needed to indicate their perceived peri-operative risk on another adapted VAS from 0 mm (low) to 100 mm (high). Peri-operative risk was explained to the patients as the risk of adverse outcomes associated with surgery during the hospital admission for surgery, e.g. death and major adverse cardiac events.

Section five calculated the patients' predicted peri-operative risk according to the South African Vascular Surgical Cardiac Risk Index (SAVS-CRI). The SAVS-CRI is a cardiovascular risk stratification index used to predict the risk of peri-operative major adverse cardiovascular events (MACEs) in South African vascular surgical patients.<sup>11</sup> A total score of < 7 represents the low-risk group, a total score of 7–11 represents the intermediate-risk group and a total score of > 11 represents the high-risk group.<sup>11</sup> The predicted SAVS-CRI risk was interpreted during each interview using standardised and uniform simple terms (e.g. 'you are in the low risk group which means that you have a 1–2 in 20 chance of having an adverse outcome').

Section six estimated the acceptance of peri-operative risk by the patients using an adapted VAS from 0 mm (unacceptable) to 100 mm (acceptable). This was understood as the patients' willingness to tolerate or withstand their peri-operative risk.

It was calculated that a sample size of 60 patients would achieve a 90% power to detect an  $R^2$  of 0.20 attributed to the independent variables using an F-test with a significance level ( $\alpha$ ) of 0.01. Categorical data were analysed using descriptive statistics and presented as proportions. Continuous data were analysed using descriptive statistics and presented as mean and standard deviation. The association between the potential determinants of the acceptance of surgical risk were analysed using Pearson's correlation coefficient, as all variables were normally distributed. Linear regression analysis was used to determine independent predictors of an acceptance of peri-operative risk. A  $p$ -value of < 0.05 was considered to be statistically significant. Results are presented as standardised coefficients ( $\beta$ ) and 95% confidence intervals (CI). All statistical analyses were performed using SPSS® (IBM, Armonk, NY, USA) version 22.

## Results

Sixty patients were prospectively recruited into the study between April 2014 and June 2014. The characteristics of our study cohort are given in Table 1.

A large proportion of our patients had a high-school or lower level of education (54/60 patients, 90%). Approximately 10% of the cohort had no pain (VAS 0 mm) and their primary diagnosis was predominantly carotid artery disease. The remainder of the cohort reported moderate to severe pain (mean VAS 57.05 mm, SD 33.02) and the primary diagnosis in 80% of our cohort was peripheral vascular disease. In addition, 6.7% of patients had maximal pain (VAS 100 mm) and their primary diagnosis was

**Table 1:** Baseline patient characteristics, expressed as mean (standard deviation) or number (proportion)

	Total (n = 60)
Age; years	64.15 (9.7)
<b>Sex</b>	
Male	37 (61.7%)
Female	23 (38.3%)
<b>Highest level of education</b>	
Tertiary	6 (10%)
High school or less	54 (90%)
Pain VAS* score; mm <sup>†</sup>	57.05 (33.02)
BIS 11 score <sup>‡</sup>	63.83 (6.97)
<b>Surgical diagnosis</b>	
Peripheral vascular disease	48 (80%)
Carotid artery disease	7 (11.7%)
Carotid artery disease and peripheral vascular disease	4 (6.7%)
Infra-renal abdominal aortic aneurysm	1 (1.7%)
Patients' perception of the benefits of surgery VAS score; mm	74.95 (25.09)
Patients' perception of peri-operative risk VAS score; mm	40.13 (29.55)
SAVS-CRI score <sup>§</sup>	6.7 (2.8)
<b>SAVS-CRI risk group</b>	
High	1 (1.7%)
Intermediate	32 (53.3%)
Low	27 (45%)
<b>Actual subsequent patient management</b>	
Conservative management	13 (21.7%)
Surgery	47 (78.3%)

\*VAS: Visual analogue scale.

<sup>†</sup>mm: millimetres.

<sup>‡</sup>BIS 11: Barratt Impulsiveness Scale 11.

<sup>§</sup>SAVS-CRI: South African Vascular Surgical Cardiac Risk Index.

peripheral vascular disease. Fifty patients (83%) had a BIS 11 score of 52–71, which is by definition normal (mean BIS 11 score 63.83, SD 6.97).

Pearson correlational analysis demonstrated only a moderate association between the predicted peri-operative risk (SAVS-CRI score) and the patients' perception of peri-operative risk ( $r = 0.33$ ,  $p = 0.01$ ). Of note is that all of the remaining correlations between the potential predictors of acceptance of peri-operative risk were not statistically significant.

The results of the linear regression are shown in Table 2. The perceived benefit of surgery by the patient ( $\beta$  0.36, 95% CI 0.14–0.70,  $p = 0.005$ ) was the only predictor of peri-operative risk acceptance. We did not find any statistically significant association between pain ( $\beta$  0.07, 95% CI -0.16–0.28,  $p = 0.582$ ), impulsivity ( $\beta$  0.12, 95% CI -0.59–1.59,  $p = 0.360$ ), the patients' perception of peri-operative risk ( $\beta$  -0.05, 95% CI -0.31–0.22,  $p = 0.711$ ) and predicted peri-operative risk ( $\beta$  -0.26, 95% CI -5.48–0.08,  $p = 0.057$ ) on acceptance of peri-operative risk in this population.

## Discussion

The main finding of our study is that the only significant predictor of acceptance of peri-operative risk is the perceived benefits of surgery by the patient. There were no statistically significant associations

**Table 2:** Linear regression analysis for acceptance of peri-operative risk by vascular surgical patients

	$\beta^*$ (95% CI)	p-value
Pain VAS score <sup>†</sup>	0.07 (-0.16–0.28)	0.582
BIS 11 score <sup>‡</sup>	0.12 (-0.59–1.59)	0.360
Patients' perception of the benefits of surgery VAS score	0.36 (0.14–0.70)	0.005
Patients' perception of peri-operative risk VAS score	-0.05 (-0.31–0.22)	0.711
Predicted peri-operative risk — SAVS-CRI score <sup>§</sup>	-0.26 (-5.48–0.08)	0.057

\* $\beta$ : standardised coefficient.

<sup>†</sup>VAS: Visual analogue scale.

<sup>‡</sup>BIS 11: Barratt impulsiveness scale 11.

<sup>§</sup>SAVS-CRI: South African Vascular Surgical Cardiac Risk Index.

between (i) pain, (ii) impulsivity, (iii) patients' perception of peri-operative risk and (iv) predicted peri-operative risk on the outcome of acceptance of peri-operative risk in this cohort.

According to the Institute of Medicine, 'patient-centred care' is one of the key components of health quality.<sup>12</sup> Shared decision-making plays a pivotal role in this paradigm.<sup>12–15</sup> This shared decision-making relies on the doctor collaborating with the patient to share information regarding the risks, benefits and limitations of available treatment options that are based on current research evidence.<sup>12–16</sup> Following this, it is hoped that a consensus on medical treatment is reached that is in harmony with the patient's values, goals and preferences.<sup>12–16</sup> This ideal model of patient decision presupposes that patients receive accurate information regarding risks, costs and benefits, that they accurately represent that information when deliberating, and that their reasoning does not systematically drive them away from conclusions that are in their genuine interests. There is reason to doubt that these assumptions are generally true.<sup>17</sup> Some personality traits, especially impulsivity, are associated with differences in sensitivity to risk and delay. There are various indications that temporary states, including some diseases and conditions such as pain, are associated with impulsivity, and disturbed cognition or decision-making.<sup>18</sup> The construct of impulsivity is understood as a personality trait associated with willingness to take risks, lack of planning and future orientation, and making quick decisions.<sup>19</sup> Impulsivity is understood more narrowly as having high sensitivity to delayed rewards or a stronger preference for relatively immediate rewards,<sup>20,21</sup> which is associated with decision-making deficits (i.e. an impulsive person exhibits reduced reflection on the consequences of his/her choice).<sup>22–24</sup> We could not explore these associations, as the majority of our patients did not exhibit impulsivity characteristics on objective assessment.

The literature on pain and decision-making in clinical settings is rather small, and very few studies have investigated the factors influencing acceptance of peri-operative risk by surgical patients.<sup>25–29</sup> Pain competes for attention with other cognitive processes. Activities that demand attention or executive cognition can be compromised by analgesic effects and pain, which is well documented with chronic pain.<sup>30,31</sup> Chronic pain patients show worse than normal performance at the Iowa Gambling Task, widely regarded as an important assay of ability to learn and respond to feedback mixing gains and losses that differ in both magnitude and frequency, and the extent to which performance was degraded was correlated to pain intensity.<sup>32–35</sup> With specific reference to treatment choices, Bono *et al.* determined that the intensity of pain is the most influential factor affecting a patient's decision to accept surgical complications when considering lumbar spine fusion,<sup>25</sup> and Andrade *et al.* found that recent pain influenced decisions concerning the scheduling of future treatments.<sup>36</sup>

These considerations suggested assessing impulsivity and pain in vascular disease patients making treatment decisions. The present study is the first to attempt to investigate the proportional contribution of (i) pain, (ii) impulsivity, (iii) patients' perception of the benefits of surgery, (iv) patients' perception of peri-operative risk and (v) predicted peri-operative risk on acceptance of peri-operative risk by a surgical population. In contrast to Bono *et al.*,<sup>25</sup> we found a negligible relationship between pain severity and treatment choice. In fact, in our patient population the only significant predictor of acceptance of peri-operative risk was the perceived benefits of surgery by the patient. There were no statistically significant associations between (i) pain, (ii) impulsivity, (iii) patients' perception of peri-operative risk and (iv) predicted peri-operative risk on the acceptance of peri-operative risk in this cohort. The correlation between predicted peri-operative risk and patients' perception of their peri-operative risk suggests that the patients understood their surgery-associated risk. As it was impossible to determine the proportional contribution of a perception of pain resolution to the patients' perceived benefits of surgery, a *post hoc* regression analysis was conducted where the 'perceived benefits of surgery' was removed from the regression. In the *post hoc* model, pain, impulsivity, the patients' perception of peri-operative risk and the predicted peri-operative risk all remained not associated with acceptance of peri-operative risk. This *post hoc* analysis strengthens our confidence in our primary results. Consequently, the fact that patient decisions were strongly determined by perception of benefits but weakly by perception of risks is suggestive, but does not point to a specific model of the patient decision process.

Our study has a number of salient limitations. First, most participating patients did not report severe pain, and did report satisfactory pain control with their current analgesic management. It is possible that a patient population with greater variation in pain severity would enable the detection of an association. Second, and similarly, most patients in our study had impulsivity scores in the normal range. Again, a cohort containing greater variation, and in particular more patients with higher impulsivity, might enable detection of an association between impulsivity and acceptance of surgical risk in vascular patients. Third, our study represents a predominantly relatively poorly educated patient population from a single cultural and linguistic group. On the other hand the fact that many South African patients differ from those participating in previous research may be an advantage. South African patients are different from the subject pool of most empirical research. These differences include various cultures and differences in material circumstances (wealth, education, burden of disease, life expectancy, co-morbidities) when compared with the subjects of the cognitive and behavioural literature from the developed world, which includes predominantly undergraduate students from highly developed Western countries. Fourth, we used an adapted VAS to assess

the patients' perception of the benefits of surgery, perceived peri-operative risk and acceptance of peri-operative risk. We used an adapted VAS instead of other decision analysis instruments because of its simplicity and the low numeracy literacy of our population. Furthermore, the VAS has been used in other studies to assess parameters other than pain.<sup>37,38</sup> Arnold *et al.* sought to determine the association between chronic stress and long-term adverse outcomes after acute myocardial infarction.<sup>37</sup> The VAS was modified and used as a 'feeling thermometer' where patients rated their general health state from 0 mm (worst imaginable) to 100 mm (best imaginable).<sup>37</sup> Gerlach *et al.*, in a systematic review of primary studies from 2005, evaluated how the sensation of breathlessness has been assessed in adults with increased adiposity.<sup>38</sup> The authors highlighted that the VAS was one of the instruments recommended based on reliability ( $r > 0.8$ ) and concurrent validity (correlation with severity of airway obstruction and walking distance).<sup>38</sup> These studies suggested that the VAS was potentially an acceptable tool.

Lastly, the subgroup of patients with carotid artery disease may have potentially confounded the relationship between pain and acceptance of peri-operative risk in this cohort. These patients are not generally in pain but might be more willing to accept peri-operative risk since the alternative of conservative therapy may include a catastrophic cerebrovascular accident. However, we conducted a *post hoc* analysis, where we removed the patients with carotid artery disease from the analysis, and all the study outcomes were unchanged. As in the full analysis, the perceived benefit of surgery by the patient remained the only predictor of peri-operative risk acceptance ( $\beta$  0.36, 95% CI 0.08–0.67,  $p = 0.013$ ).

## Conclusion

Many factors influence a patient's decision to proceed with surgery but the manner in which risks are balanced and information integrated still remains poorly understood. We have shown that the perceived benefit of surgery is an important predictor of acceptance of peri-operative risk. However, we have been unable to adequately address the importance of severe pain and an impulsive personality in terms of acceptance of peri-operative risk. Further research is required to adequately address these issues.

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**Appendix 1.** The structured standardised questionnaire (English version) completed by all eligible vascular surgery patients in our study

KZ

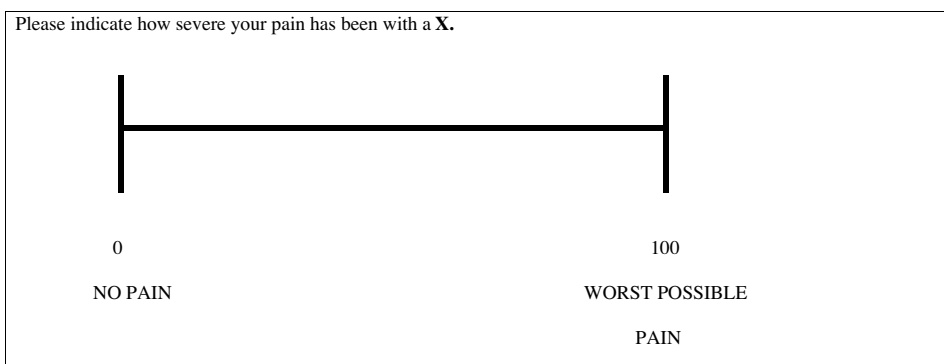
Date: / /2014

Thank you for agreeing to complete this questionnaire and for taking the time to be a part of our research project.

**PART 1: DEMOGRAPHIC DATA** (Please X where appropriate)

1. Age									
2. Sex	Male				Female				
3. Race	Black			White			Asian	Coloured	
4. Highest level of education	High school or less								
	Tertiary (University, College, Technikon etc.)								

**PART 2: PAIN ASSESSMENT**



Please list your current pain medication:

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Do you find this effective? YES/NO

**PART 3:** People differ in the ways they act and think in different situations. This measures the ways in which you act and think. Place a **X** next to how often each statement applies to you

	Rarely/Never 1	Occasionally 2	Often 3	Almost always 4
I plan tasks carefully				
I do things without thinking				
I make up my mind quickly (I decide what to do quickly)				
I am happy-go-lucky (I am easy-going. I am carefree)				
I don't 'pay attention'				
I have 'racing' thoughts (I have quickly changing thoughts that I can't stop or control)				
I plan trips well ahead of time (Trips doesn't only mean holidays, or long-distance journeys)				
I am self-controlled				
I concentrate easily				
I save regularly				
I 'squirm' at speeches or meetings (I have trouble keeping still at speeches or meetings)				
I think carefully about things				
I plan for job security (I think about what I need to do to make sure I am employed or have an income in the future)				
I say things without thinking				
I like to think about complex problems				
I decide to change jobs (This means leaving a job, not losing it)				
I act 'on impulse'				
I get easily bored when solving thought problems (I get easily bored when working on games of thought like riddles and number games)				
I act on the spur of the moment (I act without thinking)				
I am a steady thinker (I can think about one thing without getting distracted)				
I decide to change where I live				
I buy things on impulse				
I can only think about one problem at a time				
I change hobbies (Hobbies include sports and other recreational activities)				
I spend or buy more on credit than I earn				
I have outside thoughts when thinking (I have distracting or unintended thoughts when I'm trying to think about something else.)				
I am more interested in the present than the future (I am more concerned about the present than the future)				
I am restless at talks or in church				
I like puzzles (I like games and tasks that require thinking about one thing for some time)				
I plan for the future				

**TOTAL:**

**PART 4: PERCEPTION OF SURGERY**

Surgical diagnosis: 1) \_\_\_\_\_ 2) \_\_\_\_\_

Please indicate how beneficial you think undergoing surgery will be with a **X**.

0 50 100  
DEATH NO CHANGE 'CURE'  
IN CONDITION

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What do you think is your peri-operative risk associated with your surgery. Indicate with a **X**.

0 100  
LOW HIGH

**PART 5: PREDICTED PERI-OPERATIVE RISK — South African Vascular Surgical Cardiac**

**Risk Index (SAVS-CRI)**

Patient characteristics		SAVS-CRI point score
Age (>65 years)		2
History of ischaemic heart disease		2
Chronic $\beta$ -blockade		4
Diabetes		2
Prior surgical intervention for coronary artery disease		-3
Intermediate-risk surgery		3
Open supra-inguinal vascular surgery		7
<b>TOTAL</b>		<b>17</b>

Your predicted peri-operative risk is .... This means that you have a ... in 20 chance of having an adverse outcome.

**PART 6: ACCEPTANCE OF PREDICTED PERI-OPERATIVE RISK**

Please indicate how acceptable you find your predicted peri-operative risk with a **X**.

0 100  
NOT ACCEPTABLE ACCEPTABLE

Thank you for your time.

Dr Pooveshni Govender

Date: / /2014